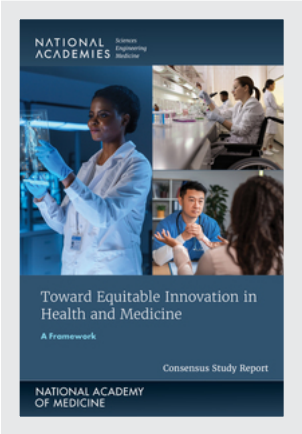

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Toward Equitable Innovation in Health and Medicine

A Framework

Committee on Creating a Framework for Emerging Science, Technology, and Innovation in Health and Medicine

Board on Health Sciences Policy

Health and Medicine Division

Consensus Study Report

NATIONAL ACADEMY OF MEDICINE

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[1] NOTE: See Appendix E, Disclosure of Unavoidable Conflicts of Interest.

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This Consensus Study Report was reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise. The purpose of this independent review is to provide candid and critical comments that will assist the National Academies of Sciences, Engineering, and Medicine in making each published report as sound as possible and to ensure that it meets the institutional standards for quality, objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

We thank the following individuals for their review of this report:

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Although the reviewers listed above provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations of this report nor did they see the final draft before its release. The review of this report was overseen by **ELISABETH BELMONT,** MaineHealth, and **ERIC LARSON,** University of Washington. They were responsible for making certain that an independent examination of this report was carried out in accordance with the standards of the National Academies and that all review comments were carefully considered. Responsibility for the final content rests entirely with the authoring committee and the National Academies.

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Summary[1]

Innovation in health and medicine emerges from novel applications of knowledge that bring health and economic benefits to patients, consumers, and society. But alignment of the ecosystem for science, technology, and innovation (STI) with such ethical concepts as equity, justice, fairness, and the common good has not always been a priority. This report is motivated by the goal of achieving an innovation system that advances emerging science and technology while recognizing and mitigating potentially harmful applications, that fairly distributes potential benefits and burdens arising from STI, and that engages and meets the needs of the system's full range of users. A central emphasis of the report is that users of the innovation system include not only those who have typically been active in STI, such as innovators, research funders, investors, and health care experts, but also those who may not always have seen themselves as involved stakeholders and rights holders with rights in the system's functioning and outputs, including members of underserved communities and scholars from such disciplines as the social sciences and humanities. To help achieve the goal of such an innovation system, this report seeks to advance an understanding of opportunities and responsibilities across the processes by which innovation in health and medicine arises and is governed.

CONTEXT AND IMPETUS FOR THE STUDY

Technologies with the potential to transform medicine and society continue to advance rapidly through progress in such fields as synthetic biology, neuroscience, biomanufacturing, communications technologies, and others. In recent years, advances in such areas as machine learning and artificial intelligence have generated greater awareness of the potential of technology to benefit society, as well as information privacy concerns and the negative consequences of unrepresentative or biased data. Disparities in rates of infection, hospitaliza-

[1] This summary does not include reference citations. References for the information herein are provided in the full report.

tion, and death during the COVID-19 pandemic and the need to distribute initially limited vaccines and therapeutics fairly brought further attention to equity in health and medicine.

How better to assess and attend to the societal implications of emerging STI, how to balance public and private interests and advance the common good, under what circumstances government should act to steer the innovation system toward particular outcomes, how to anticipate the effects of such interventions, and what roles market forces and profit-making incentives should play are long-standing considerations for the governance of STI, with governance approaches shifting in response to political, economic, and social dynamics in the United States and globally. In the current system, market and consumer forces play important roles in who benefits from STI, and equity-focused work has sometimes been controversial, framed as unfairly privileging certain groups or perceived as government overreach. However, there have been targeted instances in which equity has shaped governance—for example, in expanding access to kidney dialysis and prohibiting discrimination based on genetic data.

The current moment provides an opportunity to reexamine the system for emerging STI in health and medicine and the processes by which it is developed and governed, including how it generates or reduces inequities, how it provides or fails to provide a fair distribution of benefits and burdens, and how public and private interests can be balanced to facilitate the development and use of transformative technologies while enhancing societal benefit and mitigating anticipated harms. This report focuses on alignment with equity not because it is the only normative principle that should guide STI in health and medicine, but because it has received less systematic attention and action than other values (e.g., autonomy) in traditional biomedical frameworks. Moral, social, and economic arguments can be made for seeking a better understanding of opportunities and potential trade-offs entailed in addressing equity; this report's recommendations can also be viewed as consistent with a vision for an innovation system that better abides by the nation's Constitutional principles and that moves toward an ideal of universalization—that an effective and fair system is one that accounts for the full range of the system's users.

This effort to address and enhance equity does not exist within a vacuum. Multiple public and private activities are focused on enhancing the STI ecosystem, including efforts to diversify the science, technology, engineering, and mathematics (STEM) workforce, establish equity-focused teams in federal agencies, strengthen patient and community engagement, and identify and collect data to inform decision making. Still other public and private actors are interested in how their work can align with equity but may be unclear about or even wary of what steps they can take.

In January 2020, the National Academy of Medicine established the standing Committee on Emerging Science, Technology, and Innovation in Health and Medicine (CESTI) to consider potential societal, ethical, legal, and workforce implications of emerging science, engineering, and technology, and to incubate ideas for a governance framework aligned with ethical principles. To build on and advance this work, the National Academies of Sciences, Engineering, and Medicine and the National Academy of Medicine convened an ad hoc committee of experts to produce this report. The committee was asked to develop a cross-sectoral governance framework for emerging STI in health and medicine with a particular focus on equity.

A FRAMEWORK FOR GOVERNANCE OF EMERGING SCIENCE, TECHNOLOGY, AND INNOVATION IN HEALTH AND MEDICINE

Aligning innovation with the ideal of equity begins with explaining what the concept of equity entails. Given the wide range of technologies, issues, and situations involved in biomedical innovation, who is underserved or marginalized depends on the context. Such groups may often include, for example, rural communities, people who experience disability, or historically marginalized racial or ethnic populations, but there is no one answer. Critically, advancing equitable innovation also involves parsing "equity," since effective solutions depend on addressing the root of the challenge. While equity can be defined in different ways, this report describes the following dimensions:

- *Topical equity*: An innovation portfolio should include topics of relevance to diverse communities, including populations that have traditionally experienced injustices.
- *Innovator equity*: Innovators should reflect diverse populations, including members of underserved or marginalized communities, so as to tap a broad scope of imagination and creativity.
- *Input equity*: Development and implementation processes should include teams with diverse representation in order to make products relevant and of interest to a wide community of users, demonstrate respect for affected communities, and enhance accountability.
- *Evaluation equity*: New technologies should be evaluated in diverse or representative populations to reduce errors in assessing their benefits and harms and broaden their eventual applications.
- *Deployment equity*: Technologies should be accessible to and benefit a diverse population, including traditionally underserved or marginalized groups.
- *Value capture equity*: The value created from new technologies should be captured and distributed fairly.
- *Contextual equity*: New technologies should not perpetuate past injustices and should address or correct past injustices where possible.
- *Attention equity*: Organizations and innovators should attend to the equity concerns outlined above, including by actively seeking and mitigating inequities in how technologies are deployed.

This report's framework for aligning emerging science, technology, and innovation with equity is provided in Figure S-1. Equity considerations can arise during all of the phases through which an emerging technology passes, and the choices made by various stakeholders along the way influence the technology's further trajectory. These choices include such decisions as funding and research approvals; identification and management of intellectual property; continued investment and scale-up; performance evaluation to support public availability; cost, insurance coverage, and other factors affecting product access and availability; and analysis of postmarket impacts and responses. The framework is depicted as a circle rather than a linear progression to recognize that information gained from prior research, development, and use ideally feeds into and informs future innovation efforts, along with the discovery of new knowledge and the incorporation of other sources of information, including community knowledge.

In applying the framework, actors in the innovation system should be guided by five imperatives to connect the actions and decisions they make individually and collectively to the goal of advancing equitable innovation:

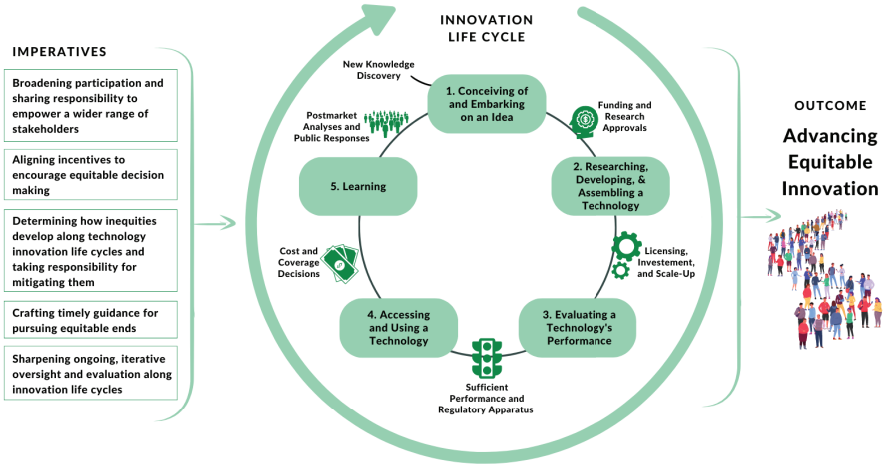

FIGURE S-1 The governance framework for aligning emerging science, technology, and innovation in health and medicine with ethical principles, emphasizing alignment with equity. The five imperatives (*left*) should be used to guide choices and actions depicted in a simplified conceptual model of the innovation life cycle (*center*) to support the desired outcome of advancing equitable innovation (*right*).

- *Broadening participation and sharing responsibility to empower a wider range of stakeholders*. This imperative involves identifying, convening, and incentivizing diverse stakeholders to center equity in their respective roles and to work in coordination to help achieve the vision for a system that fairly and equitably meets the needs of all users.
- *Aligning incentives to encourage equitable decision making*. To address limitations and bridge gaps in the current system, this imperative recognizes the role of incentives in influencing the interests and behaviors of stakeholders to center and prioritize equity in innovation.
- *Determining how inequities develop along technology innovation life cycles and taking responsibility for mitigating them*. Collective curiosity about the dynamic causes and patterns of inequity is needed. This imperative asks how the equity dimensions associated with the development and deployment of new science and technology can be identified proactively and reassessed periodically in light of information gained.
- *Crafting timely guidance for pursuing equitable ends*. Given the wide-ranging nature of STI in health and medicine and the diverse needs and issues associated with differing technologies and contexts of use, this imperative recognizes the need for specific, context-relevant guidance to aid stakeholders as they make decisions about what to do at key choice points.
- *Sharpening ongoing, iterative oversight and evaluation along innovation life cycles*. Finally, reflexive governance provides the mechanisms for encouraging or enforcing actions that track and shape the system's alignment with equity.

RECOMMENDATIONS

As can be inferred from the framework above, the ecosystem of STI in health and medicine offers opportunities for multiple public and private actors—affected and underserved communities, researchers and inventors, funders, investors, regulators, end users, and many others—to consider questions of equity. And many ongoing efforts can help address equity considerations with regard to particular stakeholders, types of technologies, and phases of development.

A shared vision is needed for identifying what can and should be done in the innovation ecosystem in ways that bridge, integrate, and expand on current efforts. This report's governance framework is one key element in achieving this systems-level approach. The report also offers six recommendations for supporting an equitable ecosystem for STI in health and medicine. An important thread running through these recommendations is the need to convene those individuals, organizations, and groups doing thoughtful work in these six areas as a next step in building the coalitions necessary to accomplish these goals—whether in the development of equity science, the establishment of substantive community partnerships, the crafting of context-specific guidance, or other key areas.

The six recommendations are presented below and summarized in Table S-1. The full text of each recommendation is provided in Chapter 5, which also includes implementation guidance consisting of suggestions for and actions that can be taken by multiple parties. Although this guidance is targeted largely to U.S. actors, the report's proposed framework may be adaptable to and help inform other national and international conversations on centering equity in the development and governance of science and technology.

TABLE S-1 Summary of Recommendations

Recommendation	Actions	Desired Outcomes
Establish a National Vision and Priority Setting Body (Recommendation 1)	• Foster leadership and coordination to align innovation with ethical principles that include equity. • Convene a multistakeholder, cross-sectoral Equity in Biomedical Innovation Task Force. • Build public and professional awareness of the role of equity in emerging science, technology, and innovation in health and medicine.	• A U.S. innovation system that translates emerging science and technology into innovative applications while addressing the needs of the system's full range of users and reducing health inequities. • A set of initial priorities and goals for better aligning equity with innovation in health and medicine. • New partnerships, synergies, and collaborations that increase the alignment of innovation with equity.
Reorient the Culture of Innovation (Recommendation 2)	• Incorporate equity as a principle in required ethics training and practice. • Where appropriate, require investigators to address equity associated with proposed work, including community engagement plans. • Incorporate ethics and equity more fully into technology licensing and investment practices, including through equity-focused provisions. • Require study designs and results to reflect a diverse range of anticipated postmarket users and contexts.	• Integration of ethical concerns, including stakeholder needs and values, into the formulation and conduct of research, decisions on funding and investments, and regulation and performance assessment. • Policies and practices that recognize the importance of aligning technology development and use with equity.

continued

TABLE S-1 Continued

Recommendation	Actions	Desired Outcomes
Incentivize Equity (Recommendation 3)	• Draw on available governance levers to incentivize stakeholders to incorporate ethics and equity-focused assessments more fully into the process of emerging science, technology, and innovation in health and medicine. • Based on the results of such assessments, incentivize stakeholders to make decisions and take action to address misalignments that arise.	• Governance of emerging science, technology, and innovation in health and medicine that addresses barriers to effective alignment with equity and supports actions and accountability to mitigate misalignments and inequities within and across institutions and actors.
Expand Participation in innovation (Recommendation 4)	• Identify best practices and lessons for engaging with underserved and marginalized communities throughout the innovation life cycle. • Where relevant to the research, identify aims and methods and establish sustained, bidirectional partnerships with affected and traditionally underrepresented communities. • Incorporate policies and practices that recognize and value a community's contributions to and participation in research. • Support the capacity of underserved and marginalized communities to engage in innovation.	• Practices and tools for addressing decision making across the innovation life cycle. • Substantive participation in the innovation system from a wider range of users and communities, driven by enhanced trust, engagement, and capacity.
Develop Equity Science (Recommendation 5)	• Catalyze the development of equity science and the validation of qualitative and quantitative methods, metrics, and benchmarks. • Develop associated data collection and reporting systems and data quality standards. • Adopt resulting equity science methods, metrics, and benchmarks to assess and monitor technology implications.	• An expanded set of evidence-based methods, metrics, and benchmarks for assessing the alignment of emerging science, technology, and innovation with equity while supporting informed decision making and action throughout the technology life cycle.
Create and Promote Context-Relevant Equity Playbooks (Recommendation 6)	• Develop and disseminate specific guidance targeted to particular roles in the technology life cycle, types of inequity, or particular areas of emerging science and technology.	• Enhanced implementation of a governance framework for aligning emerging science, technology, and innovation with equity through actionable guidance on key questions, practices, and strategies in specific contexts.

National Leadership

Addressing the six recommendations will require sustained engagement from many participants, involving individual and collective action. Culture change to drive greater equity is a leadership issue and thus requires coordinated action. Building on and expanding beyond ongoing White House equity efforts in this area (see Chapter 1), national leadership from the White House Office of Science and Technology Policy (OSTP) is necessary to set priorities and goals, monitor progress, and harness current opportunities across multiple agencies and departments, as well as extensive public and private interests and efforts, to produce improved cross-sectoral governance and a consistent focus on equity in the innovation ecosystem.

RECOMMENDATION 1. Galvanize national leadership for aligning emerging science, technology, and innovation in health and medicine with principles of equity. To focus attention on establishing equitable, holistic, sustainable, and cross-sectoral innovation in health and medicine:

- The White House Office of Science and Technology Policy (OSTP) should lead the cohort of federal departments and agencies that fund and oversee science and technology in their efforts to translate and operationalize the governance framework for equitable innovation laid out in this report in accordance with their specific mission and life-cycle phase (i.e., from ideation to postmarket use).
- OSTP should convene a multistakeholder, cross-sectoral Equity in Biomedical Innovation (EBI) Task Force to galvanize action in the areas recommended in this report.
- Federal, state, and local policy makers should upgrade existing or create new policy and oversight mechanisms to drive the alignment of emerging biomedical science, technology, and innovation with the priorities and goals identified by OSTP, relevant departments and agencies, and the EBI Task Force.

This recommendation calls for OSTP to lead the effort to translate and operationalize this report's governance framework, including through a multistakeholder, cross-sectoral task force. Building on the areas identified in this report, the EBI Task Force should articulate near-, intermediate-, and long-term priorities and work with agency equity teams and the White House Steering Committee on Equity to translate those priorities into an initial set of goals over the next decade. The EBI Task Force should also partner with the broader community of biomedical innovation stakeholders, including underserved communities, to provide insight on benchmarks, measures, and metrics that can be incorporated at each point of the life cycle to achieve greater equity in the innovation process.

Culture of Innovation

Actors across the innovation ecosystem have roles to play in its governance. Needed to support these efforts is a culture of innovation that builds awareness of equity and its intersection with STI. Disciplinary norms for fields of emerging science and technology can further integrate information on the forms and dynamics of inequity and on the governance imperatives identified in this report, providing guidance on roles and responsibilities.

RECOMMENDATION 2: Enhance a culture of innovation that incorporates equity as an ethical concept in technology development and integrates it into organizational practice. The research and development enterprise in health and medicine should more fully incorporate the concept of equity into the foundational ethical principles that guide innovation. Achieving this shift will require a culture of innovation that takes responsibility for incorporating ethical principles across the innovation enterprise and leverages expertise in such fields as bioethics; science and technology studies; and the history of science, technology, and medicine.

This recommendation is particularly relevant to organizations that establish norms, conduct and oversee research and development, and generate intellectual property, including funders, universities, companies, and licensing and patent offices. To implement this recommendation, organizations can take multiple actions to demonstrate a commitment to the report's governance framework in their operations and processes. Selected examples include requiring and incorporating case studies in training on responsible conduct of research to

raise awareness of the consequences of misalignment of innovation and equity; assisting researchers and developers in assessing and mitigating equity implications associated with proposed designs; enhancing engagement with researchers, social science experts, and others to address equity considerations in new intellectual property; and adopting equity science tools and data systems to link choices to financial or logistical implications for populations of intended users or to assess whether a portfolio represents an equitable distribution of investigators, institutions, and anticipated risks/benefits.

Aligning Innovation with Equitable Benefit

Achieving a more equitable system of emerging STI in health and medicine will also require reassessment and deployment of governance levers that affect incentives, as well as disincentives in the system to facilitate attention to societal benefit. These levers can take many forms, and this recommendation is particularly relevant to those stakeholders able to direct such levers, which include the imposition of requirements (whether via federal and state laws and regulations; professional standards and best practices; or policies affecting research design, funding, approval, publication, and evaluation) and the use of positive motivations for equity (such as targeted funding and enhancements to market incentives such as patent rights).

RECOMMENDATION 3: Incentivize the alignment of innovation with equitable benefit. Those who fund and oversee innovation in health and medicine should incentivize their grantees, researchers, and partners to assess periodically an emerging technology's alignment with equity, focusing on choice points during the technology life cycle and on governance actions that can be taken to mitigate any misalignments that arise.

This recommendation highlights choice points in which assessment of alignment with equity should occur, including

- funding and research approvals;
- patenting, licensing, investment, and scale-up;
- assessment and approval for widespread use;
- cost and coverage decisions; and
- postmarket analyses.

The implementation guidance for this recommendation provides examples of actions that can support or enhance alignment with equity, including use of equity-focused proposal requirements and scoring elements; partnerships with historically underserved and marginalized communities in research codesign, credit, and benefit; use of funding, tax incentives, public–private partnerships, and other models to spur targeted investment in new technologies or alternative designs for existing technologies to address an identified need or inequity; emphasis on maintaining patent quality and transparency and on intellectual property and licensing arrangements that align with equity; use of postmarket surveillance to identify and understand any inequitable distribution of medical benefits and risks; and other actions.

Empowering Participation in Innovation

To achieve the system vision described above, it will be necessary to expand who participates in innovation in health and medicine and who sees themself as a stakeholder or rights holder with a substantive role in technology development and governance. A consistent theme in this report's framework is the need for more comprehensive stakeholder engagement and for enhanced cross-sectoral participation. Opportunities to inform the innovation process begin with conceptualization and will need to include sustained, bidirectional engagement that advances the ability of currently underrepresented and underserved groups to take part.

RECOMMENDATION 4: Empower diverse communities to participate in the innovation system. Conveners appropriate to stages of the innovation life cycle in health and medicine should bring together experts and practitioners in effective community engagement, participatory research and codesign, inclusive design principles, and participatory technology assessment, along with leaders of model engagement partnerships, to analyze lessons learned from these efforts and identify best practices, standards, and tools for designing and maintaining bidirectional engagement with members of marginalized or underserved communities.

No single actor is responsible for convening across the suite of issues relevant to different phases of emerging science, technology, and innovation in health and medicine, although critical roles can be played by the EBI Task Force proposed in Recommendation 1; federal agencies carrying out their respective activities in research, technology development, and innovation; and philanthropic organizations. Multiple, focused opportunities are likely needed to delve deeply enough into lessons, models, tools, and best practices on specific topics (such as research codesign or community data ownership). As described in the recommendation, such convening should help center the interests of affected communities in the innovation ecosystem and address such areas of decision making as

- how substantive input during research priority setting, funding, conception, design, and conduct can be empowered;
- policies and practices that recognize and value a community's contributions to and participation in research, including around data access, management, and ownership and intellectual property identification and management; and
- technology performance evaluation, coverage and use determinations, and monitoring of a technology's impacts and implications.

Equity Science

Methods, metrics, and benchmarks are needed to guide decision making at all stages of STI planning, development, assessment, and oversight. An improved understanding of the causes of and explanations for inequity can inform the specific remedies that will be most effective in redressing or mitigating that inequity. An effective STI system should also be a learning system capable of both anticipatory and retrospective analyses, monitoring, and iterative improvement. To support such a system, a robust field of equity science is needed, building on and extending current efforts directed at identifying and deploying equity metrics.

RECOMMENDATION 5: Invest in developing equity science for technology innovation. The National Institutes of Health and the National Science Foundation should partner with philanthropic organizations to support the development of a robust, multidisciplinary equity science that builds on current efforts to develop equity-relevant metrics while establishing a wider range of qualitative and quantitative methods, metrics, and benchmarks encompassing the forms of equity and governance imperatives laid out in this report.

As described in this recommendation, equity science methods, metrics, and benchmarks should enable the improved assessment of

- how inequities arise, in which contexts, and for which communities across all phases of emerging science, technology, and innovation in health and medicine;
- how innovation systems and processes can change in response to the evidence obtained, including better understanding and evaluating the impacts of different stakeholder actions and choices; and
- near-term and longer-term changes in response to governance choices.

As equity science is developed, actors throughout the innovation process can support system-wide change by adopting the resulting methods, metrics, benchmarks, and data systems to assess the equity-relevant implications of their technology innovation decisions.

Playbooks for Context-Relevant Guidance

Playbooks can serve as important guides for interested stakeholders on practical strategies, key questions, and specific suggestions that can translate the governance framework in this report into practice in different areas of STI and for different stakeholder communities and choice points in the innovation life cycle. Existing playbooks, such as those directed toward artificial intelligence (AI) ethics, community impacts, or environmental heath, can serve as models for the types of information that playbooks for equitable innovation might usefully contain. Materials developed by CESTI and in this report—including the articulation of equity dimensions, the governance framework and its five imperatives, illustrative case examples and boxes, and implementation guidance—can all serve as starting points to inform further discussion and development.

RECOMMENDATION 6. Develop context-specific guidance on translating the governance framework for emerging science, technology, and innovation into practice. Innovation stakeholders in professional, government, and community settings should strongly consider developing equity playbooks providing strategies, key questions, and advice targeted to particular roles in the technology life cycle, types of inequity, or specific areas of emerging science and technology, including context-specific guidance on incorporating equity science into technology assessment (see Recommendation 5).

This recommendation focuses on operationalizing the report's key messages for different fields and purposes. To this end, federal, philanthropic, and private funding organizations in the innovation system for health and medicine should support the development and dissemination of equity playbooks by their stakeholders, including model playbooks created in partnership with affected communities to provide historically marginalized and underserved communities with guidance, strategies, and tools that can enhance their participation in the

innovation system. Professional associations should also play important roles in developing and disseminating equity playbooks as a professional norm for their communities.

LOOKING TO THE FUTURE: AN ACTION AGENDA

Table S-2 provides a high-level summary of opportunities for actors throughout the ecosystem of emerging science, technology, and innovation in health and medicine to help translate the above recommendations into practice.

TABLE S-2 An Action Agenda for Stakeholders

Actors	Actions	Desired Outcomes
White House Office of Science and Technology Policy (OSTP) and Equity in Biomedical Innovation Task Force	• Identify priorities for aligning emerging biomedical science, technology, and innovation with the report's governance framework for equity. • Work with department and agency equity teams and White House Steering Committee on Equity to translate these priorities into goals to be accomplished over the next decade. • Partner with biomedical innovation stakeholders to engage proactively with underserved communities.	• An innovation system that catalyzes the discovery, translation, and use of emerging science and technology in health and medicine and leads to innovation aligned with ethical principles, including equity. • Federal and multistakeholder leadership to advance equitable innovation.
Funders of emerging science, technology, and innovation	• Mandate ethics training that incorporates an understanding of equity. • Support efforts that broaden views of who is part of the innovation workforce and where innovation occurs, including by supporting underserved communities to enhance their ability to participate in innovation. • Where appropriate, require applicants to address types of equity associated with proposed work, including community engagement plans, and/or to reassess a technology's alignment with equity periodically. • Include diverse perspectives on funding panels and periodically undertake portfolio for alignment with equity aims, to inform decision making. • Support the development of equity science and enhanced equity measures and benchmarks usable at multiple points throughout the technology life cycle.	• Expanded methods, metrics, and benchmarks for assessing alignment with equity to inform decision making by stakeholders throughout the innovation system. • Policies that recognize the importance of alignment with equity and evaluation criteria for undertaking assessments. • Integration of ethical concerns, including stakeholder needs and values, into the formulation, funding, and conduct of research.
Researchers and organizations, from academia and industry, that conduct research and development	• Demonstrate organizational commitment to equity in biomedical innovation, including in training programs and technology assessments. • Develop guidance and standards for academic and professional training incorporating equity. • Use best practices for codesigning research with affected communities, and implement designs that mitigate biases and consider the full range of anticipated users. • Include diverse perspectives on review panels, and consider whether research designs are likely to benefit or burden particular groups unfairly.	• Integration of ethical and equity concerns, including stakeholder needs and values, into the formulation and conduct of research and development. • Policies that recognize the importance of alignment with equity and evaluation criteria for undertaking assessments. • Substantive partnerships, synergies, and collaborations that address needs and opportunities.

continued

TABLE S-2 Continued

Actors	Actions	Desired Outcomes
U.S. Patent and Trademark Office, technology transfer and licensing offices, law firms, and venture capital and other investors	• Expand engagement with research and social science experts to understand ethical and equity considerations associated with new intellectual property. • Incorporate ethics and equity assessment more fully into licensing and technology transfer practices, including developing and making use of enhanced equity provisions in licensing and start-up agreements. • Make use of models and practices for recognizing the contributions of research participants to resulting intellectual property. • Require patent descriptions to be transparent about the data, populations, and algorithms on which they are based. • Periodically undertake portfolio analyses for alignment with equity aims to inform decision making.	• Enhanced use of provisions in IP identification, management, licensing and start-up agreements that facilitate public benefit and equity.
Affected communities, including those that are historically marginalized and underrepresented	• Identify questions and research areas that would address areas of community interest and need. • Participate in developing a shared vision for engagement for a given research project. • Participate in developing equity science.	• Sustained, bidirectional participation and engagement in the innovation system. • Expanded methods, metrics, and benchmarks for assessing alignment with equity.
Regulatory stakeholders	• Require testing and analyses that meaningfully reflect the full range of intended users and contexts. • Incorporate mechanisms for engaging with affected communities, considering input received, and explaining how the information will be used in decision making. • When relevant, require postmarket analyses to identify whether inequities have arisen, and take action to address them.	• Policies that recognize the importance of alignment with equity and evaluation criteria for undertaking assessments. • Governance that is responsive to changes in equity impacts.
Health care payers and delivery stakeholders	• Include equity science metrics and analysis in purchasing, use, and coverage decisions. • Use postmarket analyses to identify whether inequities have arisen, and take action to address them. • Periodically conduct or require portfolio analyses for alignment with equity aims, to inform decision making.	• More equitable access to new technologies and more equitable health outcomes.

TABLE S-2 Continued

Actors	Actions	Desired Outcomes
All stakeholders	• Promulgate a culture of emerging science, technology, and innovation that includes awareness of equity as a normative principle. • Consider how information learned from the development and use of a technology provides new conceptual understanding or new problem formulations or identifies future research needs. • Consider whether a fuller understanding of the technology's impacts through the life cycle reveals a need for governance changes (to oversight mechanisms, incentives, or other actions). • Support and take part in the development and dissemination of context-specific equity playbooks.	• A learning system that fosters equitable innovation in health and medicine. • Context-specific guidance on equity tools and strategies targeted to particular fields, roles in the innovation life cycle, or equity considerations.

1

Introduction

Progress in science, technology, and innovation is a collaborative effort that involves choices and actions made by multiple parties, acting within systems that begin even before the conception and development of research questions; encompass the experiences of those who use the resulting products; and extend to analyses that inform the next generation of questions, approaches, and technologies. The development of emerging technologies is also integrally embedded in national and international ethical, social, economic, and regulatory contexts, which shape the values reflected in the innovation process, as well as influence who participates in and controls the choices made along the way, who receives the benefits and bears the burdens generated in the process, and how elements of the system are governed.

A vast array of technologies is applicable to the health and medicine sphere: tools for more precise genome editing, mRNA platforms for faster vaccine production, new sources of transplantable organs, research aimed at counteracting effects of aging, the integration of data and machine learning algorithms to accelerate cancer diagnosis, consumer products such as transcranial brain stimulation devices, and many, many others. One estimate has placed the annual direct economic impact of biotechnology advances in the domain of "human health and performance" at $0.5–1.2 trillion (McKinsey Global Institute, 2020).

PAST AND CURRENT EFFORTS TOWARD ADVANCING EQUITY

It would be impossible for a single set of recommendations to address in detail the implications of this landscape and its alignment with ethical and social values. Rather, multiple efforts by national and international networks of researchers and policy makers, along with numerous publications from scholars of emerging science and technology, responsible innovation, bioethics, and anticipatory governance, have explored these questions through the development of frameworks and strategies and in the context of given questions and technologies. Government agencies, foundations, professional societies, and philanthropic

BOX 1-1 SELECTED EXAMPLES OF RECENT PUBLICATIONS AND INITIATIVES EXPLORING IMPLICATIONS AND GOVERNANCE OF EMERGING TECHNOLOGIES IN HEALTH AND MEDICINE

Research ethics and responsible innovation

- *Responsible Conduct in the Global Research Enterprise* (IAP, 2012)
- *Integrity in Practice Toolkit* (The Royal Society and UK Research Integrity Office, 2018)
- *Research Culture: Embedding Inclusive Excellence* (The Royal Society, 2018)
- *Responsible Research and Innovation (RRI) Toolkit* (European Union, n.d.)
- *Emerging Biotechnologies: Technology, Choice and the Public Good* (Nuffield Council on Bioethics, 2012)

Governance of emerging technologies

- *Governance of Emerging Technologies: Aligning Policy Analysis with the Public's Values* (Hastings Center, 2018)
- *Human Genome Editing: A Framework for Governance* (WHO, 2021)
- *Technology Governance* (OECD, 2023)
- *Global Technology Governance: A Multistakeholder Approach* (WEF, 2019)

Addressing ethical or social Implications of areas of science, technology, and clinical care

- *Realizing the Promise of Equity in the Organ Transplantation System* (NASEM, 2022)
- *Mitochondrial Replacement Techniques: Ethical, Social, and Policy Considerations* (NASEM, 2016)
- *Statement on Regenerative Medicine* (IAP, 2021)
- *Gene Editing in the Wild: Shaping Decisions through Broad Public Deliberation* (Hastings Center, 2021)
- *Recommendation on Responsible Innovation in Neurotechnology* (OECD, 2019)

Intersections of technology and health equity

- *Access to COVID-19 Tools Accelerator* (ACT Accelerator, n.d.)
- *A Critical Moment in Bioethics: Reckoning with Anti-Black Racism through Intergenerational Dialogue* (Hasting Center, 2022)
- *Framework for Equitable Allocation of COVID-19 Vaccine* (NASEM, 2020b)
- *Health Inequalities Research: New Methods, Better Insights* (ALLEA, 2021)
- *Catching Technological Waves: Innovation with Equity: Technology and Innovation Report 2021* (UNCTAD, 2021)
- *Exploring Tax Policy to Advance Population Health, Health Equity, and Economic Prosperity* (NASEM, 2019b)

Governance to address security implications of emerging technologies

- *Proposed Biosecurity Oversight Framework for the Future of Science* (NSABB, 2023)
- *Global Guidance Framework for the Responsible Use of the Life sciences: Mitigating Biorisks and Governing Dual-Use Research* (WHO, 2022)
- *Safeguarding the Bioeconomy* (NASEM, 2020a)
- *Governance of Dual Use Research in the Life Sciences: Advancing Global Consensus on Research Oversight: Proceedings of a Workshop* (NASEM, 2018)

Governance to address sustainability implications of emerging technologies

- *Enhancing Governance for Sustainability* (IIASA and International Science Council, 2021)

donors all contribute to supporting and advancing efforts directed toward the ethics and governance of emerging technologies. A very small sampling of these efforts—intended only as broadly illustrative and far from comprehensive—is presented in Box 1-1.

Advancing equity is also an ongoing priority across the U.S. government. In 2021, President Biden issued Executive Order 13985 on *Advancing Racial Equity and Support for Underserved Communities through the Federal Government*. This Executive Order called on federal agencies to develop equity action plans; evaluate whether agency policies produce racial inequities; and identify opportunities to increase coordination, communication, and engagement with community-based organizations and civil rights organizations supporting underserved communities (White House, 2021a). The Executive Order also called on the director of the Office of Management and Budget to "study methods for assessing whether agency policies and actions create or exacerbate barriers to full and equal participation" and "identify opportunities to promote equity in the budget that the President submits to the Congress." Finally, recognizing that a first step in promoting equity is to gather the data necessary to inform that effort, the Executive Order established an Interagency Working Group on Equitable Data. In addition, the White House issued Executive Order 14020, establishing a White House Gender Policy Council (White House, 2021b), and Executive Order 14031, aimed at reinvigorating the White House Initiative on Asian Americans, Native Hawaiians, and Pacific Islanders to advance equity, justice, and opportunity (White House, 2021c).

Agency equity plans were released in 2022. According to its plan, for example, the Department of Defense is attempting to mitigate algorithmic bias and increase the safety and equity of artificial intelligence (AI) by investing in such actions as partnerships with historically Black colleges and universities and minority-serving institutions to create a more diverse workforce (White House, 2022a).

The above Executive Orders prioritize equity in ways that encompass the whole of government and go well beyond the domain of biomedical science, extending to agencies whose purviews range from the U.S. tax code to housing.

The focus on this priority has continued. In December 2022, the White House Office of Science and Technology Policy (OSTP) released a vision for a national effort toward achieving equity in the U.S. science and technology ecosystem, supported by $1.2 billion in funding for science, technology, engineering, and mathematics (STEM) programs, investments, and opportunities targeted to historically underserved populations and areas. The programs thus supported include degree and teaching scholarships, experiential learning and training programs, internships, grants, and technical assistance. Agencies such as the National Science Foundation and the National Institutes of Health (NIH), nonprofit and educational institutions such as Spelman College and The Johns Hopkins University, and private companies such as Micron and Intel are contributing (White House, 2022b,c). In February 2023, the White House issued Executive Order 14091 on *Further Advancing Racial Equity and Support for Underserved Communities through the Federal Government*,[1] establishing Equity Teams within agencies to coordinate the implementation of initiatives (White House, 2023). Each agency Equity Team is to be led by a senior designee responsible for ensuring "sufficient

[1] The term "equity" as defined by Executive Order 14091 "means the consistent and systematic treatment of all individuals in a fair, just, and impartial manner, including individuals who belong to communities that often have been denied such treatment, such as Black, Latino, Indigenous and Native American, Asian American, Native Hawaiian, and Pacific Islander persons and other persons of color; members of religious minorities; women and girls; LGBTQI+ persons; persons with disabilities; persons who live in rural areas; persons who live in United States Territories; persons otherwise adversely affected by persistent poverty or inequality; and individuals who belong to multiple such communities."

resources, including staffing and data collection capacity, to advance the agency's equity goals" and to deliver equitable outcomes. The Executive Order also established a White House Steering Committee on Equity to coordinate government efforts, monitor agencies' activities, and promote accountability.

Federal investments and priority setting in the U.S. science, technology, and innovation enterprise also encompass recent actions such as the *Creating Helpful Incentives to Produce Semiconductors (CHIPS) and Science Act* (Public Law 117-167) and Executive Order 14081, *Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy* (White House, 2022d). All of these actions reflect substantive recognition of the importance of equity across the U.S. government, providing substantial opportunities to support equitable science, technology, and innovation and foster a system that recognizes and can meet the needs of the many diverse populations that live and work in the United States.

This body of work—from both the U.S. federal government and public and private actors such as those listed in Box 1-1—forms the context for this report. Collectively, these and other efforts have helped advance an understanding of shared responsibilities in health and medicine and the identification of additional opportunities to better anticipate and manage the benefits and harms of emerging technologies.

NATIONAL ACADEMY OF MEDICINE'S EMPHASIS ON EMERGING SCIENCE, TECHNOLOGY, AND INNOVATION

Under its current strategic plan, the National Academy of Medicine (NAM) emphasizes the vision of "a healthy future for everyone" (NAM Strategic Plan 2018–2023). In early 2020, NAM established a standing Committee on Emerging Science, Technology, and Innovation in Health and Medicine (CESTI) to explore technologies contributing to this future and discuss how to address their potential societal, ethical, legal, and other implications. CESTI's discussions emphasized the importance of developing approaches for integrating multiple sectors of the innovation ecosystem, including academia, industry, government, venture capital, philanthropy, and members of the public. Over the course of 2 years, CESTI developed illustrative case studies in regenerative medicine, telehealth, and noninvasive neuromodulation devices. Each case study included a visioning component exploring possible future scenarios for how the technology might develop and what additional ethical, legal, and regulatory concerns such futures might raise. Drawing on these cases, CESTI articulated five foundational ethical principles for emerging technologies in health and medicine—justice, autonomy, fairness, collective good, and individual good—concluding that commitments to upholding the values embodied by these principles could guide the further development of policies and practices for the governance of emerging technologies (Mathews et al., 2022a,b) (see Figure 1-1). Other committees have developed similar sets of ethical principles as the basis for assessing implications associated with new biomedical technologies (see, for example, NASEM 2019a).

CESTI's analysis emphasized the engagement of multiple actors—including those who play central roles in the design and development of a technology, policy makers and regulators, and individual users and society—as an essential component of the technology landscape. Its analysis also highlighted the importance of considering the principles cited above and included in Figure 1-1 as early as possible in technology development, stating that "if a governance structure is not designed to consider equity questions early in a technology's life cycle, it may be considerably more difficult to address them later…. A governance structure

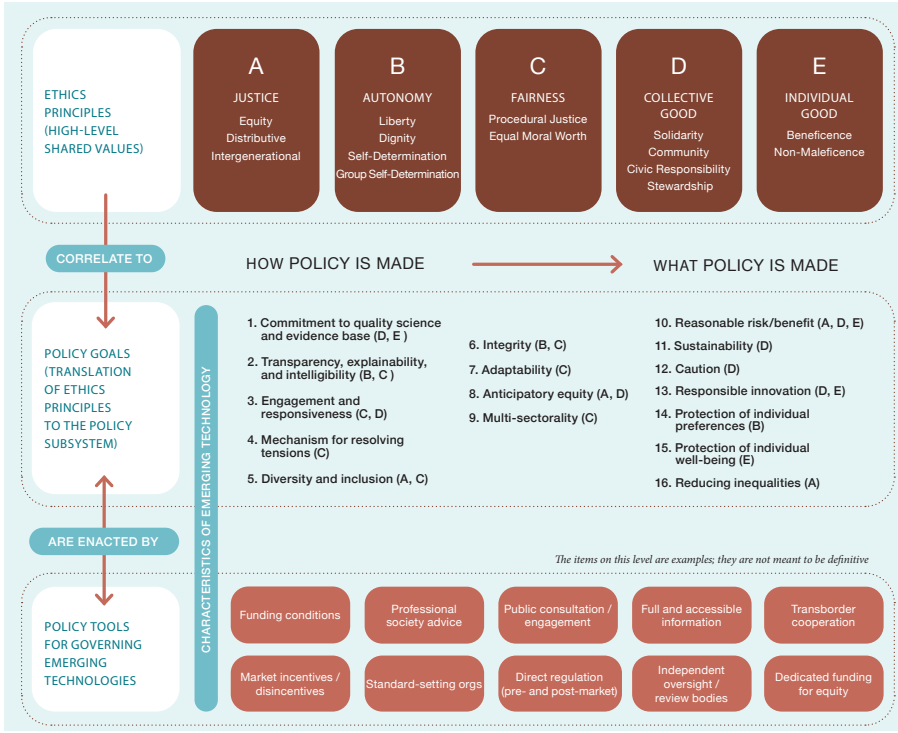

FIGURE 1-1 Principles and commitments articulated by the National Academy of Medicine's Committee on Emerging Science, Technology, and Innovation in Health and Medicine.
SOURCE: Mathews et al., 2022b.

that could anticipate this potential challenge through fair and inclusive procedures and attention to structural injustice might prevent similar equity concerns from arising in the future" (Mathews et al., 2022b, p. 46).

BEYOND RESEARCH ETHICS: ENHANCED ATTENTION TO EQUITY, JUSTICE, AND FAIRNESS

The body of work described above and other efforts described in the text and boxes throughout this report reflect how responsible research and innovation in health and medicine is built on foundational research ethics that guide what is considered acceptable or unacceptable while requiring a focus that extends beyond individual-level concerns to encompass collective values and needs. Which aspects are emphasized by these guiding principles and how those principles have been implemented in national and international oversight structures have evolved over time, as reflected in extensive bodies of scholarship on the development and evolution of bioethics in health and medicine (see, e.g., London, 2022).

The current approach to responsible conduct and oversight of research with human subjects was significantly informed by events and discussions during the 1960s and 1970s, including public revelations about the infamous Tuskegee Syphilis Study (carried out from 1932 to 1972) (Breed, 2022) and the publication of other examples that raised critical questions about how participants' risks, benefits, and consent were addressed in clinical studies (see, for example, Beecher, 1966). The *Declaration of Helsinki: Ethical Principles for Research Involving Human Subjects* was adopted by the World Medical Association in 1964 (WMA, 1964; multiple revisions). In the United States, the National Research Act, signed in 1974, authorized the U.S. Department of Health and Human Services (HHS) to establish regulations for research with human subjects [Pub. L. No. 93-348, § 214, 88 Stat. 342 (1974)]. This was followed in 1979 by the Belmont report from the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, which emphasized respect for persons, beneficence, and justice (Department of Health, Education and Welfare, 1979), particularly as applied to the individual risks, benefits, and treatment of research participants. The Belmont report's recommendations were pivotal in shaping the expansion and revision of federal regulations governing human subjects research under 45 Code of Federal Regulations (CFR) 46 ("the Common Rule"), most recently amended in 2018. Influential international bioethics statements and reports have also been released in prior decades, including the *Universal Declaration on Bioethics and Human Rights* (UNESCO, 2005); *International Ethical Guidelines for Health-Related Research Involving Humans* (CIOMS and WHO, 2016; multiple revisions); and documents emphasizing the right to health of such communities as persons with disabilities, women, and children (United Nations, 1989, 2006, 2015).

Structures that provide for periodic reviews and responsive decision making—including institutional review boards, bioethics committees, peer review panels to advise on funding and publication decisions, and premarket regulatory reviews—have become well established as mechanisms for embedding these principles in biomedical research and development (see Chapter 3 for more detail on the current U.S. system of science and technology research and development). New concerns arising from technical advances—those resulting, for example, from research using recombinant DNA molecules, human stem cells, or pathogen "gain of function" experiments—have led to periodic reviews of policies governing the health and medicine field. Over time, bodies such as the HHS Office of Research Integrity and the NIH Novel and Exceptional Technology and Research Advisory Committee (NExTRAC) have been established,[2] requirements for researchers to receive training in responsible research conduct have been implemented, practices for conducting clinical trials at international sites have been updated, and policies governing the protection and sharing of personal health information have been incorporated (Baker et al., 2016; London, 2022). Responsible practices continue to evolve in other areas as well, including the ethical care and use of research animals (NRC, 2011).

These developments largely reflect concepts of balancing potential benefits and harms that accrue to individual research participants, including an emphasis on obtaining appropriate, informed consent. As efforts of the federal government, CESTI, and others have emphasized, additional focus is needed on the social contexts in which research, development, and innovation take place, and thus on the importance of aligning innovation with principles that support collective good and of recognizing the social responsibility of science and technology to advance health for everyone. Research and innovation systems are not disconnected from social purposes, and so it is important to acknowledge the ethical grounds "for holding a wider range of actors accountable for decisions that affect the questions that are asked;

[2] See https://ori.hhs.gov/ and https://osp.od.nih.gov/policies/novel-and-exceptional-technology-and-research-advisory-committee-nextrac/ (accessed June 19, 2023).

the methods that are used to address them; the terms on which studies are carried out; and the prospects for incorporating the resulting knowledge, practices, and interventions into the social systems charged with safeguarding and advancing the basic interests of community members" (London, 2022, p. 25). Such issues go beyond those that have been the traditional focus of research ethics and the translation of those ethics into practice. The prioritization of principles and values addressing broad social and ethical considerations also reflects and builds on an increasing emphasis over the past decades on meaningful involvement of patients and community members in research and cogovernance and on the imperative to address the values and concerns of historically underrecognized communities, including Indigenous populations and people with disabilities (Claw et al., 2018; DeCormier Plosky et al., 2022; Fair et al., 2022; Selker and Wilkins, 2017). See Chapter 2 and Appendix B for a fuller discussion of these issues and a historical review of equity and technology governance.

STUDY SCOPE AND APPROACH

To build on and advance the work of the federal government, CESTI, and other stakeholders described above, the National Academies of Sciences, Engineering, and Medicine and the National Academy of Medicine convened an ad hoc committee of experts to consider how governance systems for emerging science, technology, and innovation in health and medicine can meaningfully incorporate ethical principles and facilitate the development and use of transformative technologies with a particular focus on equity. See Box 1-2 for the committee's full statement of task.

Study Scope

The charge to the committee supports the development of anticipatory and cross-sectoral governance and focuses on the concept of equity from among the broader set of individual- and collective-level ethical principles identified by CESTI. The understanding of equity used in this report is described in Chapter 2 and combines elements of justice and common good, used by the CESTI standing committee, along with concepts of fairness and equality. Different stakeholders and communities are likely to most resonate with different terms from among this set; the report's primary aim is to discuss how the current system of emerging science, technology, and innovation in medicine and health fails to sufficiently address the needs of all of the system's stakeholders and users, and largely uses the term "equity" to capture these gaps, challenges, and opportunities for action. Equity, as understood in this report, is about bridging gaps between the needs of community members and the ability of social institutions to respond to, protect, or advance those needs. As described in Chapter 2, an understanding of equity does not equate simply to enhancing access to resources or products, nor is it limited to considerations based on race or ethnicity. Rather, a broad approach to equity in innovation calls for an effective and fair system for the development and governance of medical technologies, one that moves toward an ideal of universalization by acting to remedy inequities across the full range of the system's users. It involves a multidimensional focus on factors that help shape the questions that are asked, the technologies that are developed, who has access to their benefits, and how they contribute to closing or widening gaps in the ability of different parties to lead healthy lives. By focusing on this multifaceted concept of equity instead of addressing all five ethical principles identified by CESTI simultaneously, the committee was able to assess the challenges, opportunities, strategies, and tools entailed in creating such a system, and

BOX 1-2 STATEMENT OF TASK

Building on the work of the National Academy of Medicine Committee on Emerging Science, Technology, and Innovation, a National Academies of Sciences, Engineering, and Medicine ad hoc committee will develop a cross-sectoral coordinated governance framework founded upon core ethical principles with a focus on equity, for considering the potential benefits and risks that emerging science, technology, and innovation in health and medicine can bring to society. The committee will:

- Assess the existing ecosystem for cross-sectoral governance of emerging technologies in health and medicine with a focus on identifying governance gaps and unintended consequences raised by the current ecosystem;
- Identify specific governance approaches at various points in the technology life cycle to meaningfully translate key ethics principles into the governance ecosystem, with a particular focus on justice, equity, and fairness;
- Consider how to empower emerging technology stakeholders by aligning incentives to facilitate the development and use of transformative technologies while also mitigating potential risks and enhancing societal benefit; and
- Recommend specific strategies and practical approaches to improve cross-sectoral and coordinated governance of emerging technologies (e.g., forecasting mechanisms, coordination across sectors, principle-aligned governance levers, and public engagement) and to align governance with guiding ethics principles.

The committee's report will provide guidance for how to manage the risks, benefits, and ethical and societal implications of new technologies. While the committee will pay particular attention to the governance ecosystem in the United States, mechanisms to coordinate cross-border governance issues should also be considered where applicable.

to consider the full complexity of the concept at a level of detail that can advance the discussion beyond an individual's potential benefits and harms.

Even with this focus on equity from among CESTI's set of foundational ethical principles, the committee's scope was unusually large. The committee's charge centers on emerging medical technologies or the direct application of related technical developments to medical products (such as the increasing integration of AI in medicine); it is not limited to a given area of research or technology development. Accordingly, this report develops a cross-cutting conceptual framework and set of action areas that draw on features common to the development of seemingly different technologies and products.

The committee recognizes that health can be advanced in multiple ways, many of which are not centered on discovering and deploying emerging technologies; examples include improving natural and built environments in ways that benefit health, better addressing socioeconomic factors such as poverty, enhancing access to information through programs that extend high-speed internet coverage, or better implementing care practices that have been shown to be effective.[3] While these action areas can have significant impacts on health and health equity,

[3] See, for example, National Clinical Care Commission (2021) as an example of a holistic approach to diabetes prevention.

the report does not address them in detail because of the need to focus rather than broaden the study scope and to adhere to the committee's statement of task, which requires that the focus be on emerging science, technology, and innovation in health and medicine.

Finally, the committee recognizes the global nature of technology development and the diversity of national, regional, and international systems for conducting, sharing, and regulating research and innovation in health and medicine. This report focuses on the U.S. system, particularly in Chapter 3, which describes U.S. policies and agencies active in the current medical technology ecosystem. Nevertheless, the concept of equity and the conceptual framework proposed in the report for aligning the development and governance of emerging science, technology, and innovation with complex ethical considerations may be applicable to other contexts and across borders. Thus, although the strategies set forth in the report are targeted to U.S. actors, the report's guidance may be adaptable to discussions in other forums, such as the Organisation for Economic Co-operation and Development (OECD) or the World Health Organization. The global reach of the implications associated with emerging technologies in health and medicine underscores the importance of global consideration of governance and equity in innovation. This report could help inform such conversations.

Study Approach

Reflecting the complexity of its task, the committee included 19 members and two fellows of the National Academy of Medicine with expertise in technology development and assessment, representing academia, industry, and government in the areas of public health, philosophy and the social sciences, economics, innovation policies, regulatory oversight, the rights and needs of historically marginalized or underrepresented communities, and other domains. The committee met five times over the course of the study to discuss and analyze the available evidence and to develop the conclusions and recommendations presented in this report.

In conducting the study, the committee drew on materials developed by CESTI and on presentations and discussions during a virtual workshop in 2022 organized by CESTI to explore examples of public engagement and health technology assessment, and to discuss the translation of guiding ethical principles into governance. The committee reviewed three case studies developed by CESTI and sought to better understand how these cases illustrate the dynamic, distributed nature of innovation, the roles of actors at different stages in the innovation life cycle, the incentives and the regulatory landscapes associated with the case study areas, and potential intervention points at which nudges to promote alignment with equity might be possible. The committee also explored a "heatmap" tool developed by CESTI to visually represent a technology's alignment with CESTI's set of foundational ethical principles for a context of use at a point in time (see Chapter 5).

Additional evidence gathered during the study included responses to a public call for input on successes and challenges in the current ecosystem for governance of emerging technologies in health and medicine, and on strategies and approaches for better aligning technology development and governance with ethical principles that include equity. Committee members also reviewed the relevant literature and prior reports of the National Academies; commissioned two white papers; and held public, virtual information-gathering sessions in June, August, and October 2022, which featured speakers who generously shared their knowledge. See Appendix A for further information on how the committee conducted its work; Appendixes B and C for the commissioned papers; and Appendix D for brief biographies of committee members, fellows, and staff.

Finally, to better understand perspectives on ethical and societal implications of emerging technologies, the committee gathered information from a public survey conducted in

2022 by The Johns Hopkins University.[4] The survey presented respondents with two short vignettes—one on genetically modified stem cells as a treatment for sickle cell disease and the other on use of a noninvasive brain stimulation device—and asked about their views on the potential benefits and harms of these technology areas, as well as their personal experiences with new technologies. Survey respondents expressed interest in using technologies for advancing health, but also raised concerns such as unknown longer-term outcomes, unequal availability, and the importance of conducting rigorous clinical trials and ensuring sufficient oversight (see Box 1-3 for selected survey responses). The frequency with which respondents identified equity and fairness as critical elements for health and medical technologies contributed to this report's emphasis on opportunities for enhancing the alignment of innovation systems with this principle.

BOX 1-3 SELECTED THEMES AND COMMENTS FROM A PUBLIC SURVEY

Genetically Modified Stem Cell Transplantation

This vignette focused on the use of stem cells and genetic modification in the context of a Food and Drug Administration (FDA)–regulated clinical trial for sickle cell disease, a disease in which research has been chronically underfunded, and for which many patients struggle to access the standard of care.

What do you see as the benefits of this new technology? What are your hopes for this technology and how it might be used in the future?

> Respondents highlighted such benefits as the potential for improved health and quality of life and the advantage of using the patient's own cells for the treatment. One added that the technology represented "an opportunity for life equity."
>
> Hopes for the technology's future included that it "be used responsibly, ethically, and equitably. I hope it will improve the lives of people with chronic diseases who currently have no good treatment options," and that "access to genetically specific health treatments…could avoid systemic drugs that don't target specific cells (like cancer treatments or oral steroids). We've gotten so much better at sequencing anything, so as long as these treatments are affordable and available to all Americans—not just those with Cadillac health care plans—I hope they become the predominant form of treatment."

What do you see as the risks of this new technology? What are your fears about this technology and how it might be used in the future?

> Respondents raised risks associated with clinical trials of a new medical product, such as the technology's not working as intended or producing side effects, emphasizing unknowns around safety and efficacy and the importance of providing clear information to facilitate informed consent. Several comments reflected the role of clinical trials in understanding benefits and harms as a basis for further evaluation.

[4] The public survey on which the content of this section draws was conducted by The Johns Hopkins University in accordance with its institutional policies and procedures (Mathews, 2022). Additional deidentified responses to the survey, reflected in Box 1-3, were provided by Debra Mathews in a personal communication (11/22/22). See Appendix A for additional information.

BOX 1-3 Continued

Many of the expressed concerns also involved issues of cost, access, and equity. For example, "My biggest fear is that these advances will literally create two classes of people—those who have access to truly groundbreaking genetic treatments and the rest of us who could be stuck back in the stone age. Accessibility and equity must be considered to avoid this two-tiered nightmare." Others noted that "there would have to be ways to offer the treatment at low cost, when needed" and expressed fear that "this technology will not be made available to people who might need it the most...."

Other concerns included "quacks offering fake services, taking peoples' money, and decreasing the overall confidence in science and medicine"; problems during early uses that could "kill useful technology, just because people fear the term "genetically modified"; and the potential for a slippery slope that might "open the door to other genetically modified practices that create and cement stereotypes" or to nontherapeutic uses, such as genetic enhancement.

Brain-Stimulating Devices

This vignette highlighted consumer use of a technology for increased focus (rather than for disease treatment) and its use by children rather than by adults in a clinical trial. As a result, the example raised additional unknowns and considerations for respondents.

What do you see as the benefits of this new technology? What are your hopes for this technology and how it might be used in the future?

Benefits and hopes included improved concentration, attention, and mood, and the potential for use as treatments for neurological disorders such as Parkinson's disease. A participant remarked, "If we can find a way to help people in noninvasive ways, it is much safer than surgically altering or putting implants into brains." Many participants noted, however, that "we also have to be careful to make sure we understand more than one side of it" and urged that we "be led by science, not profit alone."

What do you see as the risks of this new technology? What are your fears about this technology and how it might be used in the future?

A number of concerns centered around insufficient knowledge, particularly effects on a developing brain ("remain cautious and conservative when dealing with children") and limited regulatory oversight. For example, "Sounds like a marketing claim to me, and furthermore not regulated by anyone.... If the technology really does improve attention and focus that seems like a good thing for someone who needs it, whether an adult or child, but that needs to be backed up by evidence. The other question is, what is the long-term impact of using such devices." Others suggested that "the risks of over stimulating [the brain] or stimulating the 'wrong' parts are one big concern of mine, especially if nonreversible" and "Once you start being able to send signals to someone's brain... we might be going down a very scary road." Still others worried about the possibility that a "new technology is rushed to market with no guardrails, no scientific studies, inadequate knowledge about potential deleterious effects" and the "potential for pseudoscientific application of such devices, and overblown claims of their effectiveness," as well as "financial and opportunity costs" and risks of "deepening exclusion, discrimination, and inequity."

Reflections on Influences and Implications of New Technologies

Respondents were asked how a new technology has improved their life or the lives of family or friends, as well as how a new technology has made it more difficult.

BOX 1-3 Continued

Many respondents commented on advantages and disadvantages posed by access to telecommunications technologies and services, such as the internet, mobile phones, and videoconferencing, as well as expanded use of telemedicine. For example, "Telemedicine has made it easier for everyone in our family to 'see' a doctor during COVID. In addition, increased online connectivity has decreased distance barriers and brought our family members closer together." On the other hand, negative consequences included the complexity and speed of change of these technologies, the potential of such technologies to amplify mis- or disinformation, and replacement of in-person interactions, as well as concerns that not everyone can engage effectively in the digital world (for example, people who are less technologically savvy or who live in areas without sufficient internet access). Still others noted the rising cost of services, "overreliance on black box tech and unable to fix it yourself; lack of tech standardization; waste; [and] lack of privacy (data theft)." Still other respondents were concerned that "overreliance on algorithms has interfered with provider judgment of me as an individual and more hands-on, personalized assessment" and that algorithmic bias will reinforce provider bias.

Participation in Decisions about How New Technologies Are Governed and Regulated

Finally, participants were asked how they would prefer to engage in decision making around new technologies. The top three responses were: participate in a community advisory board involved in decisions, respond to public surveys to inform decisions, and read and respond to public notices requesting input on decisions. Among those who wrote in responses, the most common theme (about one-third of written responses) was interest in some form of direct participation in research, development, and governance processes. The second most common theme was related to ensuring that science and ethics experts are directly involved in or leading governance.

ORGANIZATION OF THE REPORT

In Chapter 2 of this report, the committee explains why consideration of equity is critical to ensuring that a medical technology and innovation system functions for everyone, and delves further into what attention to equity entails. Chapter 3 describes a simplified conceptual model of biomedical innovation, including the major phases of development, points at which choices are made, and who is involved in making them. It also presents the committee's analysis of potential gaps and unintended consequences arising from the current U.S. ecosystem for emerging science, technology, and innovation. Chapter 4 provides a conceptual framework guided by five imperatives for enhancing coordinated, multiactor/multistakeholder governance of emerging technologies and promoting alignment with ethical values, with a focus on equity. The second part of the chapter shows how this framework translates to the technology development life cycle and describes how the framework provides a basis for improved innovation and governance processes. Chapter 5 presents the committee's recommendations and guidance for advancing progress in key areas of action aligned with the proposed framework. It also suggests how resources developed by CESTI and described throughout the report can serve as starting tools for others interested in better aligning the development, use, and governance of emerging biomedical technology with the principle of equity.

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2

Taking Equity Seriously in Innovation

This chapter explains why equity and its absence in the development of medical technology are concerns that demand new approaches to governance. It explains why equity is important now and presents the justification for aligning the medical technology system with equity. The chapter then turns to defining equity dimensions associated with the technology development system: what equity is, and what it is not. Finally, the chapter illustrates relevant considerations using the case example of concerns of the disability community, and summarizes the application of equity principles in the development and innovation of medical technology.

WHY EQUITY IS IMPORTANT NOW

The COVID-19 pandemic revealed inequities in health care and technology both in the United States and globally. The association of death rates and longer-term symptoms with race and socioeconomic status was stark; death rates among people of color, for example, were higher than those among their White counterparts (Hill and Artiga, 2022; Khullar et al., 2023; Magesh et al., 2021). Medical and public health responses to COVID-19 also exposed inequities, as illustrated by systemic ethnic and racial biases in pulse oximetry. As a result, "arterial oxygen saturation [was overestimated] among Asian, Black, and Hispanic patients compared with White patients," which in turn led to delayed identification of treatment eligibility for people of color (Fawzy et al., 2022, p. 731) (see Box 2-1).

At the most basic level, the early public health message about washing one's hands as a means of limiting disease risk was more illusory than real for communities lacking clean water and proper sanitation. These concerns are as real in the United States as they are in the global south because in America, "millions live without access to clean water," and "the coronavirus has left them in further turmoil" (Shah, 2020). Even before the pandemic, residents of Flint, Michigan, experienced "lead seepage into the drinking water" and a significant Legionnaire's Disease outbreak that caused "a massive public health crisis," prompting President Obama's

BOX 2-1

THE PULSE OXIMETER: AN EXAMPLE OF INEQUITY IN HEALTH TECHNOLOGY

Invented in the 1970s, the pulse oximeter is a real-time and low-cost tool that shines red and infrared light through a person's fingertip or earlobe to estimate blood oxygen concentration via oxygen saturation level (Keller et al., 2022; Tobin, 2020). A higher level of absorption of infrared light relative to red light indicates oxygenated hemoglobin, which in turn indicates well-oxygenated blood. Conversely, higher absorption of red relative to infrared light indicates deoxygenated hemoglobin, an indicator of low blood oxygen (Keller et al., 2022). The device was developed by Japanese bioengineer Takuo Aoyagi to improve on previous oximeters, which were invasive and sometimes inaccurate.

The technology became a crucial tool during the COVID-19 pandemic, when the health system was overwhelmed by high rates of pulmonary and cardiovascular complications and injury due to the SARS-CoV-2 virus, along with workforce shortages and the limited availability of medical equipment such as diagnostic tests, mechanical ventilators, and gold standard blood gas tests (Aziz et al., 2020). In this context, pulse oximeters were deployed en masse to triage the use of intensive care unit (ICU) beds and ventilators to treat hypoxemia or low blood oxygen (Aziz et al., 2020; Keller et al., 2022).

In August 2020, a few months after the pandemic's onset, anthropologist Amy Moran-Thomas wrote an article questioning the pulse oximeter's accuracy among people of color (Moran-Thomas, 2020). Light photons scatter differently in the presence of melanin, a phenomenon that had produced inaccuracies in photographic film until recalibration was performed in the 1970s (Lewis, 2019). Moran-Thomas was also aware of the history of embedded racial bias in other medical technologies, such as the spirometer (Braun, 2014), as well as the concerns raised by scientists about the pulse oximeter for years, to little effect (Bickler et al., 2005). Studies confirmed that pulse oximeters are approximately three times more likely to miss low blood oxygen levels in Black than in White patients, a condition known as hidden hypoxemia (Sjoding et al., 2020; Wong et al., 2021). Furthermore, darker-skinned people are more likely than White people to experience hypoxemia due to delayed or unapplied treatments (Keller et al., 2022). As a result of these problems, darker-skinned people are more likely to receive inadequate care and experience adverse health outcomes compared with their White counterparts.

Ongoing research focused on further understanding the effects of pigmentation on pulse oximetry and manipulating the technology to cancel out the effects of melanin on its accuracy (Howard, 2022). At a more comprehensive systems level, the Food and Drug Administration (FDA) issued a safety communication in February 2021 highlighting the limitations of pulse oximeters, highlighting the need for personalized care for Black and Indigenous people and other communities of color (Keller et al., 2022). The FDA's Medical Devices Advisory Committee also was convened in November 2022 to determine what coordinated actions among health care workers, device manufacturers, researchers, and the FDA would improve the accuracy of pulse oximeters (Keller et al., 2022).

declaration of a federal state of emergency (Kennedy, 2016). For Indigenous Americans, the crisis is long-standing. In a groundbreaking empirical study, *Closing the Water Access Gap in the United States*, researchers reported that "Native American households are 19 times more likely than white households to lack indoor plumbing" (Dig Deep and U.S. Water Alliance, 2019, p. 12). Throughout parts of the United States, access not only to water but even to electricity cannot be presumed. In addition to the roughly 40 percent of Native American people who must haul their water, more than 25 percent report having problems

with or no electricity (Morales, 2019), to which families respond by turning to propane lamps and flashlights to see at night (Morales, 2019). And as with water and electricity, access to telephone service and high-speed internet is not a given. For rural American families, even hospitals may be out of reach. In a 2019 poll, "one in six Black rural Americans report[ed] recent hospital closures in their community" (NPR et al., 2019, p. 25).

All of these inequities are aggravated by race, poverty, sex/gender, and disability status. In the United States, "more women than men live in poverty," and their economic insecurity affects not only them but also their children (Bleiweis et al., 2020, p. 1). The poorest American women are Indigenous, Black, and Latina. In fact, Latinas constitute "27.1 percent of women in poverty," even though they represent only "18.1 percent of all women in the U.S. population." (Bleiweis et al., 2020, p. 2). Likewise, women with disabilities experience a higher poverty rate compared with their counterparts without disabilities (22.9 percent compared to 11.4 percent).

At a macro-level, structural and infrastructural inequities in access to such necessities as water, transportation, and communications technology, compounded by the impacts of socioeconomic status, result in disparities in health and well-being and in patterns of outcomes that limit the life prospects of members of groups that bear a disproportionate burden of avoidable morbidity and mortality. Inequality in access to health care and in the equitable provision of safe and effective health services compounds these outcomes. Disparities in health outcomes operate across scales. At a less obvious level, disparities in health outcomes also reflect ways in which design bias is built into technology and health care delivery systems that put historically disadvantaged groups at further risk.

At all levels, moreover, people's lives are shaped by social institutions and practices that intersect to shape their experiences of inequity. Social structures of race, gender, disability status, sexuality, geographic location, nationality, and socioeconomic status are not mutually exclusive; one's lived experience of inequity typically reflects a combination of multiple factors that interact and shape patterns of penalty and privilege. The reality that people's experiences are shaped by multiple, intersecting social structures demands an intersectional approach to advancing equity (African American Policy Forum, n.d.; Black Feminist Health Science Studies, n.d.; Homan et al., 2021).

What mechanisms should be deployed to address the complex patterns of inequity in health care and health technology innovation? What roles should the private sector play? What roles should other actors, including funders, philanthropic organizations, and civil society groups, play in the technology development life cycle? The COVID-19 pandemic rendered these questions urgent not just in responding to what has happened over the past few years, but as essential considerations in preparing for future health emergencies. These questions about basic infrastructural needs also are being asked at a time when game-changing innovations in technology—from gene editing, to regenerative medicine, to artificial intelligence and machine learning—are changing society in unprecedented ways. In this context, it is essential to develop governance capacity that encompasses an ever-accelerating frontier of emerging technological development while eliminating the ever-more-glaring discrepancies in who has the resources to benefit from these developments, who is neglected or left behind, who is discriminated against in new ways and old, and who gets a say in how the technology is developed and disseminated.

The foundational premise on which the discussion in the chapter rests is that inequalities and inequities embedded in race, gender, sexuality, disability status, geography, and other circumstances, both in the United States and globally, are ethically unacceptable, economically debilitating, and scientifically diminishing. These patterns result from intersectional, multilevel social structures and have broad secondary effects on social and

economic life. With respect to the focus of this report, these patterns can be mitigated by robust, reflexive, cross-sectoral governance across the technology life cycle, especially when applied at critical choice points in technology development. The application of this premise argues that any consideration of the governance of emerging technology in health care requires an understanding of the disparate harms experienced by communities that have experienced structural (often intergenerational) inequality and injustice and economic distress, and it requires in turn the development of strategies for prioritizing participation, resources, and care in ways that address and mitigate these harms. Developing more robust scientific and technological innovation that is responsive to and addresses social needs in the broadest possible manner is not only a social and ethical imperative, it is also an economic one.

While focusing on equity in innovation in health care technology, the committee stresses that equity is a concern with deeper structural and contextual roots that go beyond the question of access to an emerging technology, however important that might be. This perspective suggests that institutions, both public and private, can be both incentivized and held accountable to produce systems that magnify and amplify inclusion, belonging, and equity in ways that can better realize the social potential of emerging science, technology, and innovation. This chapter thereby provides the foundation for future chapters that detail the contours of what a governance infrastructure for emerging science, technology, and innovation that is grounded in a concern with equity might look like and identify opportunities for advancing toward that goal.

JUSTIFICATION FOR CONSIDERING EQUITY IN THE MEDICAL TECHNOLOGY SYSTEM

Acknowledging that remedying inequities in technological innovation in health care cannot address all inequities in health or society, there is a particular justification and duty within the health sphere to attend to issues of equity. In the first instance, this is a professional imperative. While no overall ethical imperative formally guides the entire U.S. health care delivery system, individual components of this complex network have established core professional principles that provide an important normative foundation. For example, reducing barriers to equitable health care is a professional imperative for physicians. The 2002 Charter on Medical Professionalism included social justice among its three core principles, described as follows: "Physicians should work actively to eliminate discrimination in health care, whether based on race, gender, socioeconomic status, ethnicity, religion, or any other social category" (ABIM Foundation et al., 2002, p. 244). In 2020, the American College of Physicians issued a *Call to Action*: *Envisioning a Better Health Care System for All*. This statement notes "the many systematic barriers to care that Americans face, including discrimination because of personal characteristics, such as race, ethnicity, religion, language, sex and sexual orientation, gender and gender identity, and country of origin" (Doherty et al., 2020, p. S3).[1] Arguments for equity from the scientific community have emphasized its important trust-building function as a necessary antidote to the increased public alienation from science being witnessed today; practices that support ethical and equitable science, technology, and innovation can advance this aim (Kennedy et al., 2022; Reardon et al., 2023). Simply put, technology development without deliberate attention to equity limits the technology's positive impact.

[1] It is worth noting that this call to action does not include people with disabilities, among whom disparities are well documented.

A second obligation is that of governments and government agencies to create conditions that promote freedom, opportunity, and well-being for the populations they are intended to serve, without discrimination. Governments have obligations at two relevant levels: (1) the direct obligation to ensure that public institutions advance the important interests of all community members, and (2) the obligation to craft incentives that align the interests of private actors with the public interest and the common good. As described by London (2022, pp. 162–163):

> Governments are responsible for allocating resources and creating the institutions and systems of rules that are necessary to effectuate three goals. The first is to ensure that the research enterprise functions to generate the knowledge needed to bridge gaps between the basic interests of community members and the ability of the basic social institutions in their community to meet those needs. The second is to ensure that the system of norms, rules, and incentives that govern the research enterprise align the personal and parochial interests of stakeholders with the promotion of this end. This includes providing credible public assurance to all stakeholders that no party has the ability to co-opt this division of social labor to exclusively advance their own parochial interests. The third is to provide credible public assurance to all stakeholders that as each seeks to pursue their personal interests in this arena—to seek profit, career advancement, or access to novel medical interventions—no party will be subject to domination, exploitation, abuse, or other forms of unfair or harmful treatment.

In subsequent chapters, the report distinguishes between governance mechanisms more applicable to government agencies and public actors (emphasizing their societal obligations) and those more applicable to private actors (emphasizing their social responsibilities, for which a range of governance mechanisms, from the creation of incentive structures to the development of regulations, may be applicable). Suffice it to say at this point that there is strong justification for both public and private actors, including expert and professional bodies, as well as those lay communities most impacted by the consequences of inequitable technology development, to be involved in the development of governance mechanisms that center equity in the medical science and technology system.

There is both encouraging precedent and a disappointing lack of attention to equity in the history of technology governance in the United States, especially as related to health care. A review of the past eight decades of U.S. science, health, and technology policy reveals that federal government efforts to promote equity and fairness in technology development have been piecemeal and unsystematic. In one of the papers commissioned for this study (see Appendix B), Michael McGovern and Keith Wailoo report that policy makers have embraced equity—usually defined as attention to justice, proportional fairness, and inclusion—as a value only in particular social contexts and instances. They cite the examples of efforts to ensure equitable access to new technologies such as kidney dialysis in the early 1970s, to incentivize industry to develop "orphan drugs" to benefit disease populations whose small numbers attracted little private-sector research and development (R&D) in the 1980s, and to restrict insurance-based discrimination against people on the basis of their genetic information in the 2000s.

These actions in the name of equity and fairness in science and technology governance have been sporadic, often contested, and uneven. Nonetheless, over time there have been identifiable trends in equity and technology governance as government policies have shifted. In the 1950s, innovation was promoted without guardrails, and inequities in the system were widespread. The 1960s and 1970s witnessed important attempts to govern innovation, with modest attention to removing system-wide inequities—for example, in the exploitation of vulnerable subjects—and to using the lever of government programs to equalize access to

technology products. And while the decades since the 1980s have seen rollbacks on these commitments, they have also seen specific, targeted, piecemeal efforts to advance equity in science, technology, and medicine.

A major finding of McGovern's and Wailoo's paper is that over the past 80 years, equity concerns have never been a primary focus of technology policy and assessment. Nor has the U.S. government taken a systematic approach to equity in technology development. Another finding is that the goal of incorporating equity into technology innovation has been contentious and difficult to sustain, and small progress in specific areas has been vulnerable to rollbacks. For most of the past eight decades, other values have guided innovation governance—namely, a commitment to laissez-faire innovation, deference to the pursuit of profit and speed in innovation, and a willingness to allow market and consumer forces to play the leading role in determining who benefits from science and technology innovation. The result of this policy approach has been persistent and sustained large-scale inequity, punctuated by specific, narrow instances (protection of research subjects, health insurance access, genetic discrimination, orphan drugs, and kidney dialysis access) in which equity ideals have surfaced and shaped laws, procedures, and policies.

This history makes attention to inequity all the more urgent and vital. The time is right. Both the National Academies, the funders of this study, and the current U.S. administration have identified equity as a crucial agenda. Multiple agencies are involved in implementing steps to advance equity in health care, but clarity is as yet lacking about what that effort entails or what steps might be taken in a coordinated and sustained fashion to achieve it. For example, funders evaluating which research ideas to support (such as the National Science Foundation) may wrongly perceive the ideal of equity as somehow at odds with objectivity and excellence, when in fact an obligation to consider equitable access and impacts on users and communities would serve to strengthen the rigor of scientific research and technology innovation—a point recognized by many scientists (especially among the younger generation as they rise to professional prominence), including those who work in the private sector.

Indeed, it is important not to underestimate the interest of some private entities in considering equity in their business models, for ethical reasons but also for any number of pragmatic and economic reasons. Barriers that prevent people from accessing, using, and benefiting from products and services can undercut profits by shrinking the pool of customers. Similarly, barriers that prevent diverse entrepreneurs from attracting investors can limit the potential financial gains of those investors.[2] These observations are reflected in the Kaiser Family Foundation's forceful "business case for racial equity," which argues that growth, productivity, output, and revenue would all increase in a more racially equitable climate. Specifically, a 2018 report from the foundation argues that "by 2050 [the United States] stands to realize an $8 trillion gain in GDP by closing the U.S. racial equity gap" and eliminating "current disparities in health, education, incarceration, and employment opportunities" (Turner, 2018, pp. 3, 8). The authors of another analysis estimate that the economic burden of racial and ethnic health inequities in the United States amounted to about $420–450 billion in 2018 and more than twice that amount for adults without a 4-year college degree, as reflected in excess medical care expenditures, lost labor market productivity, and the value of excess premature death (LaVeist et al., 2023). Inaction has costs. Analysts have argued that inequality threatens future value creation, stating that "the breadth and depth of racial and economic inequality in America present profound systemic risks to our markets and economic stability" (Getachew and Boyea-Robinson 2023, p. 15). In this view, investors ignore inequity at their peril as the gaps in society widen and the risks of destabilization rise.

[2] https://www.morganstanley.com/ideas/venture-capital-funding-gap (accessed June 19, 2023).

There are indications that the business community is paying attention, as seen in the actions of multilateral economic governance organizations such as the Organisation for Economic Co-operation and Development (OECD), as well as moves toward responsible investing and innovation (Turner, 2018). Although efforts to incorporate social and governance factors into decision making are not without contention (Morgan, 2023), there is growing evidence that attending to environmental, social, and governance concerns not only does not necessarily compromise returns but actually can increase them (Henisz et al., 2019).

Finally, private actors need to attend to equity concerns if only to cater to the new generation of scientists and attract the best talent. Anecdotally, it is noted that many scientists, engineers, and physicians are interested in promoting social equity and justice and sometimes make career decisions accordingly. However, they do not necessarily have the tools to think broadly about all the dimensions entailed in attention to equity, or how those dimensions could be integrated into processes of research and development as part of institutional governance mechanisms. One aim of this report is to broaden such understandings.

In sum, the centering of equity within a governance framework for emerging science, technology, and innovation is important because equity is a fundamental moral good that helps ensure fair treatment, access, and opportunity. But equity is important not solely because it is morally just, it contributes to excellence, merit, and objectivity by broadening the demographics that must be considered, included, and heard during innovative research and development (issues also explored, for example, by Haraway [1988] and Harding [1995] from the viewpoint of feminist theory). Equity is economically beneficial in contributing to more inclusive growth, and equitable innovation will also help mitigate the erosion of social and political trust in science and technology. Most of all, equity is fundamental to any innovation that is responsive to the general welfare, a foundational principle that appears in the Preamble to the U.S. Constitution, even before "individual liberty." (See also Schwartz [2022] on federal powers to address the general welfare.) At a time when global inequalities are increasing, science and technology have a crucial role to play in either exacerbating or ameliorating them: "The shared goal of improving human well-being that undergirds associated government funding, regulation, and oversight and professional commitments creates a responsibility not to exacerbate such inequities and to ameliorate them whenever possible" (Mathews et al., 2022a, p. 2239).

This report provides a roadmap for how this responsibility might be fulfilled. It does so while considering equity not in punitive or mandatory terms, but as an unmet need that is recognized as much by practitioners as by historically disenfranchised and underserved communities.

DEFINITION OF EQUITY: WHAT EQUITY IS, AND WHAT IT IS NOT

This report makes the case that equity is a foundational structural principle upon which a governance framework for emerging science and technology must be based. It construes equity as the overarching driver of a process for identifying and ameliorating structural and social conditions that disadvantage individuals and groups by unfairly limiting their freedom, their opportunity, or the conditions needed for well-being. Advancing the goal of equity is thus a fundamentally ameliorative effort in that it seeks to rectify legacies of neglect, exclusion, or domination. But it is also an effort to move toward a more just social order in which all individuals have access to the conditions necessary to enjoy freedom, opportunity, and well-being. This pursuit represents a significant advance over previous normative frameworks for biomedical research and practice, such as the Belmont Report, which articulate in detail the requirements of beneficence and respect for autonomy while leaving justice largely

disconnected from concrete issues of policy and action (London, 2022, pp. 27–84). What, however, does equity require?

The 2021 White House Executive Order *Advancing Racial Equity and Support for Underserved Communities through the Federal Government* includes the following definition: "The consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders, and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality" (White House, 2021). Individual agencies have also defined equity in various ways (see for example, the discussion of the National Institutes of Health and the Federal Trade Commission in Appendix C).

This useful working definition notwithstanding, the answer to what equity means as it becomes operationalized in a governance framework for emerging science and technology in medicine is not simple. It depends on historical context, the differential experiences of various marginalized or excluded groups, and how multiple facets of identity and experience intersect within individuals and communities. It manifests differently in different health care situations. For example, aspects of inequity can be exacerbated, magnified, or rendered explicit in public health emergencies, as was seen in the case of pulse oximeters (Box 2-1) and vaccine access during the COVID-19 pandemic. Thus, no single definition of equity is adequate to cover the multiple existing and potential manifestations of inequity in science and technology innovation in the health care arena.

Accordingly, a governance framework for medical innovation cannot be a one-size-fits-all model. It must have *flexibility, reflexivity, iterativity, intersectionality, and the participation of affected communities* built in as core features of its operation. These features mean the system must be adaptable to address those elements and issues most relevant to a particular type of technology, setting, and set of interested parties (flexibility); collect the data needed to understand and assess how well it is achieving its goals, and incorporate an ability to revise policies, incentives, and other mechanisms in response to lessons learned (reflexivity and interactivity); recognize the existence of multiple and overlapping histories of disadvantage (intersectionality); and strengthen the engagement of diverse innovation actors (participation). Future chapters will elaborate on the aspects of such a governance framework, offering specific recommendations. The goal of this chapter is to provide an understanding of the various facets of equity and how different kinds of inequity might manifest during technology development and innovation.

At the outset, it is important to emphasize that equity is something more or other than equality. Rather, *it reflects a context-dependent combination of principles of equality, justice, fairness, and the common good*. While this report focuses on equity, it is important to highlight that such a commitment overlaps considerably with the commitment to enhancing fairness, justice, and the common good in technology innovation. A discussion documented by the Committee on Emerging Science, Technology, and Innovation (CESTI) defined justice, fairness, and collective good as follows:

> Justice, in the CESTI principles, refers to equity between groups faced with structural and systemic inequalities, a fair distribution of risks and benefits of technologies, and considerations about intergenerational justice, such as how decisions made now will affect future generations. Fairness refers to fair procedures for the creation of governance structures that are grounded in a view that all human beings are of equal moral worth, and may also reflect

> predictability and consistency, as well as transparency and accountability … and collective good requires the recognition that technologies have societal-level impacts (both benefits and harms) that are not captured by an exclusive focus on individuals. (Mathews et al., 2022b, p. 44)

The concept of equality, meanwhile, includes both formal and substantive dimensions. Formal equality is a belief that, for fairness, people must be consistently or equally treated at all times. Substantive equality goes beyond the basics of recognizing the equality of all people, identifying differences among groups of people with the long-term goal of equalizing to address historical discrimination or injustice.

While there is no one-size-fits-all definition of equity, it is important to recognize that it is not just a formal rendering of equivalence, but a complex value that is related to justice and fairness and incorporates a substantive dimension of equality. In other words, equity is based on the idea that people have different circumstances, and different resources, and society should therefore direct resources and opportunities toward ensuring that all people have comparable opportunities, as a precondition for measuring or evaluating comparable outcomes. The Americans with Disabilities Act (ADA) (and the principle of social accommodation for people with disabilities), for example, is rooted fundamentally in a commitment to equity. Importantly, the ADA's commitment to social accommodation is also deeply rooted in principles of enhancing fairness, justice, and the common good.

The images in Figure 2-1 from the Robert Wood Johnson Foundation conceptualize equity as something more or other than equality and provide a helpful lens on the operationalization of equity in the context of technology.

Each "equality" image includes individuals whose freedom is limited or whose needs are otherwise not being met. Relevant to the topic of this report, technology has been used in each "equity" image to address context-dependent barriers faced by each individual. For the purposes of this report, it is worthwhile to highlight dimensions of equity in these images that may not be immediately apparent. First, the operationalization of equity involves intentional upstream design choices on the part of a technology developer that explicitly consider the eventual downstream users and consumers. Second, while the two equity scenarios display technology's role in promoting equity, their contexts differ with respect to the technology's ownership or use: in the image with bicycles, equity is considered in the context of a user-specific or user-owned device, while the crosswalk image displays the use of technology to promote equity in the context of a shared, publicly used resource. Third, while the equity scenarios illustrate a situation in which there were likely costs associated with the design and production of the technologies, there are also costs associated with *not* considering equity. These costs are displayed as the limited freedom, unmet needs, and barriers imposed on specific individuals with different individual contexts. Fourth, the consideration of equity in each technology's design is displayed both as a developer's choice to meet consumer need or demand and in some context as a legal or policy requirement (e.g., the angle of the crosswalk ramp). Lastly, it is important to note that the images are not (and not intended to be) inclusive of every dimension of equity.

From the perspective of the governance of emerging science and technology, a centering of equity (as opposed simply to formal equality) is an acknowledgment of the fact that new technologies have unequal benefits and risks in ways that can exacerbate histories of injustice. Equity requires not merely equal access to emerging technologies but also fair distribution of the risks and benefits of technologies and consideration of intergenerational justice, such as how decisions made now will affect future generations. Governance structures in the United States and elsewhere are not adequately responsive to the full range of

FIGURE 2-1 Scenarios conceptualizing equity as something more or other than equality. Given the specific context shown in each scenario, each individual in the two "equity" images highlights specific actions that grant the freedom, opportunity, and well-being offered to all other individuals through intentional choices in technology design and use. The images also reflect how equity relates to overlapping goals of advancing fairness and justice and serve the common good.
SOURCE: Robert Wood Johnson Foundation, June 30, 2017. https://www.rwjf.org/en/insights/our-research/infographics/visualizing-health-equity.html.

implications of these features. A stronger notion of governance is required, going beyond a mere "right to equality" toward a more substantive "right to be treated as an equal" (in accordance with the famous distinction make by Ronald Dworkin [1977]). In other words, the task is not just about making emerging technologies available to multiple groups, but developing a framework that accounts for the conditions of access (including health care and socioeconomic disparities, as well as environmental disparities) by attending to historical injustice (in the form of discrimination, segregation, and dispossession). Thus, redistributive and reparative dimensions need to be incorporated in any governance framework. So, too, must a framework think about equity for future generations. It must do so formally, by incorporating conditions that allow for access to a technology not just at a moment in time but over the long term—for example, not just emergency access to a vaccine in the middle of a pandemic, but the development of mRNA vaccine hubs to ensure, including through fair licensing mechanisms, that technologies for mRNA vaccine development and distribution do not repeat the cycle of tragedy experienced during the COVID-19 pandemic whereby the haves get immediate access to the technology while the have-nots die.[3] And it must do so substantively, by building mechanisms for nonrepetition of harm into research and innovation such that emerging technologies do not reproduce or exacerbate historical injustice for future generations.

Finally, a consideration of equity cannot simply be based in the abstraction of philosophical definition, but must engender actual, diverse community participation in governance decisions about emerging technologies. This is not merely about facilitating inclusion. For example, including historically disenfranchised communities among study participants without having clear terms for how they will share in the benefits of the technology being studied does not address equity concerns. Addressing inequity requires an adequate understanding of the role of power relationships in creating inequities. A governance framework that adequately centers equity requires new models of public and community engagement that are not merely inclusive but actively participatory, such that historically excluded voices are heard and integrated throughout the design and innovation process rather than merely accommodated.

To summarize what equity is and what it is not:

- Equity is both a *principle* like fairness, justice, and the common good, and a *process* of identifying and eliminating social, structural, and infrastructural conditions that unfairly restrict the freedom, opportunities, or well-being of individuals or groups. It is a process that can be put into action and operationalized, and that should be attentive to ways in which histories of neglect, exclusion, or domination have created unfair limitations on social opportunity for some individuals and groups, including conditions that undermine their freedom and well-being. Ameliorating these conditions may require a diverse range of actions across social sectors or spheres.
- Equity is not the same as inclusion. Merely asking for the increased inclusion of underrepresented communities in biomedical or clinical research is not sufficient to redress problems stemming from structural barriers to health. In a worst-case scenario, equating equity with inclusion via recruitment may lead to coercion to increase study enrollment, lack of full disclosure (including group risks) that might infringe on informed consent and individual and community agency, and failure to conduct a global investigation of all factors contributing to health inequities.

[3] See, for example, the World Health Organization's mRNA vaccine technology transfer hub initiative (https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub; accessed June 19, 2023).

- Equity is not access. Increased access to health technologies and interventions alone should not be fully equated with equity. Indeed, access is often defined and operationalized in ways that do not benefit those who are disenfranchised by health inequities within the system. For example, merely giving communities access to clinical genetic tests will not remediate inequities in genomic and precision medicine if the tests are not affordable, have limited clinical utility for specific at-risk variant groups, or result in the collection of data from communities without their having agency to direct decisions related to their data and health care.
- Equity entails agency (the ability to act) in decision making, which in turn requires increased transparency in the informed consent process, especially concerning who will have access to communities' data, for what purposes, and for how long, as well as the interests of data users in accessing the data. Broad consent terms that simply permit "researchers" to access data for the "greater scientific good" grant data users too much research authority to determine benefits on behalf of communities, and often without responsibility for imparting this information. Also required are stronger mechanisms for civic participation in decision making about science and technology innovation in ways that are grounded in reliable knowledge, that contribute to more robust institutional expertise, and that foster public trust in science and technology.

CASE STUDY: EQUITY IN RELATION TO DISABILITY

Histories of injustice and marginalization are critical to understanding the imperative for and goals of a governance framework for emerging science and technology in medicine. Just as no single definition of equity adequately covers all of the ways in which inequity can arise in the process of science and technology innovation, there is no single criterion for determining which individuals or groups are affected by such histories. Social structures such as race and ethnicity, gender, sexuality, disability, and socioeconomic status have clearly featured prominently in systemic inequalities and persistent disparities in U.S. society. While overarching principles of equality, justice, and fairness apply to any effort to remedy inequities, the historical context matters and can be instructive in understanding how best to recognize and address different types of inequities or the ways in which inequity plays out in different groups. In addition, it is important to recognize how forms of inequity intersect and exacerbate the challenges faced by individuals who fall within multiple marginalized groups, underscoring the need for an intersectional approach to equity considerations.

This section explores the example of disability as an illustrative case study of how histories of injustice and marginalization lead to inequities in health care and medical technology. While many of the particulars are unique to the disability context, this example highlights broadly how attitudes and practices among clinicians, researchers, lawmakers, and the public interact in complex ways to perpetuate, or in some cases help to remedy, inequities.

Defining Disability

Approximately 1 billion people worldwide have at least one disability (WHO, 2011), and about one in four U.S. adults has one or more disabilities (CDC, 2020). Disability is "a continuum, relevant to the lives of all people to different degrees and at different times in their lives," virtually a "universal phenomen[on]," and "a common (indeed natural) feature of the human condition" (Üstün et al., 2003, p. 82). Disabilities are diverse. Some are present at birth; others arise suddenly, such as with an injury or acute health event; and still others

progress over time. Certain disabilities are readily visible, while others are invisible or less apparent. Nevertheless, disabilities share one common element: persons with disabilities perform basic human functions—such as seeing, hearing, speaking, communicating, moving, thinking, or experiencing emotions—in different ways or in different relationships to their social environments compared with some presumed normative person (Garland-Thompson, 2017; Kafer, 2013).

Attitudes toward Disability

Despite its near universality across the lifespan, disability has been stigmatized for millennia (Reynolds and Wieseler, 2022; Stone, 1984). After studying disability worldwide, Charlton (1998) argued that "a hierarchy of disability" exists. Regardless of country or continent, Charlton found that people disabled by mental illness or intellectual disability are most marginalized, followed by those who are deaf or hard of hearing. In contrast, people with physical disabilities and those who are blind or have low vision generally have stronger support systems and greater political, social, and economic opportunities.

Centuries ago, when societies began providing basic subsistence supports to their most vulnerable members, disability posed a problem: it could be feigned to gain these benefits (Stone, 1984). Beginning in the early 19th century, rapid innovations in diagnostic medical technologies gave physicians the tools to determine, supposedly objectively, who was a valid and thus meritorious disabled person, that is, deserving of these societal benefits (Stone, 1984). This development led to the "medical model" of disability, which "views disability as a problem of the person, directly caused by disease, trauma or other health condition, which requires medical care" (WHO, 2001, p. 20).

In the early 20th century, questions began arising about whether physicians wielded their diagnostic technologies truly objectively. After World War I, U.S. physicians who assessed veterans for service-related disability benefits "routinely applied not medical criteria but cultural and racial values" (Hickel, 2001). Without scientific evidence, physicians widely believed that Black people were more susceptible to certain illnesses than were White persons. These erroneous presumptions led physicians to delegitimize claims of service-related disability among Black veterans: "In attributing a medical condition to congenital weakness, low standards of personal hygiene, or moral degradation, rather than military service, physicians invalidated the disability claims of many black veterans" (Hickel, 2001, p. 237). These racially biased decisions fractured trust between many racial minorities with disabilities and physicians.

Attitudes toward disability started changing during World War II as previously unemployed Americans with disabilities were hired and worked on the home front alongside women, while men without disabilities fought overseas (Linton, 1998). Over the ensuing 20 to 30 years, other forces stimulated transformative social changes, including the independent living movement, increasing interest in self-help rather than professional direction, the large-scale deinstitutionalization of persons with various disabilities, and nationwide campaigns for civil rights and equal opportunity for racial and ethnic minorities and women (Linton, 1998; Shapiro, 1994). These attitudes coalesced into a "social model" of disability, which "sees the issue mainly as a socially created problem, and basically as a matter of the full integration of individuals into society. Disability is not an attribute of an individual, but rather a complex collection of conditions, many of which are created by the social environment.... The issue is therefore an attitudinal or ideological one requiring social change, which at the political level becomes a question of human rights" (WHO, 2001, p. 20).

The United States began enacting major federal legislation to protect disability civil rights—to ensure equity and prevent discrimination—50 years ago with Section 504 of the

1973 Rehabilitation Act, which covered federal programs. The 1990 ADA and 2008 ADA Amendments Act (ADAAA), which clarified definitions of disability, extended civil rights protections to other public and private settings and services. The 2010 Patient Protection and Affordable Care Act (ACA), Section 1557, amended Section 504 of the Rehabilitation Act and several other statutes to provide additional protections against disability discrimination in health care services.

Disparities in Health Care

Despite this half century of civil rights protections, Americans with disabilities experience disparities and inadequate services across the health care continuum, from preventive care to home- and community-based services (Iezzoni et al., 2022a). One reason for health care disparities among people with disabilities is the failure of health care settings to do as the laws require—make reasonable accommodations to ensure accessibility and effective communication. Although nearly three decades had elapsed since the ADA's enactment, a nationwide survey of physicians caring for adult outpatients in the United States found that 35.8 percent of respondents reported knowing little or nothing about their legal responsibilities under the law (Iezzoni, 2022b). Not surprisingly, many physicians appear to fail to adequately accommodate their patients. For example, to accommodate deaf patients, 48.9 percent of physicians reported never using an in-person sign language interpreter hired by the practice, and 64.3 percent never used video remote interpreting (Iezzoni et al., 2022c). Just 22.6 percent always or usually used accessible weight scales, and only 40.3 percent always or usually used accessible examination tables or chairs for patients with significant mobility limitation (Iezzoni et al., 2021a).

Physicians and other health care professionals can have implicit and/or explicit stigmatized or ableist attitudes toward people with disabilities (VanPuymbrouck et al., 2020). In the above survey, 82.4 percent of respondents expressed the view that people with significant disabilities have worse quality of life than those without disabilities. Only 40.7 percent said they were very confident about their ability to provide equal quality care to patients with disabilities, and just 56.5 percent strongly agreed that they welcome patients with disabilities into their practices (Iezzoni et al., 2021b).

A Dearth of Data

Disability data are not routinely collected in administrative health care delivery or public health surveillance systems (Rios et al., 2016). Importantly, diagnosis codes, the primary clinical information in administrative files, provide little insight into disability. Most population-based information about health and health care disparities for Americans with disabilities therefore comes from surveys, which typically have substantial lag times and have historically employed different definitions of disability. Recognizing the need to facilitate analyses of disparities and improve data quality, Section 4302 of the ACA mandated specification of standardized questions for five key demographic attributes—ethnicity, race, sex, primary language, and disability status. For disability status, the six-item American Community Survey (ACS-6) disability questions were selected as the minimum standard. The ACS-6 has raised reservations (Hall et al., 2022; Livermore et al., 2011), and some prefer another standard set of disability questions (Mont et al., 2022; Morris et al., 2017). Nevertheless, many federal surveys now gather disability status using the ACS-6 questions.

The absence of disability data in health care delivery system and public health data sets impedes efforts to monitor or manage the health care experiences of people with disabilities.

This gap was especially troubling during the COVID-19 pandemic (Reed et al., 2020), when it became apparent early on that nursing homes, assisted living facilities, and group homes had alarmingly high death rates. This "lack of data perpetuates the exclusion of disabled people from discussions of health equity and policies that are data driven" (Reed et al., 2020, p. e423). Even in electronic health records, where one might expect to find routine recording of basic disability information (e.g., concerning mobility disability or wheelchair use), this information appears to be absent (Agaronnik et al., 2020a,b).

Universal Design

One lever to guide equity efforts is the concept of universal design—the basic principle that as people design products, procedures, places, policies, or other services, they consider the full range of people who might use or interact with what they design (University of Washington, 2022). North Carolina architect Ronald L. Mace (1941–1998), who contracted polio at age 9 and became a wheelchair user, coined the term "universal design" (Saxon, 1998), viewing it as a mindset or orientation (Mace, 1998; Story et al., 1998). Mace and his colleagues created the Center for Universal Design at North Carolina State University. In the disability context, pursuing a universal design mindset requires that designers appreciate the full range of human abilities and how they differ within populations and across ages, personal circumstances, and environments. Mace and his collaborators categorized human abilities into eight broad groups—cognition, vision, hearing and speech, body function, arm function, hand function, and mobility. They urged designers to consider the implications of their proposed approach within each of the eight areas (Story et al., 1998).

Mace believed that putting universal principles into practice required consulting with potential end users about their needs and preferences for proposed products or whatever designers were creating. Even with the best intentions, designers cannot assume that they appreciate fully the implications of their design choices for people with various disabilities. Without involving persons with disabilities and other potential users in the design process, designers are unlikely to anticipate how users will experience, benefit from, and accept their eventual products.[4]

Thinking about the wide variety of factors that affect health—including social determinants of health—has evolved beyond the notions Mace pioneered several decades ago. Thus, the scope of people and perspectives that designers should consult has also expanded. Proponents of universal design recognize the impossibility of achieving designs that will equitably benefit all potential end users. Nevertheless, following the aspirational principles of universal design can help maximize the utility of eventual products across various subgroups of the population.

Intersectionality

As observed by Mitra and colleagues (2022, p. 1379), "health disparities among people with disabilities are affected by other forms of marginalization." The authors found, for example, that adults who were members of racial or ethnic minority groups and had mobility disability were more likely than their White counterparts to report that their health was worse than a year ago; more likely to experience depression; and more likely to report diabetes,

[4] See https://www.washington.edu/doit/what-universal-design-0 (accessed June 19, 2023) for a specification of seven principles of universal design that can guide creators. For a range of factors affecting health and population perspectives that should be considered in universal design efforts, see Koh et al. (2011).

hypertension, or vision impairment. Likewise, compared with their White counterparts, Black and Hispanic adults with intellectual and developmental disabilities were more likely to report fair or poor physical and mental health. Gender identity and sexual orientation also intersect with health disparities among people with disabilities. For instance, LGBTQI+ versus non-LGBTQI+ people with disabilities were more likely to report worse health-related quality of life, including poor physical and mental health (Mitra et al., 2022). To be fully viable, any approaches to equity in relation to disability must therefore be intersectional, addressing disability in the context of other important social and economic categories, including race, gender, and sexuality.

Reflections

The example of disability highlights themes seen in other groups affected by inequity and the types of inequities that arise in the technology development life cycle. History matters, attitudes matter, and actions matter. The principles of universal design offer a framework for incorporating concerns about equity and access into products and processes.

In the context of a framework for better aligning emerging science, technology, and innovation with equity, the disability case example helps illustrate the need for an innovation system that involves, recognizes, and integrates the interests and needs of the diversity of people who form a society, both as innovators and anticipated users. To advance equity in health and medicine technologies requires attending to the multiple forms of inequity that can arise and taking account of the contexts in which emerging technologies will be envisioned, developed, and used. A governance framework to support equity-centered innovation must therefore be reflexive, iterative, and context-relevant.

APPLYING EQUITY PRINCIPLES IN TECHNOLOGY DEVELOPMENT AND INNOVATION

A conceptual understanding of what equity means is a prerequisite for applying equity principles in practice. To inform a framework for centering equity in the development and governance of emerging science, technology, and innovation in health and medicine, it is helpful to consider the different types of equity considerations that emerge. What are the dimensions along which equity can be promoted? What are the points of failure at which inequities might become embedded? Table 2-1 translates the broad equity concepts elucidated in the prior sections of this chapter to the more granular equity considerations that arise in the context of technology conception, development, and deployment.

TABLE 2-1 Dimensions of Equity Relevant to Innovation

Dimension of Equity	Aspect of Technology Development	Principles
Topical equity*	Someone identifies ideas to pursue, support, or fund within a portfolio of innovations.	An innovation portfolio should include topics of relevance to diverse communities, including populations that have traditionally experienced injustices.
Innovator equity*	People seek funding to pursue innovations.	Innovators should reflect diverse populations, including members of underserved or marginalized communities so as to tap a broad scope of imagination and creativity.

TABLE 2-1 Continued

Dimension of Equity	Aspect of Technology Development	Principles
Input equity	Teams are organized to guide the development and/or later-stage implementation of an innovation.	The innovation development and implementation processes should include teams with diverse representation so as to make products relevant and of interest to a wide community of users, demonstrate respect for affected communities, and enhance accountability.
Evaluation equity	Technologies are evaluated to meet regulatory requirements and protect the public, to test innovations against business goals, and/or to identify ways to make the technologies better.	New technologies should be evaluated in diverse or representative populations to reduce errors in assessing their benefits and harms and broaden their eventual applications
Deployment equity	Technologies are marketed, deployed, and adopted.	Technologies should be accessible to and benefit a diverse population, including traditionally underserved or marginalized populations.
Value capture equity	Technologies create value, and the capture of that value is distributed.	The value created from new technologies should be captured and distributed fairly.
Contextual equity	Technologies are created and deployed in a historical context.	New technologies should not perpetuate past injustices and should address or correct past injustices whenever possible.
Attention equity	Technologies are continuously evaluated after deployment.	Organizations and innovators should attend to the equity concerns outlined above, including actively seeking and mitigating inequities in the ways technologies are deployed.

* Topical equity and innovator equity are attributes of a portfolio of innovations, not a single innovation.

CHAPTER CONCLUSIONS

Clearly, equity is a vital and urgent concern in society broadly, and it is of particular relevance in the health sphere. The committee's examination of what equity is and is not, the ways in which inequities emerge and persist in the context of health technology development and use, and the ethical imperative to remedy those inequities led to the following conclusions:

Conclusion 2-1: Equity is a foundational concept that must underlie any governance framework for emerging science and technology in health and medicine. An emphasis on incorporating equity into innovation life cycles represents a significant advance from previous normative frameworks for biomedical research and practice, which have primarily emphasized the application of beneficence, autonomy, and justice to research participants instead of focusing on equity as a system-wide imperative.

Conclusion 2-2: Equity reflects a combination of the principles of equality, justice, and fairness. It requires a fair distribution of the risks and benefits of technologies, as well as consideration of how decisions made today may affect future generations. Multiple forms of equity—including topical, innovator, input, evaluation, deployment, value capture, contextual, and attention—need to be considered in emerging science, technology, and innovation.

Conclusion 2-3: Core features of a governance framework for emerging science, technology, and innovation in health and medicine that addresses equity include flexibility, reflexivity, iterative evaluation, and the substantive participation of affected communities.

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3

The Innovation Life Cycle in Health and Medicine and the Challenge of Equity

Any consideration of how the innovation system can be better aligned with equity must begin with an understanding of how technologies in health and medicine develop. This chapter provides an overview of the U.S. system for biomedical science and technology development, using a simplified conceptual model of innovation processes as they take place over time and with the contributions of multiple parties. While no single path of innovation exists, and different technologies follow variable paths of development, this generalized model can assist in identifying how and where inequities arise and how and where technological innovations in health and medicine can be better aligned with equity.

The chapter begins by presenting this conceptual model of the innovation life cycle, briefly identifying key choices and actors during each phase and illustrating them with the example of drug and vaccine development. The chapter then provides more in-depth discussion of actions during each life-cycle phase, along with analyses of how the current innovation system considers or fails to address equity. An example exploring the development of artificial intelligence (AI)/machine learning (ML) in the context of the innovation life cycle illustrates some of these alignments and misalignments.

CONCEPTUAL OVERVIEW OF THE INNOVATION LIFE CYCLE

To frame and organize its work, the committee developed a simplified conceptual model illustrating the innovation life cycle in five phases, with associated points at which decisions and choices influence how a technology progresses to the next phase (see Figure 3-1). The model is depicted as a circle rather than a linear progression to recognize that information gained from prior research, development, and use will ideally feed into and inform future innovation efforts, along with new knowledge discovery. Other sources of knowledge, including forms of community knowledge, can also play important roles in the generation and design of ideas.

The innovation process is defined by people working within existing institutions and systems, making choices at key points in each phase of the life cycle. Innovation is a process

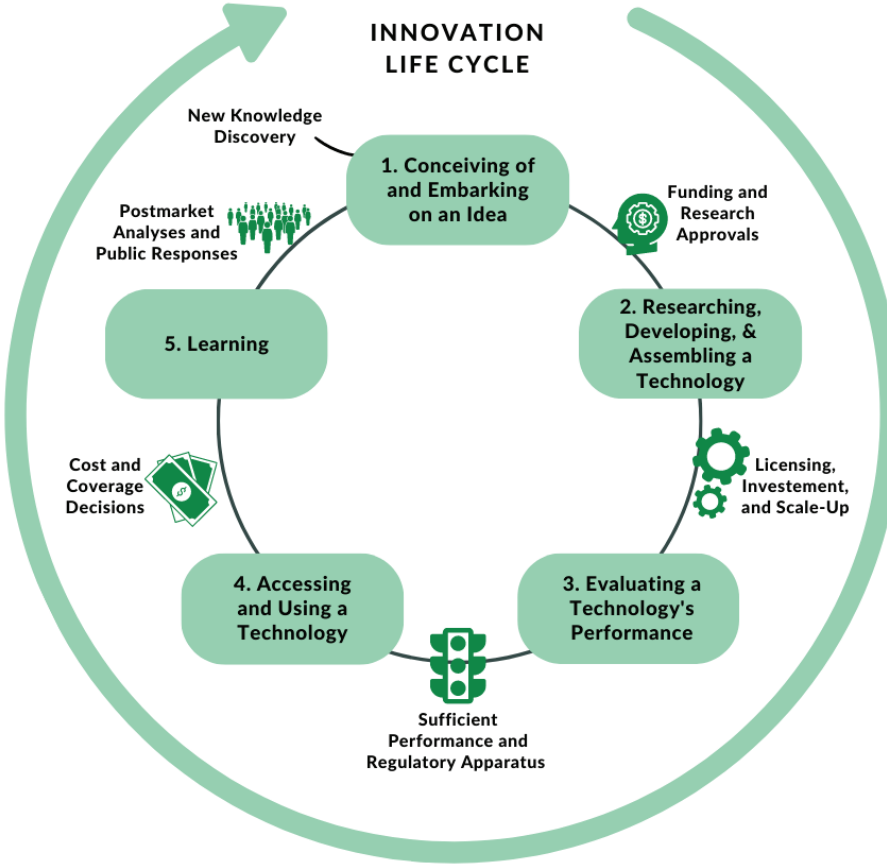

FIGURE 3-1 A simplified conceptual model of the innovation life cycle. Innovation in health and medicine is a complex and variable process, involving the contributions of a wide range of actors; potential for multiple recursions within and between phases; and often iterative cycles of research and development, evaluation, and learning. This model is necessarily a simplification: In reality, the insights from multiple groups and sources of knowledge feed into the system and it is not always truly circular.

that takes place over time and that involves the contributions of a wide range of parties. The phases and choices reflected in Figure 3-1 and described in this chapter are associated with the activities necessary to translate a body of knowledge into an intervention or technology—understood as something that clinicians or other users can employ in the real world to bring about some kind of benefit. Even this simplified model involves many different actors, some of whom are able to exert greater influence over some of the choice points than others. Ultimately, the decisions and choices made as innovation proceeds reflect leverage points at which the development process can be influenced by those involved and by changes to incentive structures (discussed further in Chapter 4).

Context for the Simplified Innovation Model

Efforts to model the innovation process necessarily reflect the goals and values of those who produce the models. The technology development model used in this report is intended to capture elements of the process relevant to alignment with ethical principles, focused on equity. In reality, there is no single innovation life cycle. Innovations in health science and technology follow diverse paths from conception to funding, design, development, marketing, adoption, market success or failure, incorporation into health care, and so on. Ideas fail at different stages, and the paths taken are often recursive and the process disjointed. New technologies in the ecosystem can expand suddenly and radically, or their development can be foreclosed. Moreover, it is important to emphasize the extent to which, throughout the system, the process and governance of science, technology, and innovation are based on data—including data from prior research as well as the collection of new data—and on the human labor of researchers, patients, and members of the public who are involved in the testing, feedback, and use of products. Important as well is to recognize that considerations of equity associated with science, technology, and innovation in health and medicine involve a web of connections that link the research and development process to goals that fall outside of this process. These goals depend on the nature and distribution of the health needs in a society, the ability of health-related institutions to meet those needs, and the alternatives that are available to close these gaps.

Figure 3-1 does not explicitly convey the social and ethical context within which any innovation process exists, but it is critical to recognize the influence of values, assumptions, incentives, and historical legacies on the choices that have been and continue to be made and that can shape innovation differently. This report focuses primarily on the U.S. context for innovation, and the U.S. legal and policy environment profoundly affects the innovation process. Other countries having different historical legacies or prioritizing other values may undertake innovation and govern it differently through their respective national and regional legal and policy frameworks. Finally, the descriptions in this chapter focus primarily on describing those processes, structures, and choice points most closely associated with the development of drugs, vaccines, medical devices, and other forms of innovation in health and medicine that are regulated by the U.S. Food and Drug Administration (FDA) and are influenced by coverage decisions by the Centers for Medicare & Medicaid Services and other health insurance payers. Other forms of health innovation, including the rapidly evolving integration of AI into consumer technologies unregulated by the FDA, are discussed in less detail and may entail different processes, structures, and choices.[1] Important health-related research can also advance knowledge without directly leading to new technologies and products.

Brief Descriptions of Phases and Associated Choice Points

Brief overviews of the phases are illustrated in Figure 3-1. The major actors, choices, and equity dimensions associated with each are reviewed below and analyzed in greater detail in later sections of the chapter. Equity and broader ethical considerations can be relevant at every stage of this life cycle. As a result, these phases and the associated choices made as innovation progresses offer opportunities for all involved—funders, inventors, designers, end users, and so on, from both public and private organizations—to consider whether inequi-

[1] Appendix C looks at roles and actions of the Federal Trade Commission in considering equity associated with products and technologies.

ties have arisen, what potential actions can be taken to mitigate them, and what actions are needed to prevent new inequities from arising (discussed further in Chapters 4 and 5).

Conceiving of and Embarking on an Idea

This phase represents the earliest points at which stakeholders adopt the commitment to pursue an avenue of emerging science or develop a particular kind of technology. Idea conception and research are themselves broad categories in health and medicine, with differing implications for equity and thus differing responsibilities for awareness and action (explored further in Chapters 4 and 5). Research may involve knowledge discovery not tied to an application in human health (e.g., new tools and techniques that advance the rate, depth, or resolution of knowledge discovery, or determination of a molecular mechanism controlling gene expression); in other cases, proposals build on and apply previously discovered knowledge to health challenges, placing a direct responsibility on the research team to address the intersection of the project design with equity. Increasingly, researchers and funders are also recognizing the importance of working not only with end users, such as health care providers, but also with nonprofit patient advocacy groups and affected communities as key partners in identifying and formulating research questions and goals and designing studies.

Choices around idea conception, design, funding, and obtaining required approvals influence whether and how an area of research is pursued and its transition to the next phase of development. After the choice has been made to pursue a particular area, actions during this phase can include the formulation of relevant research questions; development of proposed research plans; application, review, and receipt of research funding; and procurement of necessary institutional approvals associated with the safe, secure, and ethical conduct of research. In addition to researchers and research-conducting organizations, significant roles are played by organizations that provide funding support (including government agencies, private philanthropy, nonprofit organizations, and the private sector).

Equity can be relevant to decisions made during this phase in several ways: (1) because, broadly, having a research and innovation enterprise that includes members with varied interests, training, and backgrounds impacts the research ideas that are proposed; (2) because who has funding and decision-making authority affects which areas of knowledge are prioritized and funded; and (3) because decisions made during this initial phase of the innovation life cycle may influence subsequent phases. Who gets to propose and decide the questions that should be pursued, the nature of the problem, the goals of the research, and who will pursue it influence research directions and methods; whether a solution is technological, social, environmental, or infrastructural; how technologies are designed and distributed, including questions of access and affordability; and whether future ideas and research questions build iteratively on or are inspired by the results.

Researching, Developing, and Assembling a Technology

This phase includes exploratory and proof-of-concept research, along with other efforts to design and manufacture a product or intervention and accumulate the knowledge necessary to use it in practice. This phase also encompasses research and development activities at different levels of advancement toward a potential product, and the nature of the research and its progress toward technological readiness influence which governance levers and actions will be most effective at supporting equity. Significant actors during this phase include academic and nonprofit research and development organizations, as well as for-profit companies, patent and licensing experts, and investors. Choices made during this

phase continue to affect how research and development is carried out and disseminated, as well as how resulting intellectual property is managed and whether further funding and investments are obtained.

As research progresses, the translation and scaling path for biomedical technology is complex. During this phase, assessments of the potential economic value of a technology take place. Many early-stage technologies fail, and development costs can be high. As a result, many developers seek private investment, and decisions about patents, trade secrets, and intellectual property play strong roles in procuring such investment (Budish et al., 2015; Cohen et al., 2000). Further, choices made here may influence downstream choices related to the cost and coverage of those technologies that do reach the market, including how patent expiration affects pricing (Chandra et al., 2022; Vondeling et al., 2018).

As these research and development efforts are designed and conducted, developers and investors make decisions related to cost, speed, and complexity that can intersect with equity. For example, the desire to produce a technology as quickly as possible and maximize the time for which it receives patent protection can result in practices that widen knowledge gaps among potential treatment subpopulations; such gaps increase the risk that inequities may emerge later when a technology is used more widely (Kimmelman and London, 2015; London and Kimmelman, 2016, 2019). Researchers and developers must also continue to comply with relevant federal and institutional regulations and practices for responsible conduct of research. Research involving human participants is governed by a variety of requirements, including extra scrutiny on studies in certain marginalized populations, such as those who are incarcerated or are considered to have diminished competence to consent. Research involving human subjects is also subject to, for example, approval from institutional review boards (IRBs), although there are currently limited requirements for IRBs to include members of affected communities or for clinical trial investigators to consult these populations.[2] As described in Chapter 4, the FDA is currently taking action to increase racial and ethnic diversity in clinical trials.

Evaluating a Technology's Performance

This phase includes subjecting the technology to late-phase, confirmatory testing to generate the evidence necessary to justify claims of safety and efficacy before widespread public use. Choices during this phase involve the collection and assessment of sufficient performance information to support widespread use, as well as the processes used in making regulatory decisions and issuing market approvals. Contract research organizations are assuming growing roles in the conduct of clinical trials and other late-stage testing on behalf of principal investigators, and this market is projected to reach more than $60 billion globally in 2030 (Getz et al., 2014; Research and Markets, 2022). Patient advocacy groups are also playing a growing role in recruiting participants for clinical trials (Merkel et al., 2016).

Many biomedical technologies considered to be higher risk, such as new drugs, must be evaluated by expert scientific reviewers and receive regulatory authorization before they can be marketed legally. This requirement does not apply to all technologies relevant to health and medicine; it excludes, for example, those deemed to be lower risk, such as dietary supplements. Regulatory agencies, such as the FDA, often determine what testing is required before marketing, while agencies such as the Federal Trade Commission (FTC) influence consumer technologies available to the public.

[2] See 45 CFR §46.107 for information on IRB membership (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.107; accessed June 30, 2023), although, for example, IRB review for research involving incarcerated individuals includes at least one prisoner-focused member.

Equity considerations during this phase include decisions about the populations in which performance is assessed, including how representative they are of the range of potential end users. The desire to complete trials quickly can lead to recruitment of homogeneous study populations or those with characteristics that represent the most favorable case for clinical benefit, even if those populations are not representative of the population of patients likely to use the technology in practice (Sharma and Palaniappan, 2021). Recent guidance on the inclusion of participants with a wider range of skin tones (FDA, 2022a) or on the appropriate inclusion of participants who are pregnant or lactating illustrates the continuing evolution of practices in this area (NASEM, 2022b).

Accessing and Using a Technology

Broadly speaking, the technology developer, who may own some of the intellectual property, or firms that license the intellectual property decide when, how, and where the innovation is deployed and how much it will cost.[3] These decisions are often made through some form of market analysis and are sometimes made in response to pressure from public and private payers, including Medicare, Medicaid, and private health insurance providers. Health insurance providers themselves sit within a complex legal and regulatory landscape that informs the cost and coverage of medical technologies, and the eventual cost to the patient. Further, payer decisions may or may not be influenced by information on the comparative effectiveness of the technology among different groups of people.

The choices made during this phase intersect with equity, justice, and fairness primarily with respect to how and whether a patient population that would derive benefit from a given technology can actually access it and receive its benefit. Decisions on marketing, cost, health care adoption, and insurance coverage for a technology may be made without considering the range of factors that influence certain patients' ability to access and use it (such as income level, employment or insurance status, age, geographic location, disability status, or internet access).

Learning from a Technology's Deployment

Information on a technology's performance in the market is necessary for feedback and system learning, identifying new types of questions or research directions that could be pursued, and informing changes or adjustments to the technology itself or to governance mechanisms in light of the technology's real-world implications. Problems with a technology may also become apparent only after it is widely available.

This phase encompasses the commitment to ongoing monitoring of a technology's performance after it has entered the market, as well as the public's responses to the technology. Choices during this phase include the types and extent of postmarket performance analyses that are required by regulatory agencies and/or conducted by the company, and whether or how information on experience with the new technology is collected and assessed. Equity considerations during this phase include how and in which populations a technology's performance is monitored, the distribution of risks and benefits associated with the technology's use, whether and how postmarket data are collected and used, and whether and how action is taken based on the results of such postmarket surveys and studies (London et al., 2012).

[3] For university-based technologies, determinations on technology licensing are often made through institutional technology transfer offices and may involve limited decision making by the scientist or engineer. In other cases, a technology licensee, such as a private company, makes decisions on deployment and pricing.

Illustrating a Development Trajectory: Drug and Vaccine Development

Health and medicine encompass such a range of potential technologies and products that the brief explanations given above are necessarily at a very high level. An example development trajectory for drugs and vaccines provides a more granular look at this process, with the caveat that some drugs and vaccines may follow a different path, and the development trajectories for medical devices and consumer health technologies may be similar in some ways and different in others.

In this example, the first step often begins with government funding for basic research, which generates scientific insights that point to promising opportunities for medical innovation (Azoulay et al., 2019; Li et al., 2017). The contribution of public funding to drug development can be substantial. For example, a recent paper reports that during "2008–17, about 25 percent of small-molecule drugs and 42 percent of biologics had direct connections to public funding, even when in late-stage development," and that extensive federal funding for the discovery and development of anti-HIV drugs has led to debates and ongoing litigation over related intellectual property rights and the high drug prices being charged (Tessema et al., 2023). Another analysis found greater public-sector influence (government funding and public-sector patents) associated with drugs that received FDA priority review approvals (Sampat and Lichtenberg, 2011), a designation for drugs that offer significant improvements.

Scientific insights may be taken up for further development and commercialization. One route is for an entrepreneur, who may be the academic behind an idea, to form a start-up company in an attempt to translate this opportunity into a marketable product. Indeed, an analysis of new drug approvals found that half of drugs addressing an unmet medical need or considered scientifically innovative were initially discovered in universities and biotechnology companies rather than large pharmaceutical companies (Kneller, 2010). This is the point at which venture capital (VC) investors may enter the picture, providing funding needed by the entrepreneur to support the research and development necessary to create a viable product. The VC investor and company also may need to license the technology from the university that holds key patents for the idea. In other cases, a technology may be picked up or licensed by a large firm that aims to commercialize it.

Before being allowed to sell a drug or vaccine, companies must demonstrate the product's safety and efficacy and obtain approval from the FDA (or from other regulatory bodies if they wish to sell the product in other countries). This is a complex and expensive process that often takes a decade or more to navigate. Until a drug or vaccine has been approved to enter the market, it generates no revenue for the company, and the funding to support its development comes from the company itself and investors. The incentives and choices that guide investors are often about extracting a return beyond what was invested in development, and such profitability choices do not always align with equitable health outcomes. VC investors typically exit the process (and receive a payout, or not) when one of three things happens: the technology or company fails, the start-up company is acquired by a larger pharmaceutical company, or the start-up company moves to an initial public offering (IPO). From this point forward, company shareholders benefit from any profits generated through the product's commercialization.

It is worth noting that the cycle of medical innovation described in this report, particularly the role of VC investors, is largely an American industry (Chandra et al., 2022). Basic research funded by the U.S. government generates a large share of the research insights that lead to patents, and investors and companies based in the United States account for many of the medical technologies commercialized worldwide. The global engine for medical research and development is largely concentrated in limited geographic areas, including

the San Francisco Bay area, Boston, and several other locations (Chandra et al., 2022). This concentration of actors can lead to inequities, although innovation clusters also provide potential opportunities to influence research, investment, development, and deployment decisions to advance equity.

Box 3-1 provides an example of how this process played out in the case of the pharmaceutical company Moderna. The company's story is similar to that of other health technology developers in that considerations of equity were largely separate from and subordinate to other drivers behind the technology development and commercialization process. Nevertheless, the company made decisions around the location and enrollment for its COVID-19 vaccine trials aimed at improving the representation of people of color (Hill et al., 2023). Its resulting COVID-19 vaccines and boosters saved millions of lives (Watson et al., 2022).

BOX 3-1 FROM BASIC SCIENCE TO BIG BUSINESS

The history of Moderna, Inc. (Garde, 2020) illustrates one example of the roles of government-funded basic science research, venture capitalists (VCs), capital markets, regulatory bodies, the interplay of multiple scientific and technical advances, and the roles of both public and private investment in the development and commercialization of medical innovations.

The company, initially named ModeRNA Therapeutics, was founded in 2010 with a goal of using modified messenger ribonucleic acid (mRNA)—the molecule cells use to make proteins from the blueprints provided in genes—to create new therapeutics. This idea was based on the initial scientific groundwork of University of Pennsylvania scientists Katalin Karikó and Drew Weissman in the 1990s, consisting of experiments funded by a series of modest government research grants. In 2005, after hitting several dead ends and persevering through a decade of further research with funding from the National Institutes of Health (NIH), Karikó and Weissman demonstrated a method for modifying mRNA without triggering a dangerous immune response (Karikó et al., 2005). Seeing commercial potential in this fundamental research insight, Moderna's founders assembled initial funding from private investors and the venture studio Flagship Ventures, licensed technology developed by the University of Pennsylvania team, and set out to develop mRNA as a new platform for medical innovation. If they could make it work, the founders believed that mRNA could be used to make drugs, vaccines, and other biotechnologies to address a range of medical issues.

From 2010 to 2018, the company pursued this idea with sizable funding infusions from VCs, other private funders, and partnerships with other pharmaceutical companies. Moderna's push to innovate in mRNA technology was also helped by intersections with other innovations. In the 1980s, scientists at the University of British Columbia developed lipid nanoparticles and the technology to produce them, forming the foundation for protecting mRNA and delivering it into cells (Rutty, 2023). In the 2010s, work from Karikó and other scientists demonstrated that modifications to RNA could reduce its immunostimulatory potential and enhance protein production (Nance and Meier, 2021). Establishing its own small manufacturing facility, Moderna created more than 23,000 batches of mRNA-based drug and vaccine candidates for preclinical experiments with cells and animal models, although only a couple of these candidates ultimately moved into early-phase clinical trials toward the end of the decade. When the company went public in 2018, it raised $621 million in its initial public offering (IPO), setting a record among biotechnology IPOs despite having no commercial products. By late 2019, Moderna was essentially still in start-up mode, with a few hundred employees and no marketable product. However, the company continued to optimize its capabilities in mRNA technology and had facilities capable of manufacturing candidate vaccines.

At the start of the COVID-19 pandemic, the company raced to use its mRNA platform technology to create one of the first vaccine candidates for SARS-CoV-2. Moderna and other vaccine companies were aided by the sharing of key scientific information; in early January 2020, the

BOX 3-1 Continued

Chinese government shared a draft sequence of the SARS-CoV-2 virus (Cohen, 2020). By mid-January, Moderna had identified the mRNA sequence it would use to create a candidate vaccine. Around the same time, scientists at the University of Texas were developing stabilized COVID-19 spike proteins for use in vaccine development (Hsieh et al., 2020). In March, Moderna received $483 million from Operation Warp Speed and Food and Drug Administration (FDA) approval to start clinical trials. This effort also benefited from public–private partnerships such as Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) to expedite clinical testing and trials. Nine months after the start of its clinical trials, the vaccine received Emergency Use Authorization, and widespread distribution began. In fall 2021, the company reached a peak valuation of $181 billion, with share prices around 2400 percent of their price just 3 years earlier.

By late 2022, Moderna would distribute more than a billion doses of its COVID-19 vaccines and swell to nearly 4,000 employees. This period of rapid growth faced challenges, from those inherent in absorbing thousands of new employees to supply chain and manufacturing constraints during the global pandemic. But the company also benefited from government partnerships, advance purchase commitments, and collaborations with other companies to a degree likely beyond what would have been possible outside the context of a pandemic (see, for example, Lalani et al. [2023], exploring U.S. public investment in COVID vaccine development). Following the success of its COVID-19 vaccines and boosters, Moderna began using its mRNA platform to explore vaccines for other diseases.

Not every medical innovation will receive a boost akin to Operation Warp Speed and government agreements to purchase and cover the vaccine (minimizing the roles of price and insurance reimbursement in affecting deployment), or have essentially the whole world as a potential market. However, the company's story illustrates facets of the overall ecosystem that allows entrepreneurs to generate big business from basic science. Without the fundamental research, funding, and networks created through public and private partnerships, there would be no Moderna. Without large private investments that propelled the company through its first 8 years, there would be no Moderna. And without access to capital markets, the company would likely not have been able to grow as rapidly as its vaccine moved forward in 2020. These elements together created an environment in which developers had the knowledge, time, relationships, and funding to put ideas to the test, fail, learn, innovate, commercialize, and ultimately succeed.

Moderna's path parallels that of the German start-up BioNTech, which also licensed mRNA technology from the University of Pennsylvania and had been experimenting with mRNA-based cancer therapeutics before the pandemic. Instead of pursuing its own vaccine independently, BioNTech partnered with the large pharmaceutical company Pfizer to develop its successful mRNA-based COVID-19 vaccine, illustrating that more than one development trajectory is possible.

There are additional lessons to be learned from the Moderna example. First, legal clarity is needed to prevent disputes among key stakeholders. For example, Moderna is now engaged in disputes over patents and licensing with NIH and Pfizer related to the use and ownership of the mRNA technology at the heart of both companies' COVID-19 vaccine products. Second, the biomedical enterprise needs to recognize and may need to incentivize consideration of equity by for-profit companies; Moderna's trial choices to increase representation may have delayed its rollout compared with that of Pfizer (Tirrell and Miller, 2020). Third, health outcomes are affected by important factors other than innovation. Health outcomes from COVID-19, for example, were affected by individuals' occupation, ability to isolate and take time off work, and geography, factors not addressed solely by developing a vaccine. Finally, development, access, and use of vaccines exist in a global context, and the need for cross-national dialogues, diversified manufacturing capacity, and commitments to sharing technologies beyond national borders has equity implications as well.

The case of the drug sofosbuvir for treatment of hepatitis C (see Box 3-2) provides several further lessons on the opportunities and limitations of medical innovation to address health needs in alignment with equity.

BOX 3-2

PUBLIC FUNDING, EQUITY, AND TREATMENT FOR HEPATITIS C

Hepatitis C affects roughly 2.5–4.7 million people in the United States. With help from 29 directly related and 10 indirectly related awards from the National Institutes of Health (NIH) and the work of several academic centers in the 1990s, the drug sofosbuvir was developed to target the hepatitis C virus (Barenie et al., 2021), further developed by the company Pharmasset, and commercialized by Gilead Sciences. Despite significant federal involvement and support, the drug was launched by the manufacturer at $84,000 per course of therapy, or $1,000 per pill. While sofosbuvir's price later fell with the introduction of other antiviral drugs, Medicaid spent more than $12 billion from 2014 to 2017 on hepatitis C–related drugs, 5 percent of all Medicaid outpatient prescriptions (Barenie et al., 2021). The high drug price also led health care payers to restrict access by patients. Meanwhile, Gilead's revenue doubled from $11.2 billion in 2013 to $24.9 billion in 2014 (Pollack, 2015).

At the same time that the United States was struggling with the high price of and reduced access to sofosbuvir, complementary efforts to eradicate hepatitis C stagnated. Its incidence rose by 250 percent between 2010 and 2014, and more than half of people living with the disease did not know they had it because of limited screening (HHS, 2016). In comparison, Egypt refused to grant Gilead a proprietary license, leading the company to sell the drug to the Egyptian government at a 99 percent discount, or about $84 for a course of the drug. As part of a nationwide strategy to eradicate hepatitis C, the Egyptian government also enhanced screening and education, improved the safety of blood products and health care facilities, and treated 4 million Egyptians between March 2014 and January 2020 (Hassanin et al., 2021).

This example highlights how companies are likely to make business decisions to maximize profit and unlikely to prioritize equity in the absence of other incentives or regulations requiring them to do so. It also helps illustrate the potential use of government intellectual property decisions and the intersection of innovation with other forms of health intervention to advantage a public health purpose.

ASSESSMENT OF THE EXISTING INNOVATION SYSTEM

This section focuses on identifying opportunities for a coordinated governance framework to embed equity more systematically in emerging technology development and innovation in health and medicine. To this end, it analyzes U.S. practices, policies, and structures that govern innovation in health and medicine in greater detail; how ethical principles including fairness, justice, and equity are addressed during this process; and how the current system fails to systematically align innovation with equity.

Conceiving of and Embarking on an Idea

How a problem is defined and funded and who is involved in research design have downstream implications for what research is done, how it is undertaken, and how researchers assemble a technology for the next phases.

Which Problems Are Addressed and By Which Actors

Problem conceptualization and early-stage research build on the discovery of new knowledge; existing knowledge and gaps, needs, and opportunities; and insights from prior research, development, and innovation activities. Subsequent technological advances can arise from research questions developed through a discovery-based approach, as well as research directions driven by hypothesis. Further, the conception and pursuit of a research question can occur at as small a scale as a single investigator or single-team initiative, or can arise from large, mission-driven initiatives at the organizational or governmental level. In some cases, an avenue of research to pursue is selected in response to the identification of a health or social challenge for which the knowledge base is underdeveloped and that could benefit from investment of resources. In other cases, this commitment arises when stakeholders regard the knowledge base in an area as being ripe for translation into a novel technology, tool, or intervention or because actors believe it is potentially lucrative. In still other cases, new avenues of research are driven by curiosity, without direct consideration of future applications.

This early stage often takes place in nonprofit settings, such as universities, although private-sector companies and research conducted by government scientists are involved as well. Numerous considerations shape what research areas are prioritized and how funding decisions are made. Equity has sometimes been among these many factors, but the alignment of proposed research with equity is often not explicitly considered or required for the research to be initiated.

The Research Workforce and Efforts to Diversify It

Researchers study what interests and is important to them, and if the research workforce includes a narrow range of human experience, the questions asked will be similarly narrow. While Chapter 2 makes clear that diversity is not synonymous with equity, which researchers and teams conceive of and embark on an idea and get credit for resulting publications and intellectual property is an important contributor to equity. For the most part, institutions of higher education, government research facilities and national laboratories, businesses and other private entities, and nongovernmental and other nonprofit institutions include and rely on a highly educated workforce and leadership team responsible for developing research directions and business plans, applying for and securing funding, and conducting the research (Funk and Parker, 2018; NSF, 2020). Long-standing demographic disparities in science, technology, engineering, and mathematics (STEM) participation are well documented, ranging from undergraduate and PhD degree attainment, to receipt of substantial research grants such as National Institutes of Health (NIH) R01 awards, to faculty employment at major research-conducting universities, to the private-sector STEM workforce (NIH, 2021; NSF, 2019). This situation directly influences who generates the research questions that are ultimately pursued and translated to technological advances, and results in disproportionate access to funding and resulting intellectual property.

Potential solutions and recommendations for addressing these long-standing challenges to diversifying the workforce of investigators and innovators have been proposed (NASEM,

2023), and would contribute to advancing equity in innovation. Beyond traditional research pathways, small-scale and grassroots efforts have also been undertaken to experiment with generating solutions for problems identified at the community level, including by patient advocacy groups. These efforts can also include "do-it-yourself" biology and biohacking approaches. One example is the Open Insulin Project, which is seeking to develop community-centered, low-cost insulin to address an identified cost and access gap (see Chapter 4).

The Role of the U.S. Federal Government in Setting Research Priorities and Funding Early-Stage Research in Health and Medicine

The U.S. government plays an important role in generating the knowledge base that serves as the foundation for medical innovation opportunities. For example, an important breakthrough in oncology stems from understanding the role of the PDL1 ligand and PD1 receptor in the immune checkpoint system. NIH support helped create the knowledge needed to understand the roles of these molecules in the development of certain cancers. Unlocking these insights created the context in which for-profit companies were willing to embark on research into immune checkpoint inhibiters (Bardhan et al., 2016).

One of the roles of the government is creating, maintaining, and improving the social institutions that support the health and well-being of Americans. Market failures in investments to address the health needs of marginalized or underserved populations can result from immaturity of the knowledge related to health needs common in these groups. Government thereby has a responsibility to produce the information needed to close such gaps between the needs of its citizens and the ability of their individual and public health systems to address those needs effectively, efficiently, and equitably. This responsibility is grounded in the fact that whether U.S. health-related institutions can fully understand the health needs of all Americans and provide safe and effective prophylactic or therapeutic measures to meet those needs depends on the maturity of the information available about these needs and measures.

Government influences the direction of research through its control over funding. Substantial early-stage biomedical research is funded by federal agencies including NIH, the National Science Foundation (NSF), and the U.S. Department of Defense (DoD). One analysis of drug development, for example, found that 54 percent of basic science milestones were supported by public funding, while private-sector funding was dominant in subsequent drug discovery and development phases (Chakravarthy et al., 2016). The criteria used by agencies and other funders to allocate research dollars thus influence the distribution of scientific efforts and the probability that new discoveries will be made, as well as the probability that others will embark on technologies that build on these efforts. To the extent that research develops the knowledge base on which private actors later build, decisions about how to invest resources in the early phases of innovation play a role in shaping the development activities of private firms.

A number of factors influence how a funding organization allocates its resources. What research is supported by agencies such as NIH is influenced by the faculty and other investigators who submit proposals, serve on peer review panels, and assist agencies is identifying knowledge gaps and priorities. As a result, who has decision-making roles as members of funder advisory boards and review panels, as program managers, and in other decision-making positions influences the innovation system. There have been long-standing concerns about underrepresentation on peer review panels (by race, gender, research institution, and other factors [Volerman et al., 2021]), as well as calls for greater involvement by patient representatives and others.

Patient advocacy organizations can also play important roles in shaping research agendas, as affected by the capacity of patient and community organizations to engage meaningfully in these processes. Not all diseases or communities are associated with large or well-funded advocacy organizations, and in some cases, smaller organizations, including the Chordoma Foundation and Castleman Disease Collaborative Network, have also had success in advancing research in their area of interest. The Chan Zuckerberg Initiative is now funding a network of 50 rare disease organizations, modeled after the success of these and other rare disease groups, called the "Rare as One" Project.[4]

Agencies can also use such measures as the health burden of a disease to help guide funding levels and priorities, For example, NIH funding can be correlated with burden (measured as disability-adjusted life years), although some conditions, such as cancer and HIV, have received greater-than-predicted support while others, including migraine and chronic obstructive pulmonary disease, have received less (Gross et al., 1999; Moses et al., 2015). These decisions can have downstream equity implications when the knowledge base for a condition that substantially affects an underserved group remains understudied.

Health Care Organizations and Providers

Health care organizations are also interested actors during problem formulation and the definition of potential use cases. Many medical technologies, from updated dashboards in electronic records to new diagnostic tests and treatments, are used within the context of health systems. Health care organizations can influence choices in this innovation phase by leveraging their gatekeeper roles in approving research, making funding and resourcing decisions to support research, and intentionally involving care providers (technology end users), patients, and communities (users and beneficiaries) in problem definition. The response of San Francisco General Hospital and the University of California, San Francisco to the HIV/AIDS epidemic provides an example of the influence of health care organizations in defining research directions. The establishment of Ward 86 and Ward 5B in 1983—the first dedicated clinics for HIV/AIDS—produced standards of care for patients with HIV/AIDS, and ensuing work by the hospital's and university's researchers contributed to medical breakthroughs in HIV/AIDS treatment and prevention (HIV.gov, 2023).

Engaging with Communities

Engaging with those who will use and be affected by technologies is important during problem identification and formulation. It is increasingly recognized that meaningful involvement of the voices of marginalized and underserved communities may produce different paths for research and development from those that might be conceived in the absence of their engagement. This approach to community engagement has been defined by NIH as "the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people."[5] The rationale is that those directly impacted by potential inequities bring their own unique perspectives and understandings of such issues and often more nuanced and locally informed insights into how those issues can best be addressed.

The goals of such community engagement are to build trust, enlist new resources and allies, create better communication, promote sustainability, and ultimately improve health

[4] See https://chanzuckerberg.com/science/programs-resources/rare-as-one/ (accessed May 16, 2023).

[5] See https://www.nih.gov/health-information/nih-clinical-research-trials-you/community-engagement (accessed June 30, 2023).

outcomes. Without such community input, the overall effectiveness of interventions and programs addressing identified needs may be limited (Barnes and Schmitz, 2016). Engagement efforts have long been embedded in social science and public health interventions, often relying on tenets of participatory action research, including bidirectional engagement, the equitable exchange of ideas and values to drive interventions that reflect mutual benefit, and a shared commitment to health equity. Over the last three decades, such approaches have also been embraced by health care delivery organizations, research funders, philanthropic organizations, and advocacy groups, which have championed active engagement with the communities their services or programs are intended to benefit in order to drive the development and implementation of more successful solutions.

The Patient-Centered Outcomes Research Institute (PCORI) is an example of a research organization that recognizes engagement with patients and community members as essential and requires funded projects to engage those concerned in program development.[6] NIH has similarly been making efforts to ensure that projects—particularly research aimed at addressing complex, multifaceted problems such as health disparities—engage relevant communities. Examples include the Clinical Translation Science Awards (CTSA) program and the precision medicine All of Us Initiative (see also Chapter 4). Community–academic–health system partnerships have also demonstrated the value of participatory action research in building trust and accelerating innovation. During the COVID-19 pandemic, for example, a community-based initiative codesigned with San Francisco's Latino Task Force succeeded in understanding and overcoming vaccine hesitancy in the Mission District of San Francisco, where many Latinx people live and work (Marquez et al., 2021).

Central to all engagement initiatives is recognition that there is no one-size-fits-all approach, and that research approaches and engagement strategies need to be tailored to unique needs and circumstances. There are numerous ways to conceptualize "community" and "engagement" at different levels of complexity and cocreation (see Figure 3-2). As the level of community involvement increases from outreach and consultation to collaboration and shared leadership, patients and community members become more than objects of research; they become partners in a research process bolstered by earned trust, with power and decision-making authority of their own. Yet despite such initiatives, the majority of technologies are still developed with limited involvement from those who are their intended targets, consumers, or beneficiaries. As a result, instead of being driven by community needs, interests, and concerns, product development efforts can remain disconnected from the people they are intended to serve.

Researching, Developing, and Assembling a Technology

Activities and governance during this phase influence how research is carried out; how research results are reported and disseminated; how intellectual property is managed and licensed; and what technologies are selected for further investment and development, often by private investors and companies.

Research Pipeline

Early-stage biomedical research often takes place within universities. In 2019, universities performed the largest proportion of basic research in the United States (46 percent) (NSF, 2022). This research is funded by sources that include the federal government, state and local

[6] See https://www.pcori.org/ (accessed June 30, 2023).

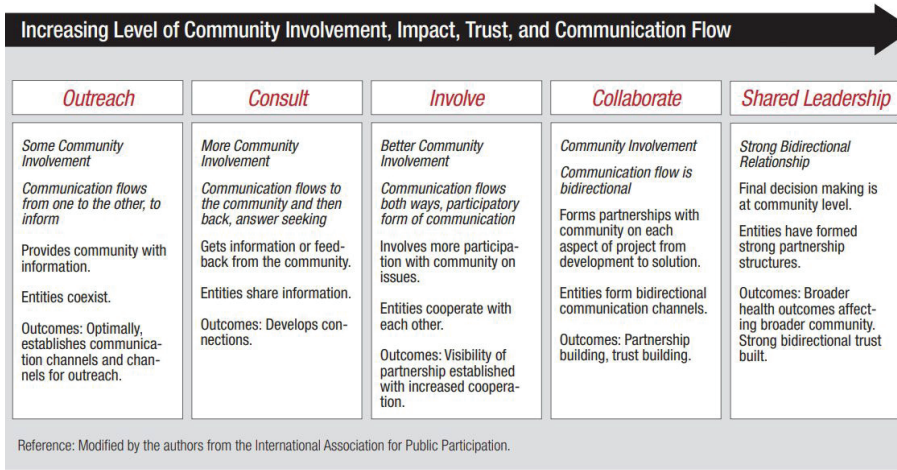

FIGURE 3-2 Varying levels of community engagement.
SOURCE: Clinical and Translational Science Awards Consortium, 2011.

governments, institutional funds, and business. In 2021, federally funded research and development at universities surpassed $49 billion, accounting for 55 percent of total research and development by academic institutions. The U.S. Department of Health and Human Services (HHS) was the largest federal source of research and development support to higher education institutions ($27.5 billion, representing 56 percent of federally funded research and development). HHS funds supported more than $24 billion in life sciences and more than $1 billion in engineering research and development expenditures (Gibbons and NCSES, 2022).

The primary means of disseminating knowledge generated from these research investments is publications in scientific journals. As a result, what gets published has a major influence on which findings are ultimately adapted for applications. Factors recognized as limiting the ability to maximize the collective benefits of research investments include the lack of mechanisms and incentives for publishing "negative" findings, along with barriers to accessing, sharing, and reusing data (Bauchner et al., 2016; Matosin et al., 2014; Zuiderwijk et al., 2020). In addition, studies that employ unconventional methodologies, as is sometimes the case with community-based research, may face greater barriers to journal publication, limiting the dissemination of their findings. This landscape may be evolving, however, with increasing use of preprint servers and open-source publishing, as well as recent guidance on public access to federally funded research (OSTP, 2022).

Private-sector companies and investors play key roles in funding efforts to translate basic research findings into commercial products. In selecting which technologies to bet on, companies and investors necessarily select from the options available. Where there are gaps or biases in the types of discoveries made and the types of insights entrepreneurs are working to translate into medical technologies, these gaps and biases are likely to be echoed in the investments of VCs and companies. For example, if NIH funding were to disproportionately favor diseases that affect men, it follows that more discoveries would be made about these diseases, more medical technologies would be developed based on those discoveries, and a disproportionate number of start-up companies would form to capitalize on those technolo-

gies. On the flip side, the pipeline for technologies benefiting disfavored groups (women, in this example) would be weaker, and the array of start-ups pitching to VCs or available for acquisition by larger companies thinner.

Intellectual Property Management

Whether the research in question is publicly funded, privately funded, or a mix of both, intellectual property management questions are likely to loom large. Even when earlier-stage work is publicly funded, key downstream patents may be owned by a private-sector firm, a situation that can arise when earlier-stage research leads to a publication that a private-sector patent builds upon. One study that examined data on patents linked to all NIH grants awarded over the period 1980–2007 found that while only about 10 percent of NIH grants resulted directly in a patent, about 30 percent of grants generated articles that were subsequently cited in a patent (Li et al., 2017).

In addition to patents, trade secrets can be important in innovation. For the biologics interventions that constitute almost half of biopharmaceutical spending in the United States (IQVIA, 2020), for example, if key information regarding FDA-required manufacturing processes is protected by trade secrecy, competition necessary to lower prices may be difficult to achieve (Price and Rai, 2016). Because trade secrecy requires demonstrated investments in efforts to maintain actual secrecy, it tends to be a private-sector regime.

Given the importance of private-sector intellectual property and likelihood that it will be managed in a manner that furthers market-driven goals, it is important for analysts concerned about equity to assess how the government confers intellectual property rights. Patents have long played a crucial role in the U.S. innovation system. The Constitution confers upon Congress the power to award patents to inventors as an incentive for "promoting the Progress of...the Useful Arts." The framers of the Constitution were, however, wary of extended monopolies, and the Constitution specifically states that patents are supposed to be awarded for "limited times." The laws that established a patent bureaucracy, now the U.S. Patent and Trademark Office (USPTO), for evaluating patent applications are similarly circumspect. They have long required that a patent application be granted only if it covers an invention that is novel, useful, not obvious, and sufficiently described to allow other scientists and technologists to replicate it. If USPTO's technically trained examiners determine that the invention meets these criteria, a patent is granted, giving the inventors the exclusive right to commercialize their technology for a limited period of time (currently 20 years).

The law on the ground has not, however, always matched the law on paper. As comprehensive empirical studies have shown (Frakes and Wasserman, 2017; GAO, 2016), USPTO examiners lack both incentives and time. As a result, patent holders have been able to claim patent protection over technical areas beyond their actual invention, which can create monopolies that limit research and raise costs over a wide swath of technologies (Parthasarathy, 2007; Trooskin et al., 2015). Inventors have also been able to obtain patents on small, often obvious changes to a technology that allow them to extend the term of monopoly power, a practice pejoratively known as "evergreening." One analysis found that for each of the 12 top-grossing drugs in the United States, companies attempted to secure an average of 38 years of patent life (i-Mak, 2022).

The U.S. patent system relies on other innovators and competitors to litigate if the scope of a patent is too broad, its term too long, or its disclosure insufficient, but litigation is very expensive, and the incentives of these competitors may be skewed. Equity is rarely front of mind among economic competitors. As a result, technologies can become unaffordable or inaccessible for those who need them most. Ensuring that USPTO and other institutions have

the incentives and resources to keep intellectual property regimes within their proper boundaries is critical to aligning innovation with equity. For patents that arise from public funding, additional legal levers may come into play. The Bayh-Dole Act, signed into law in 1980 (P.L. 96-517, Patent and Trademark Act Amendments of 1980), granted universities, not-for-profit organizations, and small businesses the right to retain title to inventions that emerged from federally funded research. Motivating the legislation were the ideas that research is key to new technologies, that technological change fosters productivity gains, and that growth in productivity supports long-term economic growth. Bayh-Dole was conceived to strengthen the first link in that chain—the transfer of knowledge from laboratory research to new technologies. Although both patents and trade secrecy represent important intellectual property for private-sector biomedical technology developers, universities usually rely on patents. Unlike trade secrecy, patents promote transparency and shared understanding of innovative science and technology, but they do so by giving inventors an extended opportunity for exclusive use of the invention in exchange for disclosing its workings.

Universities can realize significant financial gain from patenting and licensing (Mowery et al., 2001; Thursby and Thursby, 2002), although these activities can in some cases be counter to the public interests—for example, if they impede access to research materials and tools (Eisenberg, 2003; Eisenberg and Rai, 2004; Wadman, 2005). Universities and their associated technology transfer offices make key decisions about whether and when to assert intellectual property rights over the biomedical research conducted by members of their community. As an effort of collective governance to meet university needs while advancing science and the public interest, 11 research universities and the Association of American Medical Colleges in 2007 released "In the Public Interest: Nine Points to Consider in Licensing University Technology," which includes "recommended clauses" for contracts on issues that range from limiting licensing exclusivity to making medical technologies accessible to developing countries.[7] The guidance recommends, for example, reserving rights in exclusive licensing contracts that could enable universities to issue additional licenses to address unmet health needs. This guidance has since been endorsed by more than 100 institutions. Adoption of the "Nine Points" document appears to have had a significant effect on the use of clauses such as reservation of rights for education, research, and materials transfer (Contreras, 2022). However, an assessment of 220 publicly available university licenses found that the "Nine Points" language on access has not been widely adopted (Contreras, 2022).

Intellectual property looms particularly large for the small firms that often bring breakthrough products to market and provide key research and development inputs to larger firms. Consistent with economic theory holding that patents facilitate "markets for technology" (Arora et al., 2004), patents undergird interest in small-firm technology among large firms, as well as VCs and other sources of private funding (Farre-Mensa et al., 2016). Intellectual property barriers also provide "pull" incentives for investment by offering the promise of quasi-monopolistic pricing once the technology reaches the marketplace, a practice that long has caused many stakeholders to raise equity concerns (Arno and Davis, 2001; Rai, 2001). These equity concerns also motivated a patent lawsuit brought by the American Civil Liberties Union (ACLU) against Myriad Genetics over its patents on genes linked to breast and ovarian cancer. While the U.S. Supreme Court invalidated the ability to patent human genes as they exist in the body, Myriad Genetics' initial patent-based control prevented others from researching and developing competing detection tests in the late 1990s and early 2000s (Rai and Cook-Deegan, 2013). Moreover, the libraries of gene variants amassed during

[7] See https://autm.net/about-tech-transfer/principles-and-guidelines/nine-points-to-consider-when-licensing-university (accessed June 30, 2023).

the process perpetuated the company's effective monopoly (McElligott et al., 2012), as trade secret law protects a patentee's market power over data generated by patented inventions even when the patent expires or is invalidated (Simon and Sichelman, 2017). The past decade has seen a legislative effort to restore patent protection for human genes that would reverse the Supreme Court's Myriad decision and related subsequent legal developments and that, if passed, could have negative implications for equity. Such efforts underscore resistance in the innovation system to reforms that reduce profits but may better align such elements as patent regimes with the public interest.

The default approach to patents invoked by universities after the Bayh-Dole Act has been exclusive licensing. From the financial standpoint of universities, exclusive licensing is often perceived as more lucrative than nonexclusive arrangements, and universities can point to exclusive licensing as important for incentivizing investment in developing the technology and promoting start-up formation. Indeed, both universities and faculty inventors may have financial equity interests (such as stock ownership) in the start-ups (Contreras and Sherkow, 2017). Bayh-Dole has allowed some universities to accrue significant revenue from licensing. The 197 universities that responded to the Association of University Technology Managers (AUTM) 2020 survey reported filing 17,738 new patent applications and being issued 8,706 new patents that year. In 2009, universities derived total licensing revenue of $2.4 billion or approximately 4 percent of the systems' research expenditures (AUTM, 2010). For example, Columbia University and the inventors received approximately $800 million from licensing patents on how to introduce DNA into eukaryotic cells, techniques that arose from federally funded research and became important in biotechnology (Colaianni and Cook-Deegan, 2009). A small number of universities, however, account for the majority of licensing income, and many do not reap such significant financial rewards (Marcus, 2020).

Economic Viability: The Key Driver for Investment and Development

Private funders (mainly VCs or VC investors) and the companies that develop medical technologies play a central role in translating research insights into practical medical innovations. It is critical to recognize that economic viability is the key driver for both private funders and the companies that develop and market medical innovations. Because economic viability influences every decision made by investors and companies, any attempt to influence the decisions of these actors needs to connect in some way to the ultimate financial returns that may be generated.

VC investors act as both enablers and gatekeepers in the medical technology development cycle, primarily through their investments in start-ups seeking to turn research insights into successful products (Chandra et al., 2022). VC investments come at a critical point in the development cycle, and these investors therefore have an influence on everything that happens subsequently. When investing in biotechnology start-ups, VC funders attempt to identify which medical innovations are likely to succeed, make it to market, and make a profit, and which entrepreneurs are likely to succeed in this process. A VC investor typically enters at the early phases of a start-up's existence (through seed, Series A, and Series B investments), and the investor's exit typically comes when the start-up is either acquired by an existing large, publicly traded company or moves forward with an IPO to become a publicly traded company in its own right. For their part, the role of companies or technology developers takes two main forms. The first comes into play early in the development process, when companies use private funding to conduct research and development to create a product. The second comes into play later as the product nears approval and commercialization, when (typically larger, publicly traded) companies invest in bringing the product to market. In both roles,

companies must continually determine when to keep investing in a product in the hope that it will eventually generate revenue, and when to stop and cut their losses.

It is also possible that investors or companies can amplify biases and inequities that arise upstream of where they enter the innovation process. For example, investors or developers may disproportionately favor or disfavor technologies benefiting certain groups or entrepreneurs who are members of certain groups, although this is an area not well studied. In any case, inequities rooted primarily in earlier-stage research are unlikely to be addressed by placing a primary focus on investors, and inequities rooted upstream of commercialization are unlikely to be addressed by focusing solely on development and manufacturing companies playing key roles later in the innovation process. This feature helps to highlight the importance of developing a systemic framework for aligning innovation with principles such as equity.

For VCs and companies, the incentive driving participation is profit. In deciding whether to invest in a given start-up—and how much to invest—VC investors calculate how likely they are to make a profit in the end and how big a payoff they can expect. Many factors go into this calculation, but three questions loom large: How many people will use this product? How much would they pay for it? and How long, uncertain, and costly will the development process be? Wealthier people might be willing to pay a very high price for a new cure, but if it cures a disease that is extremely rare, the market size may be too small to yield much profit. Conversely, a product that would benefit millions of people may be unprofitable if the people who would benefit cannot pay a high enough price for it. In addition to calculating the expected market size, investors consider what it will take to get the product to market and the likelihood of failure along the way. These considerations include, for example, what types of clinical trials will be needed and their likelihood of success, what the overall technology ecosystem looks like, what constraints or opportunities the regulatory environment might hold, and the track record of the company leadership.

It is a complex calculation and a risky bet, in which a successful outcome depends on such factors as scientific risk, technical risk, execution risk, policy risk, and economic risk. While some investments in medical technology start-ups generate tremendous returns (2000 percent or more), the median return for this industry in the years after an IPO is negative, meaning that most investments will lose money even after a successful IPO (Cleary et al., 2021). The huge gains reaped occasionally at the top end of the spectrum essentially carry the losses that are far more frequent. The prospect of high returns provides the incentive for VCs to keep investing, but the high level of uncertainty provides a counterbalancing disincentive. To succeed in the long run, investors must be choosy. There are limited profit incentives for private investors and companies to advance innovations that would be accompanied by lower prices or that would largely benefit populations in lower-income settings or countries.

Ultimately, equity is typically an afterthought during the research, development, and assembly phase of technology development, if it is considered at all. Rather, activities during this phase are concerned primarily with the validity of the research and the eventual viability of a resulting technology. As innovation progresses through this phase, economic drivers and returns on investment become key motivating factors and incentives that spur advancement. Still, certain norms and practices that *are* embedded in this phase, including those around ethical matters guiding the responsible conduct of research, provide insight into the types of opportunities for embedding equity into this phase of technology development.

Evaluating a Technology's Performance for Widespread Use

Developers of medical technologies are subject to external governance in the generation and assessment of the evidence used to determine whether a product's performance, particularly its safety and efficacy, is sufficient to support public marketing. Many clinical studies of novel medical products are governed by regulatory controls, such as FDA application and issuance of an investigational new drug (IND) approval or an investigational device exemption (IDE).[8] Regulatory agencies such as the FDA can strongly influence the design and conduct of clinical studies intended to evaluate the performance of a product to support regulatory review.

These agencies provide opportunities for public comment, and such comments often have an impact (as was seen in the case of AIDS activists, and ALS and Alzheimer's patient advocates pressuring the FDA to approve drugs) (AlzForum, 2008; Epstein, 1998; IOM, 1991; Specter, 1989). At the same time, these agencies are often sensitive to concerns that they are bowing to political pressure. Race-based inaccuracies with devices such as the pulse oximeter (see Box 2-1 in Chapter 2) generated a warning notice from the FDA only after multiple studies had shown problems; there appears to be little proactive consideration of these kinds of issues (Brodwin and St. Fleur, 2021; FDA, 2021).

Developers of medical technologies typically choose the approach to generating clinical evidence for their products. For example, a drug or device developer decides on the type and design of clinical studies intended to generate the evidence required for evaluating its performance. Most testing focuses on establishing the safety and efficacy of the technology, but there is some attention to testing in diverse populations in terms of gender and race/ethnicity[9] (see also the discussion of Moderna vaccine trials in Box 3-1 in Chapter 3). Informed consent is a critical ethical component of the generation of evidence from trial participants, and the selection of trial participants, procedures for obtaining informed consent, and what that consent entails have equity ramifications. An IRB is responsible for ensuring that the informed consent obtained meets applicable standards (FDA, 1998).

Inequities in the current systems for pre- and postmarket performance evaluation derive from the challenges of evaluating product performance in a way that is representative across a large population of diverse individuals. The location of many trial sites in urban locations and concerns about added economic costs may deter companies from evaluating the performance of technologies across a diverse population, including those in rural communities (Chaudhry et al., 2022). The infrastructure and tools used by medical technology developers for a clinical study also affect the likelihood that the study will be appropriately representative of diverse groups of patients. For example, tools that allow study activities to be conducted remotely may permit the participation of those who live far from traditional clinical study sites (e.g., in rural areas) (Washington et al., 2023).

Beyond the important ethical reasons for limiting the size of certain types of studies, clinical trials often are also very costly on a per-participant basis (Moore et al., 2020), incentivizing medical technology developers to minimize the number of participants. Advances in the methods and infrastructure needed to improve the efficiency of generating premarket clinical evidence are important for improving the effectiveness of the medical innovation

[8] See https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application and https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-approval-process (accessed June 30, 2023).

[9] For example, inclusion of women and members of racial and ethnic groups is mandated for NIH-funded clinical research as appropriate to the question being investigated (42 U.S.C. §289a-2; see also https://grants.nih.gov/policy/inclusion/women-and-minorities.htm; accessed June 30, 2023), and the FDA is developing new guidance on diversity in clinical trials (FDA, 2022a).

system and could also contribute to equity. Increasingly, companies focused on the science and technology of generating clinical evidence play an important role in more advanced types of clinical studies, including those using novel data sources. Decisions by these companies can affect the capabilities and design of clinical studies, how risks and benefits are distributed across groups, and the bandwidth of information such a study is likely to generate (London and Kimmelman, 2019). These companies can also focus on tools for engaging with consenting research participants.

Currently, some segments of the population are unable to benefit from new technologies because they are inadequately represented in clinical research (NASEM, 2022a). Increasing the diversity of participants in clinical research is an important aim that can improve the generalizability of research findings, produce new biologic insights and therapeutic strategies, and increase patients' interest and confidence in effective new treatments (Schwartz et al., 2023).

Altogether, the evaluation of a technology's performance is conducted through layered, multidirectional interactions and communication among developers, regulators, and research oversight bodies, as well as the patients, providers, and organizations involved in clinical trials and evaluation studies. These evaluations rely on applicable guidelines and standards related to safety and efficacy and the involvement of human research participants, but they are often incomplete with regard to the full scope of equity considerations set forth in Chapter 2. This incomplete consideration of equity arises from various factors, including cost pressures and other economic factors, as well as the system's inherent structure of balancing rigid, prescribed methods of assessment (including assessments of ethical considerations) with flexible means of evaluation according to the specifics of a given technology.

Accessing and Using a Technology

For many health technologies, consumers do not directly purchase a product; access is often mediated by health care organizations and insurers. The decisions of health care organizations about purchasing and using new technologies thus affect access to and the cost of those technologies, representing a choice point for equity. However, health care organizations currently have little incentive to prioritize equity in these decisions since doing so has a limited ability to benefit their bottom line, even though it fundamentally impacts their core function of delivering health care services to all patients. Care providers, as employees of health systems, have limited ability to influence choices at the organizational level, while patients, as consumers of health care, may have more influence. Both providers and patients can contribute to the pressure required to drive change.

While health insurance organizations are not technically gatekeepers of health technology, technologies that are not covered by insurance are typically so expensive that most people cannot afford them, making these payers de facto gatekeepers. Their decisions about coverage therefore play a large role in patients' ability to access and use health technologies. Private payers may have substantial flexibility to limit coverage based on comparative effectiveness information. Government payers in the United States (e.g., Medicare and Medicaid) may be more limited in their ability to condition coverage on information about the performance of a medical technology; Medicare generally conditions coverage for medical technologies on the statutory "reasonable and necessary" requirement.[10] The Inflation

[10] See Notices, Federal Register 68(187) for Friday, September 26, 2003 (https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/FR09262003.pdf; accessed June 30, 2023).

Reduction Act of 2022 also includes provisions that enable the government to negotiate prices for some types of drugs (with exclusions) (Cubanski et al., 2023).

Private health insurance and employer-based health insurance are largely creations of the post-Depression and post–World War II eras and were strongly influenced by the cost-containment measures adopted in the 1970s—for example, by the creation of health maintenance organizations (HMOs) (Hickey, 2022). One possibility for creating system changes toward equity draws on power at the level of individual states, which have the authority to mandate coverage for specific services or to ensure some aspects of equitable access. While not a comprehensive power, such state authority has been used in the past, for example, to mandate coverage for certain fertility services, breast cancer treatments, or hearing aids.[11] States were given the power to set coverage rules for Medicaid, usually using various cost-containment methods that continue to this day under the Affordable Care Act; in addition, states have some authority to require coverage for particular services as a condition of selling insurance policies within the state (subject to some exceptions). Together, these authorities give states power to determine that equity requires coverage for certain services, or for certain forms of services.

One approach that has been suggested is for states to adopt a "vulnerability" theory to undergird their insurance policies. In the context of contraceptive access, one proponent describes this approach as follows:

> A better approach to establishing state responsibility for family planning would reframe state involvement as proactive, positive, and supportive rather than punitive and reactionary. Vulnerability theory begins with the recognition that, as embodied beings who are constantly susceptible to changes in our physical and social well-being, we are all universally vulnerable. The severely restrained state can play only a limited role in protecting the autonomous, independent, and self-sufficient legal subject from any constraint on the exercise of her autonomy. In contrast, vulnerability theory requires a responsive state that affirmatively addresses the vulnerability of its subjects. It does so by providing its citizens with the resources needed to maintain resilience in all life stages in a just and equitable manner. (Hickey, 2022, p. 99)

Stated more generally, a vulnerability approach would task states with identifying those services that are ill suited, logistically challenging, or otherwise inappropriate for meeting the needs of underserved populations, and mandate coverage for alternate therapies or delivery methods that could address unmet needs. Such an approach, of course, would require political will and decision making to enact measures at the legislative and administrative levels of state government.

In general, this phase of innovation has seen remarkable changes throughout U.S. history (see also Appendix B). It is driven by interwoven policies related to health care access, distribution, and reimbursement, which are created in various political, historical, and judgment-based contexts. Notably, the lack of federal or state policy on a given topic also plays a role in affecting access and use—for example, as pertains to direct-to-consumer and do-it-yourself markets for some technologies. Accordingly, equity as a consideration is often present only when a particular policy governing access enables equity or reflects the values that promote it. Otherwise, equity is unlikely to be embedded systematically in this phase.

[11] See, for example, state-mandated coverage of infertility treatments at https://www.kff.org/womens-health-policy/state-indicator/infertility-coverage/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D or mandated coverage for hearing aids at https://www.asha.org/advocacy/state/issues/ha_reimbursement/ (accessed May 31, 2023).

Learning from a Technology's Deployment

Existing governance systems for medical technologies include regulatory requirements to evaluate performance in the postmarket context.[12] In addition, payers exert control to the extent that they may condition reimbursement or payment for medical technologies on the generation of follow-up data. Regulators of medical products and producers of new medical technologies, often companies, also influence what postmarket follow-up is conducted after a product is released for widespread use, particularly if companies are responsible for meeting the requirements for postmarket evaluation of regulators or payers.

Companies and health care organizations engaged in health care delivery, such as health systems, are also critical to this phase because they interact directly with the medical technologies and the patients and consumers using them, can collect information about performance, and can make this information accessible with appropriate privacy and security protections. Companies engaged in health care delivery may also be incentivized to participate in postmarket performance evaluations to the extent that they depend on reimbursement by payers that is conditioned on such performance data.

Reporting by Patients and Users

The postmarket public response to a new drug or technology from patients, patient advocacy groups, and users has an impact on its overall success, adoption, public perception, and legacy. The primary actions and choices of patients and patient advocacy groups here revolved around reporting, either to regulatory agencies such as the FDA or directly to the general public. This is a phase of innovation in which the involvement of marginalized communities can be very important in illuminating performance or access concerns.

Patients and patient advocacy groups can voluntarily report serious adverse events, product quality problems, product use errors, or therapeutic failures that they suspect are associated with the use of an FDA-regulated drug or device via MedWatch, the FDA's public-facing medical product safety reporting program (FDA, 2023). While MedWatch was developed to assess potential safety concerns related to drugs or devices, however, it was not designed to assess equity concerns related to the real-world use of products.

Through its research, guidance, and regulatory actions, the FTC serves as another forum for assessing the deployment and implementation of health technologies. Additionally, nonprofit consumer watchdog organizations provide a voice for consumers and taxpayers, playing a role similar to that of patient advocacy groups in both health- and nonhealth-related sectors. These organizations use the levers of education, research, lobbying, litigation, and funding to advance their members' interests, which in more recent years have expanded to include calls for equity. Patients and patient advocacy groups can also appeal directly to their target audience (pharmaceutical companies, technology companies, health care organizations, funders, or policy makers, for example) through the press and popular media, impacting postmarket outcomes after a technology has been deployed.

What Gets Reported in the Postmarket Period

Fairly well-developed mechanisms exist for assessing issues with the safety of drugs and medical devices, but these mechanisms do not currently extend to how technologies may reinforce or exacerbate inequities and injustices. Additional postmarket data are needed to

[12] See https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarket-requirements-and-commitments (accessed June 30, 2023). However, not all requested postmarket studies are completed.

capture a broader picture of the patient experience and offer insights necessary to better monitor and evaluate health equity–related outcomes. The generation and analysis of such data may involve different or additional actors. At present, for example, safety reporting often comes from doctors and hospitals, which may not be best positioned to identify equity considerations and metrics, while reporting from patient and community groups may offer additional contributions.

Postmarket data collection mechanisms include Phase IV studies, regulator-supported systems (e.g., Sentinel, Medwatch, the FDA Adverse Event Reporting System [FAERS], and the Vaccine Adverse Event Reporting System [VAERS]), payer-supported systems (e.g., claims databases), independent systems (e.g., National Poison Control Center, National Coordinating Council for Medication Error Reporting and Prevention), information from electronic health record (EHR) systems, clinical registries, and patient- or disease-based registries. Data collected through these mechanisms include adverse events, longitudinal use or exposure, and morbidity/mortality.

Postmarket reporting systems have faced criticism for being too narrowly focused or hampered by incomplete data, lack of data standardization, and issues with data quality (Pisac and Wilson, 2021). Furthermore, these programs are likely to identify only a fraction of the total number of adverse events that occur (Ross, 2015). Passive surveillance is undermined by voluntary reporting of frequently inaccurate, untimely, unverified, and/or biased data, whereas active surveillance is expensive, slow, and often narrow in scope. While these mechanisms, however flawed, are reasonably well designed to assess problems with the safety of drugs and devices, they do not currently extend to how drugs or devices might reinforce or exacerbate inequities and injustices in the real world. It is also important to remember that not all health-related innovation is subject to FDA regulation, limiting requirements and constraints around how products are tested and for which types of users before and after marketing. Ultimately, use of real-world data and real-world evidence in postmarket surveillance will be needed to strengthen existing safety monitoring, as well as to enable equity monitoring in the future. These efforts can be augmented by the addition of a Unique Device Identification System integrated with multiple data sources (including EHRs, administrative claims data collected by payers for billing purposes, and clinical registries), allowing the FDA to conduct large-scale, proactive surveillance of devices (Rising et al., 2014). Real-world data on patient characteristics and health outcomes associated with the use of technologies would allow the FDA to better identify patterns of inequity related to access, efficacy, and unintended consequences. Many equity concerns can be revealed only when the experiences of some individuals or groups are contrasted with those of other groups. To the extent that an equity concern is revealed only in analyses at the population level, it cannot be addressed in systems designed to report on individual occurrences. Thus, combining multiple sources of real-world data can offer additional insights about equity.

Additional issues in postmarket data collection and analysis involve challenges with the "data substrate," particularly the availability and quality of data from real-world clinical practice and other sources needed to monitor performance, including aspects of performance related to equity (Tang et al., 2023; Zhang et al., 2022). Significant advances are also needed in the ability to collect, characterize, and analyze nontraditional sources of data, including data on social determinants of health, geographic variables, and social vulnerability. Companies focused on the science and technology of generating clinical evidence can be critical actors in follow-up because the methods and technical infrastructure for analyzing data on the real-world performance of medical technologies are still at a relatively early stage.

The development of the infrastructure, methodology, scientific consensus, and community and public support needed to apply these types of evidence sources to decision making

(e.g., governance decisions around a technology) represents a significant opportunity to advance equity in health innovation. As with premarket performance evaluation, appropriate incentives and resources will need to be dedicated to producing useful evidence that can help in better evaluating aspects of equity. Incentives during this phase can be shaped by regulatory requirements, payers, and other levers. Without these levers, equity issues may not be explicitly considered unless driven by demand among those for whom inequities are at play. To inform and support these choices, better methods and metrics are needed to measure how inequities arise in different contexts and in relation to the types of equity described in Chapter 2, as well as to capture and assess the impacts of any actions taken to enhance the alignment of an innovation with equity.

Artificial Intelligence/Machine Learning Technologies in Health Care: An Illustrative Example

Box 3-3 provides a case study of equity concerns associated with the development and use of AI and ML in health care, an area that has been receiving increasing attention. It helps illustrate the rapid pace of technology evolution; potential tensions between innovation and nuanced equity considerations; the need for actors across the technology life cycle to discuss and align technology development and governance with aims such as equity; and the need for guidance to address equitable development, evaluation, and deployment of AI-based innovations.

FAILURE TO ADDRESS EQUITY HOLISTICALLY IN THE CURRENT SYSTEM

An important purpose of emerging science, technology, and innovation in health and medicine is to help people live longer, healthier lives. But as this chapter illustrates, the current system is often shaped by goals promoting the rapid advancement of technology and the influence of incentives such as profit making. Considerations relevant to equity can arise throughout the innovation life cycle, but alignment with equity is often an afterthought and subordinate to other considerations.

Actors across the ecosystem for emerging science, technology, and innovation can take a wide range of actions to recognize and address inequities, biases, or unfairness, with research and development organizations, companies, patient and community groups, federal and state government agencies, funders, investors, care delivery and payer organizations, and others having particularly impactful roles at different phases of the innovation life cycle. However, the varied and fragmented nature of the system and the lack of a holistic, systems-level view of equity may limit the impacts of individual actions.

One mechanism by which actors and governance bodies can understand the implications and effects of a technology is through technology assessment methods. Current processes for technology assessment in the United States do not necessarily include equity-related impacts, and traditional technology assessment also has not involved substantial community input (see Appendix B). The development of enhanced forms of technology assessment through the work of such institutions as the Government Accountability Office's (GAO's) Science, Technology Assessment and Analytics team[13] (the organization that has assumed the mission of the former congressional Office of Technology Assessment), academic institutions, involved communities, and others developing deliberately democratic models, such as participatory

[13] GAO also published a Technology Assessment Design Handbook (GAO, 2021).

BOX 3-3 CASE STUDY OF ARTIFICIAL INTELLIGENCE/ MACHINE LEARNING (AI/ML) TECHNOLOGIES IN HEALTH INNOVATION

As AI and ML proliferate in every aspect of people's lives, there is growing societal awareness of their capacity to inflict harm and exacerbate existing health disparities. This example contextualizes equity challenges and opportunities during the innovation life cycle, including who participates in AI/ML innovation and where it takes place, how representative the designs and training data are, how AI/ML-based health technologies are tested and regulated pre- and postmarket, and how AI/ML-based technologies are used in real-world health care settings.

Embarking on a Technology

Disparities in funding and problem selection priorities can affect justice and equity "if the research questions that are proposed, and ultimately funded, focus on the health needs of advantaged groups" (Chen et al., 2021, p. 125). The current lack of diversity in the AI/ML workforce, geographic maldistribution of AI/ML innovation centers, and funding priorities risk exacerbating existing socioeconomic, racial, and gender inequities.

Lack of diversity in the AI/ML workforce. The socioeconomic composition (i.e., class, race, sex, age) of the AI/ML workforce does not reflect that of the general U.S. or global population. More than 80 percent of AI/ML professors are men; limited numbers of AI/ML researchers are women (15 percent at Facebook and 10 percent at Google); and less than 4 percent of the workforce at Facebook, Microsoft, and Google is Black—a status quo that has been called a "diversity disaster" (West et al., 2019). Evidence indicates that "diversifying the scientific workforce will lead to problem selection that more equitably represents the interests and needs of the population" (Chen et al., 2021, p. 127).

Geographic maldistribution of AI/ML centers of innovation. AI/ML innovation activity in the United States is highly concentrated in metropolitan centers arrayed along the coasts, with the San Francisco Bay Area commanding preeminence in venture capital funding. The Bay Area, Boston, and a limited group of early-adopter hubs account for most of the nation's current AI/ML activities in federal contracts, conference papers, patents, job postings, and start-ups (Muro and Liu, 2021). This disparity lays the foundation for unequal benefits from AI/ML innovations.

Biased funding priorities. Funding for health care AI/ML has disproportionately favored inpatient hospital use cases over outpatient use cases, as well as specialty care use cases over primary care and population health use cases. Of the Food and Drug Administration (FDA)–approved AI/ML medical devices on the market, only 3 percent are intended for primary care clinicians (Benjamens et al., 2020), even though primary care accounts for 52 percent of all health care delivered in the United States—more than all other specialties combined (Willis et al., 2020). Investing in AI/ML use cases for primary care and population health will be necessary to unlock the promise of AI/ML for the broadest population of patients and communities (Lin, 2022).

Assembling a Technology

Disparities in data collection, outcome definition, and algorithm development present equity challenges during assembly of an AI/ML technology (London, 2022). A focus on convenient data samples, such as electronic health records (EHRs), administrative health records, and social media data, risks perpetuating patterns of bias and discrimination baked into those data sets. The selection of the outcomes of interest, such as clinical diagnosis, risk prediction, or health care costs, can be influenced by biased clinical knowledge or implicit power imbalances and social disparities within the health care sector. Biased or exclusionary design and model building practices also lead to differences in the technologies' performance and experience with them among different populations.

BOX 3-3 Continued

Nonrepresentative and discriminatory data. Biases baked into EHR, administrative/insurance, and social media data are a well-known threat to equity. Biases in EHR data may arise because of differences in patient populations, access to care, and availability or functionality of EHR systems. Administrative records, such as billing claims and clinical registries, are biased by lower participation of minority populations by race, ethnicity, sexual orientation, gender identity, and language. Individuals with internet access provide the data from search-based research and social media platforms, limiting participation by age, technical literacy, and socioeconomic class. Representative data collection must be understood as a front-of-mind concern during the assembly phase to support equitable AI/ML development (Chen et al., 2021).

Biased proxy selection. In AI/ML model development, selecting the wrong proxy for outcomes, however well intentioned, can have serious consequences for equity. In one canonical example, a widely used algorithm designed to allocate care management slots to high-risk patients reduced the number of Black patients identified for extra care by more than half compared with White patients with similar conditions (Obermeyer et al., 2019). Discrimination occurred because "the algorithm used health costs as a proxy for health needs"; "less money is spent on Black patients who have the same level of need, [so] the algorithm falsely concluded that Black patients were healthier than equally sick White patients" (Vokinger et al., 2021, p. 1). Removing the use of costs as a proxy for health needs eliminated the racial bias in predicting who needed extra care.

Biased or exclusionary design. Technologies focused on the health concerns of advantaged groups often ignore the needs of patients with disabilities, limited language proficiency, and low health or technology literacy. UNICEF estimates that 1 billion people lack access to the assistive technologies they need for living (WHO and UNICEF, 2022). AI/ML has the potential to improve health equity by, for example, leveraging voice assistants to help patients with visual impairment, or natural language processing to translate American Sign Language, the standard form of communication used by deaf people, to spoken English and vice versa. Focusing on accessibility awareness, advancing human-centered designs that support accessibility, and codesigning technologies with members of marginalized and underserved populations are ways to support design equity.

Evaluating Performance

Rigorous testing is needed to determine the safety, efficacy, and adverse effects of any technology, yet the vast majority of FDA-approved AI/ML algorithms and devices have not undergone multisite prospective evaluation. Default practices, such as evaluating performance on large populations, mask potential disparities when algorithms do not work for subpopulations.

Limitations in FDA premarket clearance of AI/ML. One recent review showed that 97 percent of FDA-approved medical AI/ML devices underwent only retrospective studies; none of the "high-risk" devices were evaluated by prospective studies; and a substantial proportion were evaluated at a small number of sites, which tend to have limited geographic diversity (Wu et al., 2021). One study of imaging-based AI/ML found that 14 percent of algorithms had no validation data, and only 8 percent had a validation data set of more than 1,000 patients (Ebrahimian et al., 2022). These situations occur because the FDA approves the overwhelming majority of AI/ML devices and algorithms through the 510(k) clearance pathway (Reuter, 2022), which is granted when an algorithm or device has been shown to be "substantially equivalent" to another approved product. In 2011, the Institute of Medicine (now the National Academy of Medicine) published a report critical of the 510(k) process, concluding that it was "neither making safe and effective devices available to patients nor promoting innovation in the device industry" (IOM, 2011). Strengthening and modernizing premarket governance has been a major focus of the FDA since, including reforming the 510(k) pathway and recommending that some AI/ML-based clinical decision support tools, previously unregulated, now be regulated as medical devices (FDA, 2022b).

BOX 3-3 Continued

Access and Use

Disparities in who gets access to AI/ML technologies and how the technologies are applied in the real world are likely to perpetuate real-world patterns of health inequality and discrimination. Application unfairness can deepen digital divides, exacerbate rich–poor treatment gaps, and bias clinical decision making. The repurposing of biased AI/ML systems ("dual use"; see below) can turn algorithms into instruments of discrimination.

Unequal access and resource allocation. Payer reimbursement and incentive structures for AI/ML tools in health care are still in their nascent stages (Adler-Milstein et al., 2022). How these payment systems are established will have a significant impact on who gets access to AI/ML health innovation, and who does not. Direct-to-consumer AI/ML excludes patients who cannot afford to pay out of pocket, which exacerbates existing health disparities and widens the rich–poor treatment gap.

Biased clinical decision making. Little is known about how AI/ML might bias the clinical decision making of health care providers in the real world. For example, clinicians who overrely on an AI/ML-based decision support system might take its recommendations at face value even when the AI/ML-generated result is biased. On the other hand, clinicians who distrust an AI/ML system might disregard its recommendations even if it offers helpful corrections designed to debias current care and reduce known discriminatory behaviors (Leslie et al., 2021). Further research is needed to understand clinical human–machine interactions and how AI/ML can bias or debias clinical decision making.

Dual use. During the COVID-19 pandemic, in an attempt to curb the spread of COVID-19 in U.S. prisons, officials repurposed an algorithm developed to measure recidivism risk to determine which inmates to release to home confinement (Xiang et al., 2020). The algorithm, which was found to exhibit racial biases and not developed or validated for the repurpose, made Black inmates more likely to remain in prison and consequently more likely to be infected with and die from COVID-19. The dual use of this algorithm occurred while COVID-19 was raging in prison systems and against a backdrop of inequities in incarceration (Leslie et al., 2021).

Follow-up and Learning

Robust performance reporting, auditing of model generalizability (whether AI/ML models perform with equal accuracy in new settings on data on which they were not trained), clear documentation, and postmarket surveillance of AI/ML technologies are needed to protect patient safety, as well as identify harms to marginalized groups.

Need for audits. In addition to the issue of generalizability, many AI/ML algorithms tend to become less accurate over time, a phenomenon known as calibration drift. Without periodic monitoring using audits and potential retraining of models when performance deteriorates, concerns about safety and equity will arise. AI/ML models that fail ongoing fairness and reliability audits will need to be subject to reevaluation and considered for deimplementation.

Limitations in FDA postmarket surveillance of AI/ML. The FDA's postmarket surveillance program does not extend to how technologies, including AI/ML algorithms and devices, might reinforce or exacerbate inequities and injustices in the real world. Treating algorithms like prescription drugs and establishing an FDA-regulated, equity-focused pipeline for health care AI/ML development could help reduce bias and define protocols for adverse event reporting or model recalls when safety or equity is at risk (Coravos et al., 2019).

technology assessment, are continuing to innovate in this space, inclusive of the need to evaluate equity in the innovation system (Ada Lovelace Institute, 2021; Kleinman et al., 2007; Tomblin et al., 2017; Weller et al., 2020). Enhancing technology assessment methods in health and medicine to better identify and incorporate equity-relevant metrics and impacts across innovation phases provides a useful opportunity to engage diverse stakeholders and to collaborate both within the United States and internationally on shared ideas, needs, practices, and tools.

Government plays a crucial role in the development and use of science, technology, and innovation, yet this role is distributed across agencies with different areas of jurisdiction, missions, authorities, budgets, and priorities. In general, there are two drivers of government activities promoting aspects of equity in innovation: direct mandates provided by Congress or legislatures that are focused, targeted authorizations of activity (but are not necessarily identified as an effort toward "equity"); and top-down directives by government leaders to incorporate explicit efforts on equity within a preexisting agency authorization. In response to these drivers, agencies deploy varied approaches with varied intensity or resources and directed toward varied points along innovation pathways. Approaches taken can include financial, regulatory, and process-related practices promoting equity in innovation. Financial mechanisms can be upstream (e.g., in research grants) or downstream (e.g., procurement specifications supporting equity-relevant processes or outcomes). Process-related practices can include targeted outreach related to agency programs; collaboration with nongovernmental organizations; technical assistance for government programs and funding; and the inclusion of equity factors in grant reviews and decisions, such as evaluations of equity in research participation or in outcomes associated with the use of technology. Examples of how authorities and responsibilities for considering equity have been implemented at NIH, FTC, and additional federal agencies are described in Appendixes B and C.

Each government agency intersects with and exercises influence during only certain phases of the innovation life cycle, and may have a limited view of the overall innovation ecosystem and how to align it with equity. In the absence of an explicit mandate from Congress, some agencies may not consider themselves to be legal authorities for addressing equity. The politicization of discourse around equity may also lead some agencies to shy away from explicit efforts to address equity so as to avoid becoming embroiled in controversial issues.

Even when government agencies explicitly seek to address inequity, the roles of agencies active during a particular phase of the technology development life cycle can overlap with the purview of other agencies, which may use different definitions and processes and devote different levels of attention, effort, and resources to these concerns. Some agencies have an organizational structure that places their explicit work on equity in discrete offices. Others embed equity throughout their structure and operations, typically through a set of guiding principles or an internal ethos—all of which may vary in intensity and enforcement. Agencies also differ in how they interpret and deploy definitions of "equity," often using such terms as "health disparities," "diversity," "equality," and others to capture equity-related work (see Appendix C), and potentially overlooking such issues as topical equity, evaluation equity, and contextual equity (as described in Chapter 2). Further, some agency efforts aligned with advancing equity are not necessarily "branded" or identified as such; for example, the FTC's activities around the use of AI technologies have implications relevant to equity even though equity is not necessarily seen as a primary driver of these activities. There are also inconsistencies in agencies' approaches to collecting and analyzing data related to equity. All of this variation can lead to fragmentation of efforts across government bodies and agencies.

Another pervasive challenge in the ecosystem for emerging science, technology, and innovation is a lack of sufficient mechanisms for engaging and empowering groups that

have historically been marginalized or structurally disadvantaged, and that are thus not well served by the current system and may not view themselves as "stakeholders or rights holders" within that system. As a result, innovation and stakeholder needs can be misaligned. In addition, data collection and analysis undergird existing and potential efforts on equity in innovation, but gaps exist in the capacity to operationalize such data. These include gaps in what data are collected, as well as gaps in the workforce, digital infrastructure, and organizational structures, procedures, and systems used to process and analyze the data and apply them to make informed policy decisions.

A lack of coordination and coherence across the full landscape of emerging technology development and governance exacerbates such gaps and points to a need for systems thinking. Some combination of top-down governance from policy makers, funders, and regulators and bottom-up pressure from patients and affected communities, consumers, providers, and technology developers is likely to be required to create incentives in the system, ensure appropriate engagement, and collect and use data to drive change toward a more holistic approach to centering equity in the innovation ecosystem.

CHAPTER CONCLUSIONS

This chapter describes the life cycle of innovation in health and medicine, including the types of actions taken and the choices and considerations arising at each life-cycle phase. From this description, it is clear that the U.S. ecosystem for emerging science, technology, and innovation in health and medicine is dynamic and diverse but does not currently prioritize alignment with equity, leading to the following conclusions.

Conclusion 3-1: Pathways of innovation in health and medicine are varied, nonlinear, and difficult to map. Nonetheless, every technology's development progresses through phases from idea conception to postmarket learning and is shaped by the actions and choices of multiple participants across sectors—including funders, researchers, developers, regulators, users and affected communities, health care organizations, and many others.

Conclusion 3-2: With limited exceptions, the current system of innovation in health and medicine is not sufficiently aligned with values such as promoting equity.

- *The current governance model prioritizes speed and efficiency of technology transfer; the incentivizing roles of patenting and profit in innovation; and the use of narrow, targeted incentives to promote fairness, justice, and equity, which remain subsidiary concerns.*
- *Emerging science and technology assessments can be updated through commitments to studying inequities and expanding keystone values and tenets, to include broadening participation and sharing responsibility for aligning innovation with equity, justice, and fairness.*

Conclusion 3-3: Crucial equity considerations arise at every phase of emerging science, technology, and innovation. Ongoing efforts to enhance equity include increasing the diversity of the science, technology, engineering, and mathematics (STEM) workforce, incorporating patient input, addressing discrimination and the rights of patients and research subjects, and increasing access to new technologies. Aligning innovation with equity requires continued attention to these areas while going further to embed equity throughout the innovation process. An equity-aligned

system for the development and governance of innovation will require new processes that shift and diversify the traditional innovation life cycle by incorporating new considerations and a wider array of stakeholders from communities that offer specialized expertise, such as marginalized communities and social scientists and humanities scholars with expertise in equity. These new processes include drawing on the priorities and knowledge of underserved communities to shape ideation; valuing the contributions of people whose data and biological materials inform research; evaluating design, performance, and deployment according to a technology's implications for the full range of users; enhancing equity assessments; and learning from the resulting information to improve the system iteratively.

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4

A Governance Framework for Aligning Innovation in Health and Medicine with Equity

The prior chapters describe various ways in which the innovation life cycle can lead to anticipated and unanticipated patterns of inequity. Those chapters also establish an ethical imperative for improved governance of innovation in health and medicine and make a business case for moving toward an innovation framework that is more aligned with principles encompassing equity. This chapter describes such a framework. It begins by articulating the five key imperatives that guide the framework, and then explains how the application of these imperatives enables the forms of equity defined in Chapter 2 to be integrated more fully into the innovation life cycle described in Chapter 3, thereby helping stakeholders identify points at which the current ecosystem is misaligned with the principles of equity and fairness. The final sections of this chapter translate the governance framework to the phases of technology innovation, provide illustrative examples of these imperatives in practice and a vision for various stakeholders of what is possible, and describe leverage points in innovation life cycles that might be used to shift structural and institutional dynamics to realign those pathways with equity. Chapter 5 presents the committee's recommendations for concrete actions that would advance this more equitable innovation ecosystem.

FIVE IMPERATIVES THAT GUIDE THE FRAMEWORK

The equity-aligned governance framework proposed in this report is designed to help a wide range of social actors in the innovation system see how they are positioned to effect change toward a system that centers equity as a social good and a normative principle in scientific innovation. Social equity aligns with scientific and business opportunities for innovation and with shared responsibilities for the ecosystem. And alignment with equity can be enhanced as levers and incentive structures in the innovation system are changed. The aim of this report is to draw attention to the alignment of these imperatives for equity with the need for innovation and scientific advancement.

The purpose of the governance framework is to help diverse people, organizations, and institutions with different stakes and roles in the innovation system prioritize equity as a norm, and to allow them to envision how a renewed focus on equity can shift common innovation pathways toward more equitable processes and outcomes for users, the system, and society as a whole. This framework provides a way of identifying *who* the actors are, *what* they should do individually and together, and *when* they should do it. Taken together, the five imperatives reorient and redirect the various actors involved toward the cross-sectoral work of building a more equitable technological ecosystem across the health care landscape. It is important to stress that a flexible conceptual framework is needed to encompass the broad and complex social dynamics and interactions that unfold in the domain of health and medicine. It is important as well to note that each element of this framework can and must be applied in cross-cutting fashion—that is, iteratively and actively over the entire life course of any given technology or set of technologies.

Centering equity as a norm among the many stakeholders involved in science innovation is an expansive undertaking that will require cultural transformation across the many efforts involved in conceiving, funding, developing, evaluating, and using scientific innovations. Centering equity will entail fundamental changes that shift practice and professional norms by encouraging the use of new principles, tools, incentives, and methods of accountability; by developing new norms for how varied stakeholders engage early and often with users and affected communities; and by developing new practices that incorporate equity principles, evidence, and considerations into technology development. A framework for aligning innovation with equity will also require stakeholders across this system to develop new cultures of innovation in which awareness and curiosity are enhanced, and to develop routines and practices that prioritize engagement with users in ways that enhance equitable outcomes. To these ends, the following five cross-cutting imperatives underpin this new governance framework and will need to be embraced by innovators, funders, investors, purchasers, and users:

- broadening participation and sharing responsibility to empower a wider range of stakeholders;
- aligning incentives to encourage equitable decision making;
- determining how inequities develop along technology innovation life cycles and taking responsibility for mitigating them;
- crafting timely guidance for pursuing equitable ends; and
- sharpening ongoing, iterative oversight and evaluation along innovation life cycles.

Broadening Participation and Sharing Responsibility to Empower a Wider Range of Stakeholders

The first imperative focuses on broadening participation and responsibility in technological innovation by empowering groups to take actions that prioritize and center equity. New social groups must be brought into the innovation process, and groups of people that have long been part of the process will need to be reoriented toward equity. This process of democratization involves identifying, convening, and incentivizing diverse groups of people to work in a coordinated fashion to center equity in their respective roles along the innovation pathway and to take collective responsibility for the ecosystem as a whole.

An important principle of governance begins with expectations about what it means to "do better" by the governed. This report posits that health technologies should be developed and disseminated in ways that are fair, just, and beneficial to the broadest possible popula-

tion and with the fewest unanticipated consequences for health and well-being. In light of the pervasive inequities experienced in the United States, this means that emerging health technologies should not simply benefit the largest possible number of people but should reflect the full diversity of users and their experiences, including historically marginalized communities. This is not an "expectation" in the sense that it is not what is expected to happen on its own. Rather, it is what one would expect and value from an ecosystem that prioritizes equity.

Guided by concepts of equity (Chapter 2), broadening participation is important both for making innovations more equitable and for building and maintaining public trust in science, technology, and medicine. New people, perspectives, and experiences need to be brought into the process of technological innovation in health and medicine. These people include (1) those that have previously been seen primarily as sources of biological and/or experiential data in the name of technological innovation (e.g., through participation as research subjects in clinical trials) or have not even been included in biological data collection; and (2) experts such as social scientists and humanities scholars who historically have not been included in the innovation process but whose expertise is crucial for building a more equitable and fair ecosystem. The evidence shows that innovation in health and medicine has thus far been insufficiently informed by the diverse range of people's lived experiences with technologies and the localized social and cultural contexts in which those experiences take place. This imperative focuses on empowering people, many of whom are not necessarily organized into formal advocacy groups or other fixed social groups, in new ways as participants in a process of design and innovation.

Large and diverse groups of people have stakes in a more equitable ecosystem for technological innovation in health and medicine, and the framework presented here engages constituencies of people beyond the language of economic stakes and private ownership. Individuals and groups differ with respect to how their power and position can impact the life cycle and trajectory of technologies. Groups that are active in innovating or are seeking to make innovation equitable represent various structural positions in society—positions linked to structures of age, disability, race and ethnicity, indigeneity, gender, sexuality, social class, language, nationality, living in state custody, and others—that provide the institutional, cultural, and social-psychological architecture through which individuals and groups live out their daily lives, and that also constitute the social and political determinants of health. Therefore, efforts are necessary to address the power differentials that exist among these groups as they participate in the visioning, design, and research processes that lead to technological innovations.

In addition to engaging new groups of people in the innovation process, this imperative asks that everyone take on new responsibilities in the name of equity. All individuals who participate in the innovation process are responsible not only for their part in the process but also for the shared recognition that their actions need to come together synergistically to form a complex ecosystem. Fostering this recognition of responsibility on the part of traditional stakeholders will not come cheap; investments will be needed to raise awareness and incentivize the adoption of new understandings about how the technological ecosystem has led to inequities.

Aligning Incentives to Encourage Equitable Decision Making

Broadening participation and democratizing the innovation process will require actions that encourage, incentivize, and empower traditional innovation actors to take on new responsibilities for equity. Many people and groups play roles throughout the technology

development life cycle and have interests in and responsibility for the patterns of inequity that accompany that process for any given technology. The motivations and interests of these parties can vary widely and are not always aligned with expectations for equitable technological innovation. For example, equity considerations are often distant considerations for private companies, innovators, and some funders. To bridge these gaps in motivations and vested interests will require incentives that invite developers, designers, funders, firms, and other innovation actors to center and prioritize equity in their work.

Incentives will be particularly important in contexts where profit margins and most profitable markets are a main reason for innovation, a motivation that is often perceived as being in conflict with that of prioritizing greater equity in innovation. In fact, however, there are compelling arguments to be made that pursuing equity can *increase* profitability, such as by increasing the pool of potential customers for products and services, increasing the pool of potential innovators and entrepreneurs, improving the purchasing power of historically marginalized groups, and increasing economic stability at a societal level. There are also potential benefits to be realized in terms of a company's environmental, social, and governance rating and its reputation with customers, investors, and employees. The existence of investment firms whose strategy is to foster entrepreneurs from underrepresented groups and businesses targeting underserved markets is a testament to the fact that this strategy does not put investors at an automatic disadvantage. Thus, innovations that address unmet needs can benefit both business interests and people's health.

In some cases, however, prioritizing consideration of equity may come at a cost, or at least the perception of one. Adding constraints to investment decisions can increase costs and discourage or slow some innovation; some investors may choose to consider the implications of their investments for equity, while others may not. The burdens of inequity are often externalities—costs arising from the private sector but borne by the public sector. In this sense, efforts to increase equity that impose a financial burden on private-sector actors may represent a shifting of costs from one sector to another rather than an actual increase in costs overall. Indeed, some of those costs might in effect be shifted back, relieving the burden on private-sector actors with public–private partnerships in which the public partner brings to the collaborative both funding and a commitment to equity.[1] Another factor is timing: While venture capitalists and start-ups often make investment decisions with the goal of achieving a payoff within a few years, the financial gains that can be realized from reducing inequity (both for private businesses and society broadly) will play out on the scale of decades and generations.

One result of this complexity is that it is exceedingly difficult to quantify the trade-offs associated with prioritizing equity in health innovation. It is impossible to say that efforts to increase equity in innovation will always cost money, or that they will always save or make money. The trade-offs, where they exist, will likely be different across sectors and types of technology, and even across businesses within the same sector. This uncertainty does not mean the issue can be ignored. Indeed, even if the committee were able to determine that centering equity in health innovation will always reduce private-sector profits, the argument could still be made that it is worth doing. The constitutional concept of all persons being created equal—being of equal value and deserving of individual recognition with basic human rights—provides one basis for this argument. Thus the concept of equity as set forth

[1] Examples include BioMADE, the federal government's manufacturing innovation public–private partnership, and the Advanced Research Projects Agency for Health (ARPA-H), a new government agency that funds the development and commercialization of risky but impactful ideas to advance equitable health and medicine. These examples are discussed further in later sections of this chapter.

in this report is no more than a restatement of constitutionally bestowed rights and privileges, such that asking the U.S. innovation system to better align its incentives to enhance equity is the same as asking it to better abide by the U.S. Constitution than it has in the past. Further supporting this argument is that equity is a value in and of itself that is worth money. There are many examples in which society has prioritized public benefit over private profit. One example is the requirements imposed on the automotive industry in the 20th century: While equipping vehicles with seatbelts, impact-absorbing bumpers, and emissions-reduction technologies increased the cost of manufacturing vehicles, these costs were deemed worth incurring to realize the benefits to public safety and air quality. Sometimes it is worth doing the right thing even if it costs money.

Incentives are an important consideration for many other groups in the innovation system in addition to businesses and investors, including government actors (to encourage coordination across institutional sectors) and affected and underserved communities (to encourage engagement in processes from which they might otherwise be excluded). If incentives are to be worthwhile and sustainable, however, it is important to design guidance, regulations, and enforcement mechanisms and other governance strategies and incentives in ways that minimize the costs and unintended consequences while ensuring accountability for the desired outcomes.

Determining and Taking Responsibility for Inequities along Technology Innovation Life Cycles

People who are responsible for innovation systems need to pursue a more holistic approach to understanding the implications of technologies in society with respect to their impacts on health and well-being. The third imperative in the committee's framework is focused on building and renewing collective curiosity among innovation participants regarding the dynamic causes and patterns of inequity along innovation life cycles. These causes and patterns may not be predictable at early stages of conception and development; inequities often become clear in hindsight or only after a technology has been introduced into people's lives and broad-scale medical practice. One aspect of prioritizing equity is engaging in an active and open inquiry about the possible social harms and inequities that might reasonably flow from a particular technology in health and medicine. In other words, how can the equity dimensions of a technology's development and use be identified in advance and proactively and periodically reassessed as further information is gained? This imperative thus focuses on establishing norms and practices throughout the innovation life cycle in which stakeholders ask these questions, and the answers influence the choices they make.

Which questions about equity are asked, in what phase of innovation they are asked, and who is empowered to ask them are important to the framework.[2] Any technology's potential implications (including for equity) need to be analyzed and addressed early and often in the innovation life cycle. This process begins with questions about which technologies should be developed, why, and how, and extends to postmarket evaluations after a technology has become part of public life. This inquiry about potential harms encompasses and exceeds the normative risk-based assessments often carried out by private firms when conducting research and development on their products and markets. Traditional stakeholders tend to

[2] While this report is focused on governance of emerging science, technology, and innovation, an important question for governments, innovators, and other public and private stakeholders is whether the approach considered is the most effective and accessible solution to the problem. Sometimes developing a new technological solution does not address the root cause of a challenge or is not the most equitable approach.

focus on questions of risk, safety, feasibility, cost-effectiveness, profitability, and research ethics as they carry out their work. Centering equity involves new configurations of stakeholders asking and answering new questions about the distribution of benefits and harms of a technology or combination of technologies.

This curiosity about and awareness of how innovation can enhance equity should lead stakeholders to establish ethical norms and design practices that reflect what is learned through this more democratic and equity-focused inquiry. What should be done to steer a technology toward more equitable ends is a highly context-dependent question, one that needs to be pursued in a less hierarchical way that redistributes power over which scientific questions are posed, which technologies are designed, and what decisions are made in that case. Tools are needed to assist innovators and other actors in systematically asking and answering questions about the equity impacts of their particular technologies and what practices they can use to mitigate any related concerns. These questions need to be posed along the innovation life cycle to elucidate who holds responsibility for advancing equity and what those responsibilities look like as choices are made during the process—the moments at which actors' decisions lead to more (or less) equitable outcomes. In the past, equity has rarely been considered explicitly during these choice points.

However equity outcomes are measured, data on equity do not speak for themselves; they require theoretical frameworks for interpretation. Theoretical explanations for inequity are linked to specific remedies that, in turn, aim to repair or lessen that inequity. The social situations in which technologies are deployed have emergent equity dynamics that are not predestined, partly as a result of user innovations and unanticipated practices. Nonetheless, without the production of additional empirical data about inequity, it will be difficult to implement or audit practices that hold designers and governors accountable.

Crafting Timely Guidance for Pursuing Equitable Ends

The fourth imperative focuses on restructuring decision-making processes across and within public-, private-, and nonprofit-sector institutions involved in innovation in health and medicine. Strong context-specific guidance is needed for actors that include designers, funders, and firms about how to shift innovation pathways as they make decisions about what to do at various choice points based on what is learned iteratively through equity-focused data collection and analysis. The most actionable guidance on aligning innovation with equity is likely to be context-dependent, with the details affected by the particular area of emerging science and technology and by which actors have the greatest ability to influence decisions during different phases of development. In the artificial intelligence/machine learning (AI/ML) development community, for example, equity-relevant guidance has focused on identifying and disseminating best practices and strategies for accurate problem definition, elimination of bias, uses and limitations of training data sets, the importance of performance testing and auditability, and other practices (see also Box 3-3 in Chapter 3).

The application of this fourth imperative can involve diverse groups of people, including emerging science and technology innovators, public and private organizations that train investigators and conduct research and development, organizations that provide funding and approvals associated with emerging science and technology, those that assess, manage, and invest in the intellectual property that results; and those active in the provision and delivery of resulting products in health care and consumer settings. Once these actors have collectively determined what could be done to shift an innovation pathway toward more equitable ends that do not unduly cause social harms (in accordance with the third imperative), new and traditional actors will have to confront how to implement

these changes based on where they are positioned along innovation life cycles and their institutional capacity for making different choices and for implementing a new process for decision making.

Sharpening Ongoing, Iterative Oversight and Evaluation along Innovation Life Cycles

The fifth imperative is focused on sharpening the governance process for emerging technologies around questions of equity. Broad structures of oversight and evaluation are needed to track equity along innovation life cycles, going beyond the actions of individuals and groups in single institutions. Oversight provides a mechanism for encouraging or enforcing actions that shape ecosystem dynamics and advance equity, including the establishment of methodologies for better evaluating the equity alignment and potential risks of particular technologies. Oversight and other governance mechanisms can be voluntary or mandatory; mechanisms can be targeted at systems or particular parties; and they can be centralized or decentralized. These governance mechanisms can be formal regulatory policies, with both premarket and postmarket applications; they can be professional guidance, such as guidelines on partnering with affected communities or on inclusive design practices; they can be nongovernmental actions, as when payers decide which therapies are covered by insurance; and they can also be consumer focused, with attention to providing information that maximizes safe and effective uses by health care providers, patients, and consumers or that supply financial support for those who cannot otherwise access the technology.

One issue to consider is the permanence of these mechanisms. In public policy, the staying power of a policy often depends on the form it takes. Legislation is among the "stickiest" approaches since it is difficult to change or replace once enacted. Regulations also tend to stick. Nonbinding guidance and professional community norms are easier to change and update, and spending priorities are typically the most vulnerable to shifting priorities. In the private sector, company culture is strongly intertwined with the organization's focus and values. Once considering equity becomes embedded into the ethos of an organization, it becomes more difficult to take this value away. An ongoing and iterative program of governance, including oversight and evaluation, is necessary for addressing the cross-sector misalignments in innovation that allow for stratified processes and outcomes.

The Imperatives in Context: Learning from a Regenerative Medicine Case Example

If equity in innovation is to be advanced the five cross-cutting imperatives detailed above will need to be applied to understand and shape the dynamics of particular technologies as they travel along innovation life cycles. One case study that informed the committee's analysis (see Appendix A) is focused on regenerative medicine and governance approaches shaping this field, including the use of legislation, federal agency oversight, and the promulgation of professional norms and standards (Mathews et al., 2023). This example explores an area of emerging medical technology and illustrates how the framework imperatives can help identify and parse equity issues that arise in the development of this and other emerging technologies in health and medicine.[3]

[3] The observations on the case example presented here do not include references; extensive references are provided in Mathews et al. (2023); see Appendix A.

An overall observation illustrated by this case example is that *expectations and practices for responsible and ethical research and innovation have advanced and continue to evolve*. The history of stem cell transplantation involves recognizing the therapeutic options such cells can provide to patients with blood cancers, blood diseases, and radiation and burn injuries. However, early clinical trials took place before institutional and professional ethics infrastructures for approaches to informed consent and other protections for human participants in research had been developed. Since human pluripotent stem cells were first isolated, the field has seen evolving commitments to ethical practices for communicating and balancing benefits and harms to research participants, and recognition has grown of the importance of patient and public engagement and accountability in the development of new technologies. The need for oversight in regenerative medicine was identified at various points in the innovation ecosystem, and roles played by relevant bodies changed over time. In the 1970s, for example, the National Institutes of Health's (NIH's) Recombinant DNA Advisory Committee (RAC) established guidelines and initially reviewed all gene transfer research protocols. As the safety of DNA technology became clearer, responsibilities for evaluating proposed uses shifted more to biosafety committees at research institutions. In 2019, a successor to the RAC was reimagined, and the Novel and Exceptional Technology and Research Advisory Committee (NExTRAC) now provides advice on developments in a broader array of emerging biotechnologies.[4]

As stem cell technologies developed, research and clinical communities identified new scientific challenges and technical and logistical strategies for overcoming them, reflecting the iterative nature of innovation. For example, scientific progress in the derivation of induced pluripotent stem cells (IPSCs) intersected with concerns among some members of the public and restrictions on certain avenues of research (for example, on access to and use of human embryos for research, or on the use of federal funds to derive new human embryonic stem cell lines), helping to propel greater use of such options as IPSCs for approaching some scientific questions. In addition to the development of new stem cell sources, examples include the identification of factors underlying immune rejection to improve transplant safety and efficacy; the creation of stem cell donor registries and networks to expand the availability of donor cells; and the incorporation of emerging technologies, such as genome editing, into stem cell developments, to generate new classes of therapies.

All five of the framework's imperatives are relevant to this evolution, which will continue as scientific possibilities and societal values change. The imperative to broaden participation in innovation informs efforts to expand who joins the science, technology, engineering, and mathematics (STEM) workforce and the expectation that technology developers will seek input from a wider range of users and affected communities. Taking responsibility reflects the recognition that many actors involved in the innovation system have opportunities to mitigate misalignments between an emerging technology and foundational ethical principles. This case example also illustrates the use of incentives and disincentives; the creation and dissemination of federal, state, and professional guidance; and the role of ongoing evaluation and oversight in helping to propel change and support a responsible innovation enterprise in health and medicine.

Several additional equity-relevant observations can be drawn from this case example on the evolution of stem cell transplantation, as described below.

[4] Changes to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules were issued in 2019 (84 FR 17858). For role of the NExTRAC, see also https://osp.od.nih.gov/policies/novel-and-exceptional-technology-and-research-advisory-committee-nextrac/ (accessed June 30, 2023).

Disparities exist in the medical conditions that are prioritized for research. Given its prevalence, sickle cell disease has garnered relatively lower funding compared with several diseases affecting primarily people with greater social power. Framework imperatives that can aid in addressing this disparity include broadening participation to empower a wider range of innovation stakeholders and aligning incentives to encourage equitable policies and decision making. As noted previously, the inclusion of diverse perspectives in decision making influences how research and innovation priorities are set, how clinical trials are designed, and which incentives and disincentives are used to shape behavior. For example, funding devoted to technological advances such as stem cell transplantation and gene therapy must be balanced against funding to enhance access to current medical care and appropriate pain management for people with conditions such as sickle cell disease. Such choices about prioritization are often made by legislators through agency appropriations and mandates and program priorities set by public and private funders, reflecting the values and choices of a society as well as the views of those stakeholders consulted in the priority-setting process. Historically marginalized or affected communities have often lacked power to influence budget choices. Patient advocacy groups also vary in size, budget, and advocacy capacity—features that pose challenges when such groups are lobbying for research to address individual rare diseases and diseases affecting historically underserved or marginalized populations.

Inequities in access to effective stem cell transplantation arise from the limited availability of diverse, human leukocyte antigen (HLA)-matched donor stem cells. Currently, genomics data and stem cells available for research and care are disproportionately derived from people of European descent**,** limiting access for those with other ancestries. Framework imperatives associated with addressing this concern include aligning incentives and sharpening ongoing, iterative oversight and evaluation. Incentives provided through funding or regulatory requirements could be used to encourage the collection and banking of more diverse cells. The role of financial incentives in encouraging stem cell donation could also be revisited to increase the probability that an appropriate HLA match for patients in need of a transplant can be identified. Both the sale of bone marrow and use of financial donation incentives are banned under the 1984 National Organ Transplant Act (NOTA), and the potential benefits and harms of incentivizing such donations would need to be further explored.

The history of public and private donor registries and stem cell banks is associated with differential access to stem cell–based treatments. The creation of networks of stem cell banks and registries and the establishment of standards and accrediting bodies have been positive developments in the field. However, information on and access to these resources are uneven. In umbilical cord blood banking, for example, fee-charging private banks are more heavily advertised and accessible to parents compared with free public banks, although private banks are subject to fewer standards and have been found to have lower overall cord blood quality. Framework imperatives associated with addressing this concern include crafting timely guidance, aligning incentives, and providing iterative oversight and evaluation in response to the evolution of the market for these resources.

Stem cell clinics that market unproven remedies have emerged, posing the potential for harm to patients in the absence of demonstrable benefit. Framework imperatives that can aid in addressing this concern include members of the innovation system taking responsibility for conducting high-quality and ethically aligned research that advances the understanding and use of stem cell treatments, along with responsibility for facilitating and enhancing patients' abilities to fairly evaluate the accuracy of claims. Stem cell clinics arose and expanded rapidly in the United States and around the world, highlighting the importance of timely guidance and oversight capacity from regulatory and professional bodies on responsible

standards and practices in this field, as well as the importance of revisiting national and cross-border governance approaches in response to developments in such fast-moving fields.

A FRAMEWORK FOR GOVERNANCE OF INNOVATION: APPLYING THE IMPERATIVES TO ENHANCE THE INNOVATION SYSTEM IN HEALTH AND MEDICINE

The governance framework proposed in this report enhances the alignment of emerging science, technology, and innovation in health and medicine with ethical principles by drawing on the five key imperatives described above throughout the innovation life cycle, as shown in Figure 4-1.

The five overarching imperatives are listed at the left of the figure. Drawing on these imperatives to inform the choices made throughout the life cycle of a technology is what enables the framework to produce the desired outcome—the meaningful incorporation of equity into the innovation system for emerging science and technology. To apply the framework, actors in the innovation system would look to the five imperatives for guidance on how to make more equitable decisions.

The central image in Figure 4-1 represents the simplified, conceptual innovation model described in Chapter 3. In this model, emerging science and technology pathways include the phases of conceiving of and embarking on an idea; researching, developing, and assembling a technology; evaluating performance for widespread use; accessing and using a technology; and learning from postmarket use. Choices are made during each phase that stimulate or impede how a technology continues toward the next phase. As depicted in the figure and described in more detail in Chapter 3, these choices encompass the receipt of

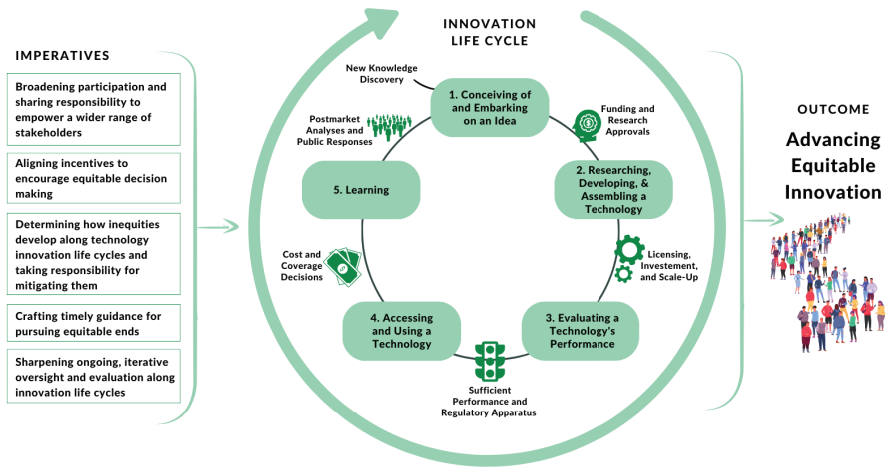

FIGURE 4-1 The proposed governance framework for aligning emerging science, technology, and innovation in health and medicine with ethical principles, emphasizing alignment with equity. The five imperatives (*left*) should be used to inform choices and actions taken during the technology innovation life cycle (*center*). Considering and embedding these imperatives supports the desired outcome of advancing equitable innovation (*right*).

funding and research approvals; identification, management, and licensing of intellectual property, and continued investment in as well as scale-up of research and development; determinations and approvals (where required) of sufficient performance to support widespread public availability; decisions affecting cost, insurance coverage, and other factors affecting the availability of the product; and the analysis of postmarket information, including public reactions and responses.

The left side of the figure represents the goal of aligning innovation with equity as defined in Chapter 2 and arising from guiding ethical principles of justice, fairness, and the common good. People are rarely represented directly in images of innovation. In emphasizing the advancement of equitable innovation, the framework also aims to recognize and incorporate the participation of humans as central to medical innovation and health.

The five imperatives are essential concepts in this framework. To apply the framework in practice, actors should pose the following types of questions during each innovation phase, enabling them to explore how each imperative can be incorporated into their work and helping them understand alignments and misalignments between their innovation and equity and opportunities for further action to support equity:

- Broadening participation: How are diverse groups brought into the innovation process and empowered to share responsibility at this stage of development?
- Aligning incentives: How are incentives at this stage aligned toward equity?
- Taking responsibility: How is responsibility for equity shared among stakeholders at this stage of development?
- Timely guidance: How are stakeholders empowered to offer guidance to each other about design choices and decision making at this stage of development?
- Sharpening oversight: What governance mechanisms can help foster equity during this phase of the innovation process?

The practical application of these questions to the phases of innovation is summarized in Table 4-1. The table identifies key leverage points and example choices made during each phase, provides examples of the types of questions that actors should consider during each phase to apply the five framework imperatives, and elaborates on how the eight dimensions of equity defined in Chapter 2 (Table 2-1) apply in aligning equity with technology development. While the table is not intended to capture every nuance of a complex ecosystem in emerging science and technology, it provides a guide to the overall system and to the ways in which interventions can nudge innovation toward equity.

ILLUSTRATING HOW THE FRAMEWORK CAN INFLUENCE THE INNOVATION ECOSYSTEM

This section explores how applying the governance framework described above to the phases of emerging science and technology development supports an innovation system better able to anticipate and address inequities. As a technology evolves from research insight to commercialization, an increasingly broad network of actors and institutions builds around it, bringing an increasingly complex array of motivations and requirements. While it may be desirable to limit inequities that are introduced or amplified along the way, preventing inequities in the early phases of innovation is likely to be more impactful than attempting to remedy them later on. On the other hand, the equity implications of an emerging technology are often undeveloped or unclear or cannot be fully anticipated at the early stages of

TABLE 4-1 Examples of Leverage Points and Choices, Questions Raised by the Framework Imperatives, and Applications of the Dimensions of Equity at Each Phase of the Innovation Life Cycle

Leverage Points and Choices	Framework Imperatives	Equity Dimensions
Conceiving of and Embarking on an Idea		
Leverage Points • Priority setting & research funding • Research approvals • Legislative incentives or prohibitions • Public & consumer expectations and pressures *Example Choices* • What research questions get asked and who gets to ask them • How the research is designed • What processes are involved in research approvals and funding	*Broadening participation; taking responsibility* • Who determines the research goals? • Who funds the research? • Who determines whether the research may proceed? *Aligning incentives; sharpening oversight* • Who stands to derive financial benefits from the ultimate research outcomes? Who incurs financial risk from undertaking the research? • Who stands to derive health benefits from the research outcomes? Who incurs risk of health harms from the research or its outcomes?	*Topical equity, innovator equity, input equity, value capture equity* • Decisions can have cascading effects on equity because they affect the areas of research and innovation pursued and influence subsequent stages of the life cycle. • The people who get to pose the questions and the ideas that receive support should reflect the diverse population of users. • Research goals and methods should mitigate biases, draw on a diverse range of expertise and perspectives, and incorporate input from the affected communities.
Researching, Developing, and Assembling a Technology		
Leverage Points • Research approvals and technology performance assessments • Intellectual property management • Investment choices • Recruitment for and participation in clinical trials *Example Choices* • How the research and development is carried out • How the intellectual property is managed and licensed • What is selected for further investment and development	*Broadening participation; taking responsibility* • How are the questions answered, and who gets credit? • Who decides whether the answer is right? • Who owns the answers? *Aligning incentives; sharpening oversight* • Who owns the answers? • Who incurs financial benefit or risk from undertaking the research? • Who incurs health benefits or harms from the research?	*Input equity, evaluation equity, value capture equity, contextual equity* • Developers make decisions on design, cost, speed, and complexity that can intersect with equity. • Research goals and methods should mitigate structural and other biases, draw on a diverse range of expertise and perspectives, and incorporate input from the affected communities. • The contributions of people and communities to the research and development should be recognized and valued. These contributions include research participation, bodily materials, and data. • Intellectual property should be identified and limited to ensure that technologies benefit and not harm affected communities.
Evaluating a Technology's Performance (for widespread use)		
Leverage Points • Technology performance assessments • Recruitment for and participation in clinical trials • Legislative incentives or prohibitions • Public & consumer expectations and pressures *Example Choices* • How sufficient product performance is assessed • What processes are used in decisions and approvals	*Broadening participation; taking responsibility* • Who evaluates the answer and who decides whether it is right? • What other impacts are anticipated, and how might these change in the future? *Aligning incentives; sharpening oversight* • How should benefits and risks be defined and measured? • How will the benefits and risks be distributed?	*Evaluation equity, input equity* • Decisions on the collection and analysis of performance data, including in which populations performance is evaluated, can affect equity. • Products should be evaluated in populations that are representative of the technology's anticipated future users. • Evaluation and approval processes should include representation from relevant populations and should draw guidance and input from a diverse range of expertise and perspectives.

TABLE 4-1 Continued

Leverage Points and Choices	Framework Imperatives	Equity Dimensions
Accessing and Using a Technology		
Leverage Points • Intellectual property management • Health care purchasing and coverage decisions • Product liability • Legislative incentives or prohibitions • Public & consumer expectations and pressures *Example Choices* • How price setting and marketing decisions are made • How access decisions (including insurance coverage) are made	*Broadening participation; taking responsibility; aligning incentives; sharpening oversight* • What mechanisms and data are used to make cost and coverage determinations? • Who will and will not have access to the benefits of the technology?	*Deployment equity, value capture equity, input equity* • Whether a group that would benefit from a technology can access it intersects with equity, including the effects of decisions on cost, coverage, and health care adoption. • Technologies should benefit a diverse population or populations traditionally experiencing injustices. Benefiting from a technology requires the ability to access it. • The value created from new technologies should be captured and distributed fairly. • Innovation implementation processes should include teams with diverse representation.
Learning from a Technology's Deployment		
Leverage Points • Technology performance assessments • Regulatory requirements • Product liability • Public & consumer expectations and pressures *Example Choices* • What postmarket assessments are conducted and what input is included • How the results are evaluated • How the results of such analyses support learning actions	*Broadening participation; taking responsibility* • What mechanisms are used to assess postmarket outcomes and public views? Who evaluates the answer? *Aligning incentives, sharpening oversight* • How should benefits and risks be defined and measured? • Has use of the technology raised additional ethical or social concerns?	*Evaluation equity, attention equity, value capture equity* • Equity can be affected by how postmarket data on a technology's performance are collected and used, how risks and benefits associated with its use are distributed, and whether and how action is taken on the results. • Postmarket analyses should collect information that can be used to identify additional impacts of the technology, such as the distribution of burdens and benefits. Analyses should include input from affected communities and consider the views and responses of consumers/members the public.

NOTE: At each innovation phase, timely guidance is also needed on practical strategies supporting action on identified equity considerations.

research and development, and it is important for later phases to incorporate strong evaluative mechanisms so these gaps can be recognized and addressed should they emerge.

As described elsewhere in this report, applying the governance framework to innovation requires culture change. All participants in the innovation ecosystem should acknowledge that inequity, injustice, or unfairness can arise during the development of a technology and be aware of the long history of inequities in health and medicine. Thus, all members of the system have a responsibility to be mindful that their choices could mitigate or exacerbate inequity; attention to equity should be considered a legitimate and essential element of responsible science, technology, and innovation. How to actualize this culture of awareness and define specific obligations that should fall on individual actors are complex matters that are explored further in the sections below.

Conceiving of and Embarking on an Idea

Scientific and technological innovation begins with an idea. Equity considerations most relevant to this phase often involve the culture and norms that guide research communities, structural and organizational policies, and portfolio priorities and decisions. As shown in Table 4-1, important choices include which research questions are asked and by whom, how research studies are designed, and what processes are involved in obtaining research approvals and funding.

Broadening Participation

The concepts of topical equity and innovator equity suggest that ideas in an innovation portfolio and the innovators who pursue these ideas should reflect diverse populations, including those that have traditionally been marginalized and underserved. Applying the framework's imperatives expands the social contract for science by identifying a broader range of actors engaged in innovation and taking steps to ensure that they are seen as equal partners. Diversifying the STEM pipeline can aid in this effort by empowering a broader range of researchers to ask diverse questions. As a result, the innovation system in health and medicine will be able to support research and development priorities identified not only by scientists and engineers but also by affected communities. Engagement will need to include traditionally marginalized and underserved communities and organizations that represent them, along with social scientists, humanities scholars, and other professionals who offer an understanding of the circumstances and constraints experienced by these communities, as well as a critical lens on how society and technology interact. To this end, researchers and research organizations may need to apply other imperatives of the framework, drawing on timely guidance on opportunities and responsibilities to better align their work with equity and strategies for translating these concepts into practice in their particular fields.

Some community organizations may not currently have the infrastructure and experience needed to identify and engage in research partnerships on topics that directly affect them. Funders can respond to this challenge not only by fostering partnerships but also by directly funding community organizations to build their organizational, scientific, and technological capacity to engage in innovation. For example, the Chan Zuckerberg Initiative is supporting advocacy organizations for rare diseases in becoming more successful at directing and incentivizing research in their disease areas (see also Chapter 3). Funders will need to apply the framework's imperatives in identifying when and how they can better foster such partnerships.

Taking Responsibility for Determining and Mitigating Inequities, Aligning Incentives, and Sharpening Oversight to Support Equitable Innovation

How a problem in health and medicine is studied has implications for how the problem is understood. Researchers customarily turn to the techniques with which they are familiar or those seen as most rigorous in their fields. Applying the framework to research design requires reflecting on the assumptions and values that underlie given research methodologies. In addition, a technical breakthrough often generates excitement and leads to new avenues of research, such as in genomics or machine learning. The availability of new tools can also trigger new funding resources, which further shape ideas about which problems to tackle and how urgent they are. The rise of CRISPR-based genome editing and its potential to address genetic diseases, for example, made the problem of sickle cell disease—which

affects approximately 100,000 Americans[5]—more urgent because it opened new avenues to address it. The development of CRISPR-based tools, arising from basic discoveries in bacteria, also illustrates how the potential impacts of subsequent human applications could be recognized, leading to multiple calls for ethical, social, and governance guidance on the technology's uses and limits (summarized further in report such as NASEM [2017]). Early-stage studies will not always provide the ability to anticipate such downstream implications.

Applying the framework requires researchers, research institutions, and funders of emerging science and technology to play roles in aligning their work with equity. Consistent with this report's call for culture change, researchers and developers should be mindful of the intersection of their proposed designs with the aspects of equity described in Chapter 2. Potential impacts on equity should be considered when the research question is posed and the research approach is designed. For example, will the findings draw on or apply to only a specific group (for example, having differential effects by biological sex because of the specific genetic material used, or not being usable by people with visual impairment)? Researchers can ask themselves whether decisions made in the design and conduct of their proposed study have equity implications; the answer to this question could be no, but the intent is to stimulate reflection, awareness, and dialogue. Research institutions and funders can ask themselves whether their cultures and organizational policies support success by a diverse innovation workforce. And funders can ask themselves whether they have considered equity in constructing the portfolio of areas and questions to fund.

Government agencies play an important role in generating the foundations of medical innovation because research funding is dominated by public sources. Philanthropic and private funding also provide valuable research support, and these funders can be leaders in catalyzing emerging or underrecognized areas of research. Some funders and institutions already take steps to recognize equity and other ethical or social considerations when setting program directions. For example, the newly established Advanced Research Projects Agency for Health (ARPA-H) has extended the Heilmeier Catechism traditionally used by the Defense Advanced Research Projects Agency (DARPA) when evaluating programs to include two new criteria: "To ensure equitable access for all people, how will cost, accessibility, and user experience be addressed?" and "How might this program be misperceived or misused (and how can we prevent that from happening)?"[6]

Some funders have also begun to incorporate the expertise of underserved populations in decision making. NIH, for example, convenes a Tribal Advisory Committee[7] to help ensure that Tribes and American Indian and Alaska Native people have meaningful input into NIH policies, programs, and priorities. Yet despite these efforts, equitable representation remains a challenge; a recent study found that women, for example, continue to have less influential roles than men on NIH study sections (Volerman et al., 2021). NIH and other funding agencies can continue and expand current efforts, or they could create similar forums for other underrepresented groups whose perspectives are crucial to areas of innovation, along with mechanisms for using their priorities to inform agency agendas. Similarly, universities and

[5] See Data & Statistics on Sickle Cell Disease at https://www.cdc.gov/ncbddd/sicklecell/data.html (accessed June 30, 2023).

[6] The Heilmeier Catechism comprises a set of questions developed by a former DARPA director and used by the agency's program managers when evaluating proposed projects. It includes questions on the project's objectives, risks, cost, and time; why it can be successful; and what difference its achievement will make (see https://www.darpa.mil/work-with-us/heilmeier-catechism; accessed May 23, 2023). The adapted list of ARPA-H questions used in evaluating new program pitches, including the two additional equity-relevant criteria, is found at https://arpa-h.gov/careers/program-managers (accessed May 23, 2023).

[7] See https://dpcpsi.nih.gov/thro/tac (accessed June 30, 2023).

companies could create community advisory committees to provide input on whether and how to invest in particular research areas.

The alignment of proposed research with equity can also be incorporated into research review processes, drawing on existing models such as those used in assessing human subjects research and data management plans. Whether by choice, policy guidance, executive order, or legislative mandate, research funders and institutions can require certain projects[8] to evaluate equity implications; provide feedback to investigators on how they might address identified equity considerations; and provide investigators with assistance from technical experts, social scientists and humanities scholars, and/or community experts on strategies for ensuring that such projects are designed equitably. Questions might include, for example, how a clinical research project considered the needs and priorities of affected communities in its focus and approach, and what steps can be taken to minimize the likelihood that inequities will arise during the phases of research and development. The history of institutional review boards (IRBs) suggests that once a particular type of review has been accepted as a best practice in responsible research, even those institutions that are not required to do so will adopt it (Babb, 2020). The development and dissemination of additional equity-relevant metrics or methods would also be needed to guide the evaluations of institutions, funders, investigators, and community organizations.

Illustrative Examples of Research Partnerships

There are at least two ways to center community knowledge, concerns, and priorities in research formulation and technological design. The first is by using deliberative democratic methods, where representative cross-sections of a population discuss problems and, working together, produce a priority list or short report describing their concerns (Ada Lovelace Institute, 2021; Phadke, 2013; Scharff et al., 2010). A second approach gathers information from leaders who are highly respected and well integrated into their communities (Barnhill-Dilling et al., 2020). In both methods, openness, humility, and respect are key, and researchers must be willing to accept knowledge offered by members of these communities, value the community's time, and commit to following the guidance provided, factors crucial to establishing community trust and participation (Brown, 2006; Kleinman et al., 2007). Effective and sustained collaborations are not easy to construct or maintain, and staff with technical, social science, and community expertise may be required to guide partnership development and serve as core members of a research team.

Initiatives are emerging across the country and the world that can serve as models. For example, research centers sponsored by the National Institute for Environmental Health Sciences, in consultation with the National Breast Cancer Coalition, pioneered a partnership model in which scientists and women with breast cancer collaborated on research priorities and design (Osuch et al., 2012). These collaborations enhanced trust because "patients felt that scientists saw them as more than just biological samples, data points, or people that needed to be educated or convinced" (Parthasarathy, 2021 p. 6). The collaborations also

[8] The committee's charge (Box 1-2 in Chapter 1) addresses emerging science and technology broadly in health and medicine and supports the importance of awareness and consideration of equity as one of the ethical principles guiding innovation. This does not mean that every institution and funder should require all individual investigators to explicitly assess all types of proposed research studies with respect to all aspects of equity. Such an exercise would quickly devolve into superficiality for fundamental knowledge discovery. Judgment and guiding criteria would be needed to identify which types of proposals require additional equity-focused scrutiny—for example, because proposed research will use certain types of patient-provided biological materials and data, conduct clinical trials, or have other salient characteristics.

changed research as scientists integrated patients' insights on prevention and treatment into choices about the research and technology to pursue. For example, women with breast cancer taught researchers investigating the impacts of environmental pollutants why they should conduct analyses by zip code rather than by county (McCormick et al., 2004). In another example, participants convinced scientists to assess low-level radiation exposure even though doing so required different measurement tools (McCormick et al., 2004; Parthasarathy, 2021). Members of communities also bring important knowledge about technology design and viability. Developers of a mobile app to improve cardiovascular health among the Black community, for example, discovered through community-based participatory research that the technology made incorrect assumptions about the accessibility of parks and sidewalks for exercise and the availability of fresh foods and vegetables (Cielito Robles et al., 2021).

Such programs help ensure high-quality science, and these partnerships can play roles across an institution's research enterprise, including by developing and disseminating metrics, tools, presentations, and playbooks that help ensure consideration of equity at the earliest stages of innovation. Other examples are provided by the Healthy Flint Research Coordinating Center (HFRCC) and Flint Center for Health Equity Solutions (FCHES), which were designed as equitable partnerships between residents and university researchers to identify needs, develop solutions, give appropriate credit to community members, create research efficiencies, and ensure ethical practices (see Box 4-1).

A cautionary example is provided by the engagement of an Arizona State University geneticist with the Havasupai tribe, in which practices that might be seen as efficient—reusing samples across studies—led members of the Havasupai to feel that their civil rights were not being respected and that the research reinforced a distorted understanding of their history. In 1989, tribe members approached a researcher to study the prevalence of diabetes among their population (Garrison et al., 2019). The researcher agreed to collect and analyze their DNA but did not inform them of a grant to study the tribe's genetic risk of schizophrenia. It has been widely reported that the researcher performed both analyses and accessed the tribe's medical records to enhance the quality of her work. The resulting publication drew conclusions about schizophrenia and inbreeding. The tribe sued the scientist and university after discovering that this topic had been investigated without their consent, feeling that they had inadvertently contributed to the production of harmful analyses about their community (Garrison, 2013; Garrison et al., 2019). While this narrative is not without controversy (Lewis, 2013), the broader lesson on the importance of thoughtful engagement, transparency, and shared decision making remains. The case, *Havasupai Tribe v. the Arizona Board of Regents*, was ultimately settled for $700,000 (Garrison et al., 2019; Harmon, 2010).

Researching, Developing, and Assembling a Technology

Choices in this phase reflect how research and technology are designed and tested; how value, including in the form of intellectual property, is identified, managed, and licensed; and what is selected for further investment and development. The framework imperatives introduce iterative governance and broaden partnerships and engagement in innovation, expanding who is involved in this phase and strengthening innovation by bringing diverse perspectives to bear on an area of emerging science and technology.

Broadening Participation

Once experts and interested parties have converged on a technology to develop and have received funding and research approvals, the challenge shifts to design and develop-

BOX 4-1

COMMUNITY AND ACADEMIC ENGAGEMENT IN FLINT, MICHIGAN

After the 2014 water crisis in Flint, Michigan (Lewis and Sadler, 2021; Peplow, 2018), researchers flocked to the city to help it cope with lead poisoning, Legionnaire's disease, and the vast number of pipes that had to be replaced. Despite the state government's switch in water supplies in 2015, a significant number of residents reported elevated blood lead levels, hair loss, depression, anxiety, and posttraumatic stress disorder (Dean, 2021). The lead-contaminated water also resulted in a 12 percent reduction in fertility rates and a 58 percent increase in fetal deaths (NPWF, 2020). But citizens were wary: As members of a low-income community with a majority of Black residents, they had been the subject of scientific inquiry before and felt observed, or that researchers had diminished their knowledge and concerns and appropriated their ideas (Parthasarathy, 2022). This perspective was validated during the water crisis when scientists initially dismissed the severity of the lead problem and a link between the Legionnaire's disease outbreak and the water supply (Pauli, 2019; Zahran et al., 2018).

The Healthy Flint Research Coordinating Center (HFRCC) was established in 2016 to ensure a coequal relationship among community organizations and academic institutions, minimize redundant research, and build community–academic partnerships. The center is a partnership between the National Center for African American Health Consciousness and the Community Ethics Review Board of Community Based Organization Partners, along with researchers from Michigan State University and the University of Michigan (HFRCC, 2022). Its primary role is to review research proposals, designs, and evaluations and approve research conducted in Flint to ensure that studies are relevant to the city's concerns and context while ensuring that research findings support as many people as possible. A key criterion in this review process is accounting for the economic, environmental, behavioral, and physical drivers of health. HFRCC studies must also be published in an open-access format to enable widespread access to their results.

The Flint Center for Health Equity Solutions (FCHES, 2022), funded by the National Institutes of Health (NIH), was also established among local and national partners to address community health equity challenges. Through the FCHES, for example, Flint residents raised concerns about high rates of asthma. Using geographic information system (GIS) data, researchers connected asthma rates to historical pollution from automobile factories, a finding that informed responses including deployment of mobile health units (Lewis and Sadler, 2021).

These two partnerships underscore the importance of involving community members in framing research questions and designs while respecting diverse community priorities.

ment. This has traditionally been the province of scientists, engineers, and their funders at both public and private organizations. The science and technology under development and its intended uses will necessarily inform who needs to be most actively involved. Funders such as NIH and the Patient-Centered Outcomes Research Institute (PCORI) provide guidance on the process of stakeholder engagement, but under the current system, innovation developers must generally think through which groups they expect to be impacted by their products and identify how to engage with them. Not all scientific and technical communities have the knowledge, infrastructure, and capacity to do this well, nor do all potential partner community organizations. Governance interventions, such as including grant requirements to craft and provide practical guidance and making flexible use of incentives such as supplemental funding or expedited review, can support the establishment and maintenance of

partnerships in applicable areas of technology development. Several examples of initiatives supporting community engagement in research and models for benefit sharing to value the contributions of research participants are highlighted in Box 4-2.

BOX 4-2 EXAMPLES OF INITIATIVES EMPHASIZING COMMUNITY PARTICIPATION AND BENEFIT SHARING

A number of ongoing initiatives focus on meaningfully incorporating members of affected communities and of underserved communities in research and development, and supporting the ability of such communities to engage effectively in the research system.

Selected examples from the Patient-Centered Outcomes Research Institute (PCORI) and National Institutes of Health (NIH) are described below. PCORI emphasizes clinical research that aligns with patient and community goals. The aim of its capacity development programs is to help communities increase their facility with and ability to participate across all phases of research supported by the institute. PCORI also seeks to achieve progress toward health. NIH, meanwhile, has been making increased efforts to ensure that research designed to address complex problems such as health disparities actively engages interested parties and incorporates community-based participatory research and capacity building.[a] Additional funders at the federal level (e.g., the National Science Foundation), state research funders (e.g., the California Health Care Foundation and Florida Bio-Medical Research Program), and private research funders (e.g., the American Cancer Society and American Heart Association) can draw on these models of community engagement and participatory research to formulate and tailor relevant approaches for the research and development they support. Examples and models include the following:

- Clinical Translation Science Awards (CTSA). This program includes a community engagement component as a core of its goals to accelerate bringing scientific discoveries to all people. The CTSA engagement infrastructure played a role during the COVID-19 pandemic though initiatives such as those addressing misinformation and promoting minority participation in COVID-19 clinical trials.[b]
- All of Us Initiative, with the aim of enrolling 1 million people from all backgrounds in an ambitious precision medicine initiative.[c] NIH's use of equitable benefit sharing and community control over genetic material used in the initiative represents one approach that has been proposed to mitigate concerns, particularly from Indigenous communities, about the uses and commodification of genetic data (Fox, 2020).
- AIM-AHEAD, established to enhance the participation of researchers and communities currently underrepresented in the development of artificial intelligence (AI)/machine learning (ML) models.[d]

The following examples illustrate how equity and benefit sharing can be integrated into the research conducted through private companies:

- LunaDNA, a public-benefit corporation that provides a platform for sharing of genomic and health data to advance biomedical discovery. LunaDNA uses a fractional-ownership model in which proceeds from the platform are distributed back to participants who shared their DNA for research.[e]
- Variant Bio, which focuses on studying digital sequence information and traits to advance pharmaceutical development. Its benefit-sharing pledge promises that it will donate a percentage of its revenue and proceeds to organizations that provide services or benefits to the partner communities that provided the genetic information, by means of a collective-interest model (Variant Bio, 2022).[f]

BOX 4-2 Continued

[a] See also https://www.nimhd.nih.gov/programs/extramural/community-based-participatory.html (accessed June 30, 2023).
[b] See https://ncats.nih.gov/ctsa/about and https://ncats.nih.gov/covid19-translational-approach/clinical-research (accessed June 30, 2023).
[c] See https://allofus.nih.gov (accessed June 30, 2023).
[d] See https://aim-ahead.net/ (accessed June 30, 2023).
[e] See https://www.lunadna.com/ (accessed June 30, 2023).
[f] See https://www.variantbio.com/ (accessed June 30, 2023).

Taking Responsibility for Determining and Mitigating Inequities, Aligning Incentives, and Sharpening Oversight to Support Equitable Innovation

How intellectual property is identified, managed, and licensed. The patent system is an important component of innovation governance. It provides an incentive to innovate, but also puts power in the hands of intellectual property holders to shape an area of science and technology, particularly if a patent involves a new tool at early stages in a field's development. Licensing fees and limits placed on a technology's uses by patent holders can also make it more difficult to build technologies that are affordable or that serve smaller markets, such as marginalized communities.

Patent and technology transfer systems can take steps to address equity without disturbing the right to intellectual property. These steps include assessment of patent "quality" and determinations about the categories of patentable subject matter, as well as issuing of narrower patents, steps that have been taken in other countries (Parthasarathy, 2017). Patent stakeholders in the U.S. system can explore similarities and differences in approaches taken by other countries, and how these policies have impacted innovation and equity (see Box 4-3).

For patents arising from public funding, the federal government also has the ability under the Bayh-Dole Act (35 USC §§ 200–212) to exercise "march-in" licensing rights if "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees." No funding agency has yet chosen to exercise these rights (Cook-Deegan et al., 2022), and NIH declined another such request in 2023, although the Department of Health and Human Services and Department of Commerce recently announced a review of march-in authority (HHS, 2023b). It has also been argued that under patent law (28 USC § 1498), the government could step in to distribute generic versions of a drug to combat high prices, an option that was discussed in the context of hepatitis C drugs (Brennan at al., 2016; see also Box 3-2 in Chapter 3), although it was not exercised.

It may be possible to broaden the range of actors involved in patenting and licensing conversations to help achieve input equity (Chapter 2), subject to applicable authorities and regulations. The U.S. Patent and Trademark Office (USPTO) has established programs, such as the Council for Inclusive Innovation, aimed at increasing the participation of underresourced

BOX 4-3 PATENT-LEVEL LEVERS USED IN OTHER COUNTRIES

The approach taken by the United States to the use of patent rights in innovation is not the only one possible. Some countries have taken further steps to use the patent system as a key element in achieving equity in innovation, passing laws aimed at ensuring that patents do not contravene the public interest, including compulsory licensing laws that allow the government to step in to force a patent holder to issue a nonexclusive license when public health is at stake, and exercising these provisions (Hilty and Liu, 2015; Parthasarathy, 2017). Some countries also incorporate equity into the rules and practices of their patent bureaucracies. On multiple occasions, for example, the Indian Patent Office has rejected patents on pharmaceuticals that it deems insufficiently "inventive" compared with previous technologies, thereby rejecting the practice of patent evergreening (Halliburton, 2017; Porecha, 2023). Meanwhile, the European Patent Office emphasizes "patent quality," limiting monopolies while issuing narrower patents that are more likely to hold up if they are challenged in the courts.

Many patent offices also seek to incorporate equity by engaging a wide variety of interested parties in analysis of whether the innovation and patent landscape is achieving social goals. For example, the European Patent Office regularly engages with marginalized communities, such as people with disabilities, through both formal opposition and appeals procedures and occasional meetings (Parthasarathy, 2017). In the early 2000s, it engaged in a comprehensive scenario-planning process that tackled public concerns about the growing number of patents and the negative impacts of patent-based monopolies on costs and access to health care (European Patent Office, 2007). This process included hundreds of interviews, including with patient advocates and civil society groups in the global South. The European Patent Office also encourages its patent examiners to consider the social and ethical impacts of their decisions so as to make them more sensitive about the consequences of their work (Parthasarathy, 2017).

These practices illustrate expanded approaches the United States could consider adopting to help support equitable innovation in health and medicine, as well as potential opportunities for further transnational discussions of innovation to compare goals, approaches, outcomes, and lessons learned.

inventors,[9] and in support of Executive Order 14036 ("Promoting Competition in the American Economy" 2021) has established collaborative initiatives with the U.S. Food and Drug Administration (FDA) on patenting, particularly in pharmaceuticals.[10] While it frequently convenes town hall meetings to understand and prepare for emerging areas of technology, participants usually include only prospective inventors, patent agents, and lawyers rather than members of affected communities who might speak to, for example, their concerns about implicit biases embedded in ML technologies that can limit utility. USPTO also convenes a Patent Public Advisory Committee to advise the director on "matters relating to policies, goals, performance, budget, and user fees" (35 USC § 5; 86 FR 99:28084–28085),[11]

[9] See https://www.uspto.gov/initiatives/equity/ci2 (accessed June 30, 2023).

[10] See https://www.uspto.gov/initiatives/fda-collaboration/what-are-uspto-fda-collaboration-initiatives (accessed June 30, 2023).

[11] See https://www.uspto.gov/about-us/organizational-offices/public-advisory-committees/patent-public-advisory-committee-ppac (accessed June 30, 2023). The Patent Public Advisory Committee was established under P.L 106–113 (1999).

although historically, this committee has been composed of the same types of stakeholders as town hall meetings and has not included civil society members. If USPTO were to take a more expansive approach to public engagement, including explicit attention to the concerns of marginalized communities, it might identify changes to administration and examination practices that could enhance the consideration and incorporation of equity. To further support this goal, a variety of other patent reforms have been proposed, the implications of which could be further explored (for example, see I-MAK's proposals for patent reform[12]).

Universities realize financial gain from patenting and licensing the intellectual property created by their researchers, and have created guidance in this area. To foster alignment with the governance imperatives in this report, research institutions could consider expanding their understanding of responsibilities and practices encompassed by the "Nine Points to Consider in Licensing University Technology" document (AUTM, 2007), particularly the application of point nine on provisions that address unmet needs.

Socially mindful technology licensing initiatives provide one model. An example is the Socially Responsible Licensing Program of the University of California, Berkeley, which aims to stimulate investment in products that bring benefits in developing countries, and to promote "affordability and accessibility of drugs, therapies, diagnostics, crops, and vaccines to the developing world by stimulating investment where it has been traditionally lacking under profit-motivated business models" (Mimura, 2006). A case example is the development of semisynthetic artemisinin, in which researchers and developers paid explicit attention to the roles of technology licensing and the needs of populations in countries in which malaria is prevalent (see Box 4-4).

Collaborations, such as public–private partnerships and product development partnerships, can also be instrumental in spurring translational research and sharing or reducing the risk involved in long-term, large-scale research and development investments. One example is BioMADE, an institute launched in 2021 with support from the U.S. Department of Defense's Manufacturing Innovation Institute program.[13] BioMADE is designed to speed the development of a substantial infrastructure for biotechnology-based manufacturing, a crucial support for the growing bioeconomy. At the request of the government, the successful BioMADE proposal included a section addressing ethical and social issues related to this area of biotechnology research and development, and the institute's website states: "A commitment to incorporating safety, security, sustainability, and social responsibility (4S) is part of the fabric of BioMADE. All technical and education and workforce development projects must include elements dedicated to relevant 4S topics….BioMADE will create new models and norms for 4S bioindustrial manufacturing."[14] In developing this concept, BioMADE adopted principles and values that include a commitment to meet or exceed existing standards for reducing risks of harm in the workplace or to the environment, welcoming people representing a diverse range of viewpoints into every stage of its activities, and collaborating with those working to diversify the pipeline for the biotechnology workforce. It also made a commitment to seeking ways to make its products and processes as useful as possible to society, with attention to equitable distribution of benefits and risks and to responsiveness to society's needs and values. BioMADE is still in its start-up phase, so it is too early to evaluate how this commitment affects the speed and efficiency of its efforts to promote innovation in manufacturing. It is notable, however, that the focus on 4S values reflects a joint decision by the U.S. Department of Defense and the private-sector companies involved in this collaboration.

[12] See https://www.i-mak.org/patent-reform/ (accessed June 30, 2023).
[13] See https://www.biomade.org/ (accessed June 30, 2023).
[14] See https://www.biomade.org/social-dimensions (accessed June 30, 2023).

BOX 4-4 EQUITY CONSIDERATIONS IN THE PRODUCTION OF ARTEMISININ

The development of semisynthetic artemisinin illustrates potential opportunities for acknowledging equity in the development of innovations aimed at addressing public health issues while also delivering economic and social benefits.

Malaria is a vector-borne parasitic disease; five species of pathogenic *Plasmodium* parasites carried by *Anopheles* mosquitoes cause severe illness and even death. Malaria affects around 250 million people and kills more than 600,000 people annually—mainly children under the age of 5 (WHO, 2022a). The disease occurs primarily on the African continent, where four countries—Nigeria, the Democratic Republic of the Congo, Tanzania, and Niger—account for almost 50 percent of all worldwide malaria deaths. However, a significant disease burden is recorded in nearly half of the global population, primarily in the tropical and subtropical regions of Latin America and Asia-Pacific (WHO, 2022a).

Where prevention and diagnosis efforts fall short, the best available treatment is artemisinin-based combination therapy to eliminate the *Plasmodium* parasite and prevent complications and mortality (WHO, 2022a). Artemisinin is derived from the wormwood plant *Artemisia Annua,* which is grown for clinical use in Vietnam, China, Kenya, Uganda, and Tanzania. However, the artemisinin content of that plant is only 0.1–1 percent, an amount that can be insufficient to meet global demand (Zhao et al., 2022). Furthermore, the plant is affected by growing season cycles and volatile prices (The New Humanitarian, 2009).

Researchers recognized that modifying yeast to produce artemisinin's chemical precursor, artemisinic acid, could provide an alternative manufacturing method to address supply chain shortages and increase access. Foundational work was conducted at the University of California, Berkeley, and through the start-up company Amryris, Inc. The synthetic biology used to recreate the artemisinin pathway in yeast also produced platform knowledge for Berkeley and Amyris on how to synthesize related chemicals with potential commercial applications, including biofuels (Asveld et al., 2019).

In 2004, the Bill & Melinda Gates Foundation provided funding to the nonprofit pharmaceutical company Institute for OneWorld Health and its partners Berkeley and Amyris to develop yeast-synthesized artemisinin for malaria treatment, aiming to meet patient need in 88 developing countries by increasing availability and lowering cost. Under its socially responsible technology licensing framework, Berkeley issued royalty-free licenses for malaria applications, and Amyris agreed to produce the molecule at cost. The Institute for OneWorld Health managed the project and established a public–private partnership with Sanofi-Aventis for at-cost scale-up, commercial production, and distribution (Mimura et al., 2011).

Artemisinin was produced successfully through this public–private product development partnership, offering an alternative to the agriculturally derived drug, although also raising the potential for economic disruption to farmers growing wormwood (Kaebnick and Gusmano, 2018). Currently, the price of plant-derived artemisinin has largely stabilized, and synthetically produced artemisinin has generally not been economically advantageous (Asveld et al., 2019; Westfall et al., 2012). Nevertheless, artemisinin provides an example of how social needs and benefits can inform such choices as selection of a research topic, technology transfer and licensing provisions, and commercial production and dissemination strategies for emerging science innovations.

Another example is ARPA-H,[15] a new agency in the Department of Health and Human Services that also promotes public–private and product-development partnerships. ARPA-H features a new operating and funding model that seeks to identify, develop, prototype, and commercialize high-risk, high-consequence strategies with the potential to transform health and medicine. Notably, from the very first step in advancing an idea for ARPA-H support, applicants are compelled to state explicitly the elements of equity and social justice that their project will address.

A collaborative effort is also under way among representatives of academic institutions and venture capital and law firms that has developed a model term sheet for the launch of a life science start-up and plans to release a full license agreement template (MIT, 2023). Although this effort is not focused on social benefit, it could similarly provide an opportunity to explore how this report's governance framework could be applied to start-up formation.[16] Other tools that could be explored as potential strategies for addressing these challenges include the use of patent pools and efforts to mitigate patent 'thickets" (Mattioli and Merges, 2017; Rai and Price, 2021; Sherkow, 2017).

What is selected for further investment and development. Research and development in emerging technology by for-profit companies is generally driven by market analyses, technological feasibility, and return-on-investment predictions. Such factors as licensing and royalties influence investment decisions insofar as they affect anticipated profits. Investors' assumptions about the downstream decisions that governments and private insurers will make on approval, prices, and coverage also factor into investment choices. Accounting for these factors, innovations with the lowest expected return on investment are most likely to be abandoned during the development process. However, government or others can "tip the scales" to incentivize the development (or at least disincentivize the early abandonment) of certain technologies by indirectly increasing the expected return on the investment. Patent protections, opportunities for expedited FDA review, guaranteed advance purchasing agreements, and expanded periods of postapproval market exclusivity can all serve as incentives for this purpose (see Box 4-5).

BOX 4-5 EXAMPLES OF THE FOOD AND DRUG ADMINISTRATION (FDA) MECHANISMS THAT CAN BE USED TO INCENTIVIZE MEDICAL PRODUCT DEVELOPMENT WITH IMPLICATIONS FOR EQUITY

The FDA has several mechanisms to incentivize particular kinds of innovation by speeding the review process and thus shortening the time to market. These mechanisms include designations of Priority Review, Breakthrough Therapy, Accelerated Approval, and Fast Track, and the issuance of Priority Review vouchers. Some evidence suggests that such designations can successfully speed the time to market without compromising quality or safety (Chandra et al., 2022), although definitive proof of this statement depends on confirmatory postapproval trials, not all of which are completed in a timely manner (Mahase, 2021).

[15] See https://arpa-h.gov/ (accessed June 30, 2023).

[16] See https://tlo.mit.edu/resources/news-events/representative-term-sheet-launching-life-science-startups (accessed June 30, 2023).

BOX 4-5 Continued

Priority Review: The FDA takes action on an application within 6 months on the basis that, if approved, the product would bring significant improvements compared with standard applications as demonstrated by increased effectiveness, reduction of a treatment-limiting drug reaction, better patient compliance, or evidence of safety and effectiveness in a new subpopulation.[a] Several of these criteria align with considerations of equity, as products thus designated address such issues as poor patient compliance due to limited time and resources or limited effectiveness due to a subpopulation characteristic, such as certain comorbidities.

Breakthrough Therapy designation: This designation expedites review of drugs that may demonstrate substantial improvement over available therapy.[b] Where existing therapies have shown variations in safety or effectiveness among subpopulations (e.g., between men and women, or among different ethnicities), existing FDA mechanisms may expedite approval of alternative formulations or dosages that address these inequities.

Accelerated Approval: This approval allows for the use of surrogate endpoints as justification for approving drugs for serious conditions to fill an unmet medical need.[c] The approval requires subsequent confirmation by clinical endpoints, which in turn requires attention to proper diversification of the populations studied in the postapproval period to ensure that any inequities in safety and/or efficacy are detected and addressed, and that any insights into variations in the underlying surrogate endpoints are incorporated into future studies.

Fast Track designation: Review of drugs for treating serious conditions and filling unmet medical needs is expedited by this designation.[d] The designation can be used in cases where existing therapies are inaccessible to subpopulations, whether because of cost, logistics, delivery systems, or other factors, thus satisfying the criterion of "unmet need."

"Priority review vouchers" (PRVs): The FDA offers these vouchers to developers of drugs with lower expected profitability, such as those used for rare pediatric diseases, tropical diseases, or some public health emergencies. The vouchers are highly valued by drug developers. They can be redeemed to speed up the review of another, more profitable drug; they can even be sold to other drug developers for this purpose. According to a Government Accountability Office (GAO) report, the value of getting a drug to market 4 months earlier than normal ranged from $67 million to $350 million, and while studies have not documented that this voucher program has affected drug development generally, "all seven drug sponsors GAO spoke with stated that PRVs were a factor in drug development decisions—six sponsors said they were one of a number of factors, while one sponsor said they were pivotal in its development of a drug" (GAO, 2020). Creating a PRV program aimed at rewarding sponsors that develop a new therapy that explicitly addresses an equity issue might provide an effective incentive. However, it should be noted that the FDA and others have expressed concern about the PRV program, including that it does not necessarily address serious and life-threatening conditions, does not guarantee a time to market or an affordable price for the therapeutic that earned the voucher, and may distort the FDA's own review priorities by pushing less essential but profitable drugs into faster review while those more needed to meet public health priorities wait their turn. Nonetheless, the program has garnered some use among drug developers, with 31 vouchers being issued between 2009 and 2019 (GAO, 2020).

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[a] https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review (accessed June 30, 2023).

[b] https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy (accessed June 30, 2023).

[c] https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval (accessed June 30, 2023).

[d] https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track (accessed June 30, 2023).

Another mechanism for incentivizing innovation in certain areas is the Orphan Drug Act (21 CFR Part 316), which incentivizes drug development to treat diseases that affect fewer than 200,000 people in the United States. Because drugs for diseases that affect relatively small populations are less lucrative than drugs with broader use, these diseases are unlikely to be targets of research and development efforts in the absence of incentives. Among other measures, the act extended patent exclusivity to 7 years and provided a tax credit for a portion of research and development expenses, making it more appealing for companies to invest in developing drugs that would qualify for these advantages. This approach involves trade-offs, and efforts to assess its effectiveness have found mixed results, leading some to call for reforms to better align its incentives with desired outcomes (Fiore, 2023). Nevertheless, the act is widely perceived as a success within the pharmaceutical industry, and orphan drugs now constitute about half of all FDA-approved drugs (Cavazzoni, 2022).

Beyond the initial decision of whether and how much to invest in a technology or company, there are many points at which investors or companies can choose to keep investing or not, but the core incentive remains largely the same: How big a payoff is expected? Therefore, applying the governance framework to influence such decisions will likely need to connect to ultimate financial returns. In this context, investors are highly attuned to signals from downstream payers; investors are unlikely to prioritize equity if an end payer is not willing to pay for it. Investing in a drug that disproportionately benefits a group that has historically received inequitable care will incur a loss if government or private payers do not view the drug as worth paying for. Price, access, and coverage concerns have been raised around emerging but expensive gene and drug therapies, including for sickle-cell disease and beta thalassemia, which benefit a relatively small number of patients, many of whom are in historically marginalized groups (Allen et al., 2023; DeMartino et al., 2021; Hiltzik et al., 2022; O'Donnell and Mathis, 2019; Thuret et al., 2022). This situation underscores the need for continued work on how incentives can be aligned across the full innovation life cycle to meet the needs of multiple actors and users.

The diversity of the innovators, investors, and entrepreneurs who pursue emerging technology development is another factor to consider. Representation—or its lack—has been shown to influence what gets invented and patented. For example, one study found that fewer women than men held biomedical patents, but their patents were more likely to focus on women's health (Koning et al., 2021). It has also been reported that "demographically underrepresented students innovate at higher rates than majority students, but their novel contributions are discounted and less likely to earn them academic positions" (Hofstra et al., 2020, p. 9284). In 2019, only 1 percent of venture capital funding went to companies with Black founders, and 2.7 percent went to companies with all-female founders (Cooper et al., 2020). Investing in underrepresented entrepreneurs and in firms that serve untapped markets can not only help combat historical underinvestment but also bring financial gains for investors. Examples of such funds include Jumpstart Nova, IndieBio, VentureWell, Harlem Capital, Backstage Capital, Black Angel Tech Fund, Kapor Capital, and others.

Other investors emphasize opportunities to align profit with approaches that also consider environmental, social, and governance (ESG) practices and frameworks for engaging in responsible innovation[17] or for considering the roles of these factors in investment decisions.

[17] The term "responsible research and innovation (RRI) gained visibility in Europe through, for example, European Commission scientific and technological programs such as Horizon 2020. Various venture capital and investment firms also use approaches designated as or aligned with responsible innovation (for example, General Catalyst; https://www.generalcatalyst.com/mission; and Phoenix Court Group; https://www.businesswire.com/news/home/20220620005322/en/Phoenix-Court-Group-Introduces-500m-in-New-Funds-to-Support-Founders-From-Seed-to-the-Public-Markets-and-Beyond; accessed June 30, 2023).

These efforts can represent potential models for supporting and investing in emerging science innovations in ways that recognize the role of profit in innovation while aligning with the equity imperatives described in this report. In particular, limited partners (LPs) can influence the priorities of venture capitalists through the venture funds in which they chose to invest. Many LPs, especially those associated with nonprofits such as university endowments and foundations, are already exerting pressure on venture funds to prioritize technologies that support decarbonization in line with goals for mitigating climate change; these investors could similarly exert pressure on venture capitalists to elevate equity considerations. The development of criteria for rating venture capital portfolios on various dimensions of equity could provide a mechanism for increasing attention to this issue and facilitating equity audits by interested LPs.

Evaluating a Technology's Performance

Whether part of required approval processes (such as through the FDA) or as part of a company's development plans, the performance of health and medical technologies is evaluated in various ways before it sees widespread use.

Broadening Participation. Taking Responsibility for Determining and Mitigating Inequities, Aligning Incentives, and Sharpening Oversight to Support Equitable Innovation

Applying the imperatives of the framework at this stage involves asking how performance and outcomes are evaluated; in which subsets of anticipated users; whether there are biases or other issues in the data, metrics, and input considered in the evaluations; and whether the innovation appears to impact equity in positive or negative ways. One example of a failure to take these steps is the recognition during the COVID-19 pandemic that many pulse oximeters inaccurately assessed blood oxygen levels among people with darker (melanated) skin (see Box 2-1 in Chapter 2). This case demonstrates the importance of conditioning approval of a device on explicit attention to how well it would perform across the entire population of users. There have also been publicized cases of bias in AI-based and other data-derived clinical algorithms. For example, racial scaling factors have been found to produce biased outcomes in algorithms for measuring kidney function and assessing disability resulting from brain injuries (Oliveira, n.d.; Vyas et al., 2020). These cases increased recognition of the problems that can arise downstream when performance data include only a subset of a technology's future users.

Applying the framework means recognizing the potential for such inequities to arise and crafting guidance to address and mitigate them, processes that are already under way in some areas. Over the past few years, a number of efforts have been directed at ethical and equitable AI, including how to benchmark for the representativeness of data. The FDA has also advanced efforts to enhance demographic diversity in participation in and the data obtained from clinical trials,[18] and recently announced plans for new requirements for late-stage clinical trials (Kozlov, 2023). Researchers are developing expanded measures for evaluating inclusion and diversity in trials, including by gender, race, ethnicity, and age (Varma et al., 2023). Companies that develop tools for clinical research can work to ensure that such tools advance equity- and inclusion-oriented objectives in a variety of ways, such as by ensuring

[18] See, for example, https://www.fda.gov/consumers/minority-health-and-health-equity/enhance-equity-initiative (accessed June 30, 2023).

that content is accessible and understandable to as many potential participants as possible. For example, multiple types of media (e.g., explanatory videos) can be used in addition to traditional text consent forms while adding cultural context to broaden access and inclusion.

For products that undergo premarket review, such as new drugs and some medical devices, current regulatory reviews focus largely on assessing safety and efficacy, although these are not the only considerations. In the case of drugs for HIV/AIDS, for example, advocacy from affected communities and others highlighting the urgency of the health need led to changes designed to expedite drug performance assessment, commercialization, and patient access (see Box 4-6).

The FDA can take other approaches as well, such as considering benefit implications for subpopulations. For example, if a medical product benefits many but has limited benefit (or entails extra risks) for a subpopulation, the agency often provides guidance through labeling or "dear doctor" letters about avoiding use by those at added risk or drawing attention to populations that might benefit but have been overlooked. Drawing on the framework, enhancements to the methods, mandates, and consistency with which products are assessed for equity-relevant factors could be considered. Any such changes would likely require further and more detailed analysis of potential advantages and costs, and could in some cases require legislative changes. For example, current reviews for safety and efficacy could be expanded to include effectiveness measures that could be used to explore predicted effectiveness within various subpopulations or the predicted distribution of product use postapproval to inform decisions on the need for and makeup of potential postmarket studies. Or the reviews could be expanded to include input on a wider range of ethical and social considerations beyond safety and efficacy or to include a broader array of input from members of the public or affected and underserved communities.

BOX 4-6 DEVELOPMENT OF DRUG THERAPIES FOR HIV/AIDS

The history of clinical trials for therapies for HIV/AIDS reflects the action of community members in changing clinical trial practices and governance. By the time the AIDS epidemic emerged in the 1980s, the double-blind, placebo controlled, randomized approach had become the gold standard for testing new pharmaceuticals to determine whether they were safe and effective. An emphasis of this accepted experimental approach was on minimizing physical harm to trial participants and maximizing the generation of statistically significant results. Given the severity of the health crisis posed by AIDS, however, activists saw the risk calculation differently and posited that faster access to new treatments (even if unproven and risky) was a better alternative than dying (Epstein, 1998). This debate led researchers and agencies to support greater variation in clinical trial protocols in response to urgent needs for life-saving technologies (Epstein, 1995; Haire et al., 2012), and the FDA developed new rules permitting expedited review and access to new drugs under emergency conditions (Grossman, 2016; IOM, 1991).

Accessing and Using a Technology

Even if a technology is shown to perform well and is approved for use, there is no guarantee that it will reach and benefit all potential users. Many factors affect who will and will not have access to a technology, including where and to whom it is made available, how much it costs and who pays that cost, the process for gaining access to it, and the requirements for using it.

Broadening Participation. Taking Responsibility for Determining and Mitigating Inequities, Aligning Incentives, and Sharpening Oversight to Support Equitable Innovation

A variety of factors can create barriers to equitable access to and use of a technology. For example, many technologies used in medical settings—even seemingly simple ones such as the scale—were not designed with consideration for the needs of people with disabilities, thus limiting these people's access to care and exacerbating the discrimination they experience (Iezzoni et al., 2021). Even when technologies are effective, they may be so expensive that people with limited incomes cannot afford them. Hepatitis C, for example, affects approximately 5 million people nationwide, 20 percent of whom will develop severe complications that require medication, hospitalization, and liver transplant. In recent years, the FDA has approved a handful of new drugs for hepatits C (Trooskin et al., 2015), but the limited number of available treatments enables companies to charge prices on the order of $84,000 to $95,000 for a 12-week regimen, limiting the use of the drugs (Henry, 2018) (see also Box 3-2 in Chapter 2). Another example is the newest drug treatments for obesity, originally developed for type 2 diabetes but having shown benefit for people trying to lose weight (Jastreboff et al., 2022). When prescribed for obesity alone, this is often considered an off-label use and is usually not covered by insurance. Even if the drugs are approved specifically for obesity, a major insurer—Medicare—will be precluded from coverage, as it is not allowed to pay for weight loss medications (McGinley and Bernstein, 2022). Obesity is most prevalent among lower-income populations, who are least able to afford paying out of pocket for such expensive drugs (Anekwe et al., 2020). Using the power of the government to ensure coverage of these drugs to treat obesity could be viewed as a step toward more equitable access to this class of drugs, although a more detailed analysis of benefits, costs, and trade-offs would be required.

The Open Insulin Foundation is one example of an initiative exploring new models and opportunities for reducing costs of and improving access to health technologies and for bringing production closer to a technology's end users. In the Open Insulin project, technical experts and people with diabetes work together to understand needs and develop local sources of safe, affordable, and high-quality insulin (see Box 4-7).

Expanding the incorporation of equity metrics in heath technology assessment. The price of a technology and how it will be made available can be influenced by actors including the companies that sell the technologies, the health care organizations that deliver them to patients, and the government and private insurers that determine coverage and reimbursement rates. These actors approach health technology assessment in their own ways, some using formal frameworks and others using looser, unstructured methods. One commonality, however, is that none of them currently have strong incentives or governance mechanisms to establish and use equity-focused metrics in these assessments and decisions.

BOX 4-7 THE OPEN INSULIN FOUNDATION

The Open Insulin Foundation, a team of biohackers from around the world, seeks to increase the accessibility of insulin through a small-scale, community-oriented model. This nonprofit organization works to make it possible for communities to have local, accessible sources of high-quality and affordable insulin. It is currently engineering microorganisms and protocols to manufacture rapid-acting (lispro) and long-acting (glargine) insulin. Additionally, in response to the current high costs of the equipment needed to produce insulin, the Open Insulin Foundation has a goal of developing affordable equipment that is sustainable and efficient.

The foundation is currently navigating regulatory pathways at the federal and local levels to produce insulin in a safe and cost-effective manner. By limiting manufacturing to the state or local level, the organization is exploring ways to reduce the costs of regulatory compliance without compromising the safety of production. The foundation places an emphasis on keeping production means accessible to the public by making its work open source, a principle it applies to the availability of engineered microbes and expression and purification protocols. Additionally, the foundation plans to publish a guide for others seeking to produce and distribute biomedicines so as to encourage additional research, increase accessibility, and spur market competition.

SOURCE: Open Insulin Foundation, 2022.

Health care organizations and payers could incorporate equity considerations into health technology assessments to inform purchasing decisions or to support or require post-implementation surveillance that would illuminate impacts on equity as a basis for altering purchasing or coverage decisions. To take advantage of this opportunity may require incentives or requirements on the part of health care organizations or payers. Insurers' coverage decisions are subject to state and federal law, which offers one potential avenue for expanding analyses of ethical and equity implications as part of purchasing and coverage decisions. In addition, developing and using equity-focused metrics would require the collection and use of relevant data. Accordingly, a coordinated framework must consider what, when, and how data are collected, analyzed, and used to advance equity.

Organizations that play outsize roles in the overall health care ecosystem also have an opportunity to lead the way in advancing equity. For example, the Veterans Health Administration (VHA) is the largest integrated health care network in the United States, serving 9 million veterans each year at 1,255 health care facilities.[19] Processes or requirements implemented by the VHA with regard to ensuring equity in access to health technology not only impact technology access and use within the VHA network but also can have ripple effects throughout health care more broadly by influencing how companies design and deploy technologies. With its extensive data on those it serves, the VHA is also well positioned to study technology impacts and gaps, as well as to experiment with approaches to improving equity in technology design, performance evaluation, and deployment. Another example is the Centers for Medicare & Medicaid Services (CMS). As the single largest payer

[19] See https://www.va.gov/health/aboutvha.asp (accessed June 30, 2023).

for health care in the United States through its Medicare, Medicaid, and Children's Health Insurance Plan (CHIP) programs, CMS has significant influence on the health care system. Its coverage decisions have broad implications for who can benefit from health innovations, how much the innovations cost, and the processes for gaining access to them. With the recent launch of its Framework for Health Equity 2022–2023, CMS established five priorities for advancing its infrastructure for equity-related assessment, fostering structural change, and ensuring equitable access to its services and coverage, positioning the agency to pave the way for the advancement of equity principles (CMS, 2023). The CMS Innovation Center has also announced that it is exploring a new model for expanding access to certain types of very high-cost therapies (the Cell and Gene Therapy Access Model, in which CMS would help state Medicaid agencies coordinate agreements with manufacturers) (HHS, 2023a).

Expanding global access. The World Health Organization's messenger RNA (mRNA) vaccine technology transfer hub, which aims to expand mRNA vaccine production capabilities in developing countries (Box 4-8), provides yet another model for advancing equity and improving access by bringing production of a technology closer to the people who need it.

BOX 4-8

EXPANDING GLOBAL ACCESS TO EMERGING TECHNOLOGIES: THE WORLD HEALTH ORGANIZATION'S (WHO'S) mRNA HUB

In June 2021, WHO (WHO, 2022b)[a] announced the launch of a vaccine technology transfer hub as part of an effort to increase access to emerging vaccine innovations in developing countries. The aim of the vaccine technology hub is to increase the ability of low- and middle-income countries to generate mRNA vaccines by serving as a center of excellence and training. The hub will collaborate with a network of technology receivers (spokes) in low- and middle-income countries from its location at Afrigen in Cape Town, South Africa.

With a goal of providing countries with the operating procedures and technical know-how required to produce mRNA vaccines at scale and in accordance with international standards, in February 2022 WHO announced which African countries would be the first to receive the mRNA vaccine production technology. At the time of the announcement at the European Union-African Union summit that Egypt, Kenya, Nigeria, Senegal, South Africa, and Tunisia would be the first African countries to receive the technology, more than 20 countries had requested access to the hub's technology transfer (Roelf and Winning, 2022).

Although the WHO mRNA technology transfer hub is currently aimed at the COVID-19 global emergency, it has the potential to eventually increase production capacity for other vaccines and products, helping low- and middle-income countries to address their top health concerns. As observed by South African President Cyril Ramaphosa, "The lack of a market for vaccines produced in Africa is something that should be concerning to all of us" (Roelf and Winning, 2022, para. 8). This WHO effort is one example of a move toward closing gaps and facilitating equitable technology innovation globally.

[a] See also WHO mRNA technology transfer hub; https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub (accessed June 30, 2023).

Learning from a Technology's Deployment

An important imperative guiding the governance framework is to sharpen iterative oversight and evaluation along innovation life cycles. Applying this imperative requires collecting relevant information after a technology has been deployed and using it to learn and change. This process is similar to the "learn" phase of the design, build, test, learn (DBTL) cycle commonly used in engineering disciplines. In the life sciences, the DBTL cycle has been embraced in such fields as synthetic biology. The emphasis is on learning from prior attempts to improve subsequent designs and create more effective or efficient methods and outcomes (Lawson et al., 2019; NASEM, 2018).

Broadening Participation. Taking Responsibility for Determining and Mitigating Inequities, Aligning Incentives, and Sharpening Oversight to Support Equitable Innovation

Several existing mechanisms facilitate postmarket data generation and use in the context of health innovations. For some technologies, there are regulatory requirements to evaluate performance in the postmarket context. Payers also may condition reimbursement or payment for medical technologies on the generation of follow-up data, which often helps them determine which treatment options are most effective in a real-world context. Companies engaged in health care delivery may be incentivized to participate in postmarket performance evaluation to the extent that they depend on payer reimbursement that is conditioned on such evaluation. Systems used for collecting postmarket data include registries, electronic health record (EHR) systems and case report forms, patient-reported outcome surveys, claims records, and public health data from government sources, among others. For example, the importance of ongoing postmarket analyses and audits of AI/ML-based tools is increasingly being recognized (see also Box 3-4 in Chapter 3 for a case study of AI/ML technologies in health care).

While most existing mechanisms are geared toward assessing the safety and efficacy of technologies, there are also opportunities to identify additional impacts of a technology, such as the distribution of burdens and benefits, as well as how the technology fits into the overall delivery of care. A useful framework for this purpose is the concept of a learning health system, advanced by the National Academies and others and supported by agencies such as the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ, 2019) (see also IOM, 2007; NASEM, 2016). As articulated at a 2006 Institute of Medicine workshop, a learning health care system is "designed to generate and apply the best evidence for the collaborative health care choices of each patient and provider; to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety, and value in health care" (IOM, 2007, p. ix). Accomplishing these goals requires an iterative process that includes input from affected communities and considers the views and responses of consumers or members of the public in order to translate research to practice more effectively and achieve better outcomes and better value.

Learning from a technology's deployment can influence both how that technology is used and how future ones are developed. The pregnancy drug Makena provides an example of the former (Box 4-9) and the MakerNurse initiative provides an example of the latter (Box 4-10). Fostering participation by nurse innovators enables the practical experiences and lessons from real-world health care practice to be further incorporated into the innovation life cycle, thereby informing new directions for research and innovation. It also helps broaden who becomes part of the innovation workforce.

BOX 4-9

EQUITY CONSIDERATIONS DURING THE POSTMARKET PHASE: MAKENA

Equity considerations can arise during the postmarket phase of a health technology. Discussions on whether to remove Makena from or keep it in the market reflect arguments that arose after the drug had been approved by the Food and Drug Administration (FDA) through a fast-track process and was on the market for several years.

Makena is a drug (hydroxyprogesterone caproate injection) approved by the FDA in 2011 "to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth" (FDA, 2011). The drug was granted accelerated approval based on a clinical trial conducted in 2003, in which it appeared to reduce the risk of recurrent preterm birth. A larger confirmatory trial conducted in 2019, however, showed no effect from the use of Makena compared with a placebo. In the same year, the FDA began efforts to withdraw Makena from the market after the vote of an expert advisory panel.

Arguments for and against the drug have both been rooted in health equity concerns. Covis Pharma, the company that owns the patent for Makena, argued that removing Makena would harm Black women because they disproportionately face higher rates of preterm birth. Because the drug does not show clear clinical benefit, however, others have argued that prescribing a treatment with little evidence to support its use could subject these women to exacerbated future health risks and increased financial costs, and have debated whether keeping it on the market could widen racial health disparities (Castronuovo, 2022; Cha, 2022). Removal of the drug was delayed because of the COVID-19 pandemic, but it was voluntarily removed from the U.S. market in March 2023 (Perrone and AP, 2023). The FDA issued its final decision to withdraw approval of Makena in April 2023 (FDA, 2023).

LEVERAGE POINTS FOR INFLUENCING THE SYSTEM TO IMPLEMENT THE FRAMEWORK

As the examples presented throughout this chapter illustrate, there are multiple opportunities to take action at every phase of the innovation life cycle to align emerging science, technology, and innovation in health and medicine with equity goals. Governance levers represent tools or capabilities that can be used to implement change in the system, and thus present opportunities for reimagining or revising the incentives and disincentives that affect the choices and behaviors of those who take part in innovation. Determining the points at which changes could be implemented, which players and actions should be incentivized, and for which purposes requires making choices about priorities, costs, benefits, and potential trade-offs. Identifying these priorities and weighing these trade-offs will require ongoing horizon scanning and evaluation to understand where populations are currently underserved and what impacts result.

BOX 4-10

UNLOCKING NURSING KNOWLEDGE TO DEVELOP FRONT-LINE MEDICAL INNOVATIONS

The 4.2 million registered nurses in the United States represent the nation's largest health care profession and are the primary providers of hospital patient care as well as long-term care (AACN, 2022). Trained to be versatile, adaptable problem solvers, nurses are on the front lines in most care settings, from private practices and public health agencies to the military, clinical trials, and outpatient clinics (AACN, 2022). These attributes make nurses an undertapped source for medical innovation.

MakerNurse, a subsidiary of MakerHealth, was established in 2013 to identify, incubate, and scale nurse-led innovations, tools, and resources in U.S. hospitals (UTMB Health, 2022). MakerNurse has incubated such innovations as catheter-compatible diapers for newborns and shower heads embedded within a PVC shell to facilitate irrigation of burn patients' wounds (Geere, 2016). The organization also established an incubator program at the University of Texas Medical Branch for health professionals to design, build, and prototype medical innovations (UTMB Health, 2022).

While MakerNurse is still in an early phase, its approach to empowering people on the front lines of care to develop technological innovations that address gaps and needs encountered in their work and to incorporate their end-user priorities from the prototyping stage onward is promising. This approach may help stimulate new ideas, strengthen opportunities for the needs and priorities of a technology's intended user community to serve as a basis for innovation, and improve care quality and patient outcomes.

Incentives Can Represent Both Pushes and Pulls

The forces that influence actors' decisions along innovation life cycles include both pushes and pulls.

Push incentives propel actors toward certain choices. Examples include a grant proposal requirement that clinical or translational investigators explain how their research design anticipates and addresses an equity issue, or how it values the contributions of participating patients and communities; enforcement of requirements for diversity in clinical trials to increase the chances that an approved product will be widely useful; and increased use and enforcement of Phase IV postapproval trials to confirm safety and efficacy across the broad population of users. Push incentives tend to yield more immediate short-term results relative to pull incentives, but risk overly centralizing power in the hands of those with the pushing power, such as funders. They can also risk imposing unrealistic demands and costs on entities that are unready, unable, or unwilling to change.

Pull incentives make a certain action more enticing. Examples include offering a grant specifically for work that imagines a more equitable version of an existing therapy or delivery system; opportunities for expedited FDA review; policies such as the Orphan Drug Act, which make certain areas of research and development more enticing by enhancing the rewards for success; and the issuance of priority review vouchers for a profitable product in exchange for focusing attention on products for underserved populations. Pull incentives are more about weighting aspects of the market and letting the market respond. They may

be more politically or culturally palatable than push incentives in some contexts, although they also risk expending funds without necessarily achieving outcomes that meet the need.

Combining push and pull incentives can address the different pressures to which various stakeholders best respond and help create a comprehensive system that invites innovative ways to address inequities and inspires desired outcomes. The 3P project provides an example of push and pull levers aimed at an equity outcome—in this case, the goal of accelerating innovation toward an affordable, accessible 1-month tuberculosis regimen (MSF, 2016).

In general, interventions supporting equity and mitigating inequities in early phases of emerging science and technology development—for example, by diversifying the STEM workforce or enhancing substantive research partnerships with affected communities—are likely to be more impactful than attempts to mitigate inequities that are introduced later and amplified along the way. However, the equity implications associated with an emerging technology may only become apparent or may change in nature in light of further development or widespread use. Push and pull incentives can also have unintended consequences as stakeholders attempt to use them to their advantage, a circumstance that has arisen, for example, with the Orphan Drug Act (Daniel et al., 2016; Tribble and Lupkin, 2017). Since it is nearly impossible to create a perfect system, ongoing, iterative governance and evaluation are necessary to ensure that the outcomes of interventions targeted at advancing equitable innovation continue to align with intended goals.

Leverage Points in the System Can Be Used to Implement Change

Examples of leverage points that provide key opportunities to incentivize or disincentivize changes to the innovation system in health and medicine are summarized below. This is not an exhaustive list, and not all levers will be appropriate to all areas of technology, types of actors, or points within the system. Choosing to apply some levers may require policy and regulatory changes or new funding, while essential elements may already in place for others such that they require only community or political will. Choices about which levers to apply and when and how to apply them may also have significant budgetary and workforce implications.

Leverage Point: Priority Setting and Research Funding.

Significant research support is provided by government agencies, with additional support being provided by philanthropic and private funders. Research funders influence the innovation system and its alignment with ethical principles, including equity, through such levers as

- issuing requests for proposals in an equity-aligned area, supporting increased research attention to a given topic, and decreasing uncertainty involved in making downstream investments in that area;
- supporting the generation and use of data relevant to identifying inequities and their sources;
- incorporating proposal requirements, checklists, or proposal review criteria relevant to equity;
- requiring and incorporating diverse perspectives on agency program teams, review panels, and funded research teams; and
- building capacity within community organizations to enable their participation in research agenda setting and research partnerships.

Leverage Point: Research Approvals and Technology Performance Assessments.

It is valuable to assess explicitly how a product will perform across the entire population of intended users. Regulatory agencies, research-conducting organizations, and health care organizations influence how clinical testing is conducted and what evidence is required before a product sees widespread use. For example, the FDA recently issued guidance for industry on increasing racial and ethnic diversity in clinical trials (FDA, 2022). Norms guiding professional conduct and best practices in a field can also be important. Potential levers include

- requirements that clinical testing meet minimum standards for geographic, racial, ethnic, and/or other types of study diversity and data representativeness;
- use of expedited regulatory reviews in targeted areas;
- expansion of current reviews for safety and efficacy to include effectiveness measures that reflect equity considerations, such as predicted distribution of use or predicted effectiveness within various subpopulations; and
- requirements to evaluate postmarket performance data on effectiveness and uses in order to identify inequities that may arise.

Leverage Point: Recruitment for and Participation in Clinical Trials.

Patient and consumer participation in research is a cornerstone of the advancement of science, technology, and innovation, and recruitment and retention is one of the most critical aspects of clinical trials. Patient advocacy and community organizations can play roles in fostering equity, including by funding and helping to design clinical trials and recruiting patients to participate. Half of all clinical trial sites underenroll, and 11 percent of sites fail to enroll a single patient.[20] Health care organizations can also play gatekeeping roles in approving research involving their patients, care teams, and EHR data. Levers include

- actions by patient and community groups to assist, support, or discourage members' participation in trials, including the power to pressure researchers and technology developers to design, conduct, and recruit in ways that are responsive to and aligned with community needs;
- conditions for clinical trial or site approvals requiring community advisory boards or community-based research locations that expand patient and community engagement or address such issues as data ownership and fair remuneration for those who contribute to the research; and
- support and/or requirements from funders for the involvement of patients and community groups in recruitment and participation for clinical trials and their engagement on community advisory boards.

Leverage Point: Management of Intellectual Property.

Governments set the terms and conditions for intellectual property rights, providing a powerful lever that influences the behavior of a range of actors in the innovation system, including private companies. Research-conducting organizations, such as universities, also exert influence through their technology transfer and licensing practices. Potential levers include

[20] See https://csdd.tufts.edu/ (accessed June 30, 2023).

- terms and conditions set by government, such as the nature, scope, and length of patent exclusivity;
- use of socially responsive licensing provisions aimed at addressing particular equity goals;
- exercise of government "march-in" rights to require additional licensing by a university or its licensee if "such action is necessary to alleviate health or safety needs" that are not being satisfied (35 U.S.C. § 203);[21] and
- exercise of government power under 28 U.S.C. § 1498 to enable the government to use any "invention described in and covered by a patent of the United States" without a license, provided that the use is "by or for the United States," and the patent holder is afforded "reasonable and entire compensation."

Leverage Point: Investment Choices.

Technology investors such as venture capital firms make decisions about which companies to invest in and how much to invest, and companies make choices about which products to develop, commercialize, and promote. Some funds focus on investing in historically underrepresented innovators, for example, but expected profit, including development cost, time to market, and expected return, is a key driver of investor and company choices. Two ways to influence decisions are to increase the expected profit or decrease the uncertainty involved. Actions or policies that achieve these outcomes can tip the scales toward investments that advance equity by making such investments more attractive from a financial standpoint. Potential levers include

- government policies that stimulate innovation in particular areas by offering favorable market advantages, such as opportunities for expedited FDA review, which shortens the time to market, or the Orphan Drug Act, which incentivizes the development of treatments for rare diseases;
- public or philanthropic investment in early-phase science in areas identified as equity promoting, such as the Gates Foundation's funding of nonprofit One World Health to develop yeast-synthesized artemisinin for treatment of malaria, thereby increasing the pipeline of innovations that might be commercialized and reducing downstream risk and uncertainty;
- the incorporation of equity implications of a health innovation into the criteria for assessing environmental, social, and governance factors for companies involved in its development, which could potentially improve a company's reputation and attract investors who value these factors; and
- the conduct of equity audits or other means of imposing pressure for companies to attend to equity concerns in their investment portfolios by large-scale investors such as managers of university endowments, foundations, and pension funds.

Leverage Point: Legislative Incentives or Prohibitions in Targeted Areas.

Through their legislative and policy-making authority, federal, state, and local governments can take action to incentivize or discourage choices in the innovation system. Examples of levers include

[21] While the mechanism for this lever exists, no federal agency has ever begun the process for using it and NIH has declined to initiate the process despite requests over the years (Rai and Cook-Deegan, 2017).

- legislation to incentivize the development of technologies that benefit certain groups—the Orphan Drug Act is a potential model, and although aimed at benefiting people with rare conditions, could inform use of a similar approach to incentivize investments that benefit people in other groups or situations, such as those who live in certain geographic areas, have certain racial or ethnic backgrounds, or have low incomes;
- legislation altering return on investment through direct grants, tax incentives, or nontax incentives (such as FDA priority review vouchers that incentivize the development of therapeutics for tropical diseases); and
- legislation that prohibits or restricts certain activities, such as the Genetic Information Nondiscrimination Act, which restricts use of personal genetic information by health insurance companies.

Leverage Point: Health Care Purchasing and Coverage Decisions.

Regulations and decisions about insurance coverage can send signals about potential market size and economic viability that affect investment decisions. Coverage decisions by insurers are subject to both state and federal law, and health care organizations also make decisions about the products they purchase and use. Potential levers include

- government requirements to, for example, cover drugs for certain underrepresented or underserved populations, thus increasing access to such drugs and incentivizing companies to invest in their development, although trade-offs with this approach could include increasing overall drug costs;
- public or private payer policies that enable companies to predict the price they will receive and a timeline for reimbursement;
- requests or requirements established by health care organizations, CMS, or private health insurers, such as requiring equity-focused health technology assessment as a prerequisite for purchasing, implementation, or coverage determinations (Culyer and Bombard, 2012);[22] and
- alternative pricing models aimed at reducing the high costs of certain new types of therapies, such as CAR-T and gene therapies—for example, a public–private collaboration could potentially amortize the costs of such therapies as savings emerge from prevention and disease mitigation, use outcomes-based contracts to provide payers with rebates in the event of lack of efficacy, or apply subscription-based arrangements to mitigate risk for both payers and manufacturers.

Leverage Point: Product Liability.

Federal and state liability rules and liability insurers also influence decisions in the health and medicine arena. Potential levers include

- liability rules that allow a product, even if approved for market use, to be subject to claims of design defect if it disproportionately fails to function in a particular population;
- policies or practices that reduce potential liability should a product lack efficacy or produce inequitable risks or side effects in a given population—for example,

[22] CMS does not currently conduct technology assessment of this type but could consider developing additional capacity to do so.

the National Vaccine Injury Compensation Program was established in the 1980s to provide compensation in rare cases of vaccine-caused injury, reducing risks and costs to industry and incentivizing vaccine development; and
- requirements from liability insurers to incorporate equity considerations and potential equity risks into technology assessments as a condition for coverage.

Leverage Point: Public and Consumer Expectations and Pressure.

In addition to patient advocacy organizations and organizations representing affected and historically marginalized communities, members of the broader public have expectations around the development, assessment, and use of emerging technologies and products, including what standards should be used to evaluate such issues as ethics, safety, efficacy, and privacy and the role of government in regulation. Issues of equity have also become more prominent in the public discourse within the past decade, including as a result of the disproportionate impact of COVID-19 on people by virtue of race and ethnicity, age, health status, residence, occupation, socioeconomic condition, or other contributing factors. Examples of levers include

- government calls for comments on proposed policy and regulatory decisions; and
- public opinion surveys on areas of science and technology that may influence researchers and policy makers, such as those informing recent reports on uses of AI, human enhancement, and animal-derived organs for transplant, although not focused on equity issues.[23]

CHAPTER CONCLUSIONS

Conclusion 4-1: A governance framework for aligning emerging science, technology, and innovation with core ethical principles that encompasses equity needs to incorporate five imperatives:
- *broadening participation and sharing responsibility to empower a wider range of stakeholders;*
- *aligning incentives to encourage equitable decision making;*
- *determining how inequities develop along technology innovation life cycles and taking responsibility for mitigating them;*
- *crafting timely guidance for pursuing equitable ends; and*
- *sharpening ongoing, iterative oversight and evaluation along innovation life cycles*

Conclusion 4-2: Through their choices and actions, all members of the innovation ecosystem have opportunities to implement practices that can enhance the alignment of technology development with ethical and equitable considerations. Similarly, levers that can incentivize such actions exist at every phase of the innovation life cycle. A systems-level approach is needed to implement equity-promoting practices and oversight. Steps toward advancing equity in science and technology innovation involve supplementing current governance approaches with a more robust commitment to practices that include (1) using funding, priority setting, and other levers to advance equity; (2) expanding and developing new equity-based

[23] See https://www.pewresearch.org/topic/science/science-issues/biotech/ and https://www.brookings.edu/series/public-opinion-surveys-on-ai-and-emerging-technologies/ (accessed June 30, 2023).

models of technology assessment; and (3) encouraging more robust engagement between innovators and the groups and communities that have been poorly served by the current innovation system.

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5

Reimagining the Innovation Life Cycle: Concrete Steps toward Equity

To achieve the vision described in the prior chapters, the committee advances six recommendations reflecting major areas in which efforts are needed to reorient the system of emerging science, technology, and innovation in health and medicine toward one that is equitable and responsive to the needs of a broader range of the system's users, and more capable of recognizing and addressing inequities as they arise.

INTRODUCTION TO THE RECOMMENDATIONS

Through the committee's six recommendations, this chapter provides further practical guidance on how to harness current opportunities to incorporate equity in emerging science, technology, and innovation in health and medicine through Executive Orders, agency plans, and extensive public and private efforts. The engagement of current and envisioned federal capacities and infrastructures, as described in Chapter 1, would be essential components of efforts to develop and act on the recommendation areas described below. Examples of key federal partners include but are not limited to

- the White House Steering Committee on Equity;
- the Interagency Working Group on Equitable Data;
- agency equity teams within agencies involved across the research, development, oversight, and delivery system in health and medicine;
- new and existing agencies and initiatives advancing innovation, such as the National Institutes of Health's (NIH's) Advanced Research Projects Agency for Health (ARPA-H), the National Science Foundation's (NSF's) Directorate for Technology, Innovation and Partnerships (TIPS), and the Federal Trade Commission's (FTC's) newly created Office of Technology (FTC, 2023); and
- federal offices currently focused on equity issues, often through designated offices such as the Department of Health and Human Services' Office of Civil Rights, the

Department of Veterans Affairs' (VA's) National Institute on Minority Health and Health Disparities, the Food and Drug Administration's (FDA's) Office of Minority Health and Health Equity, and the Office of Rural Health, among others.

Because many recent federal equity-focused efforts have arisen from Executive Orders, sustained commitments to addressing the principle of equity beyond the term of a given administration will be needed. Addressing the six recommendation areas detailed here will require a shared vision for what can and should be done to enhance the alignment of emerging science, technology, and innovation in health and medicine with equity in ways that bridge and integrate current efforts. It will also require making choices on how to shift the culture and ecosystem for emerging science, technology, and innovation and where to incorporate further governance levers, including policy-based and market-based incentives, to ensure that equity is taken seriously. These efforts will take sustained engagement from many parties and participants, necessitating both individual and collective actions to make progress toward this goal. Needed as well will be context-relevant capacity to measure, assess, monitor, and reevaluate how a particular scientific area, technology, or product intersects with equity as it proceeds through the innovation life cycle—capacity that currently is often fractured or insufficient. Addressing the recommendations holistically will thus require ongoing commitment, along with the investment of public and private resources of time, effort, and funding.

A summary of the report's six recommendations and their desired outcomes is provided in Table 5-1. These recommendations are necessarily high-level and cannot be fully separated from one another—they reflect interrelated needs, and their descriptions provide examples of some of these linkages. The sections that follow present the full text of each recommendation, along with implementation guidance that offers concrete suggestions for steps that various actors could take to implement the recommendation's aims.

TABLE 5-1 Summary of Recommendations

Recommendation	Actions	Desired Outcomes
Establish a National Vision and Priority Setting Body (Recommendation 1)	• Foster leadership and coordination to align innovation with ethical principles that include equity. • Convene a multistakeholder, cross-sectoral Equity in Biomedical Innovation Task Force. • Build public and professional awareness of the role of equity in emerging science, technology, and innovation in health and medicine.	• A U.S. innovation system that translates emerging science and technology into innovative applications while addressing the needs of the system's full range of users and reducing health inequities. • A set of initial priorities and goals for better aligning equity with innovation in health and medicine. New partnerships, synergies, and collaborations that increase the alignment of innovation with equity.
Reorient the Culture of Innovation (Recommendation 2)	• Incorporate equity as a principle in required ethics training and practice. • Where appropriate, require investigators to address equity associated with proposed work, including community engagement plans. • Incorporate ethics and equity more fully into technology licensing and investment practices, including through equity-focused provisions. • Require study designs and results to reflect a diverse range of anticipated postmarket users and contexts.	• Integration of ethical concerns, including stakeholder needs and values, into the formulation and conduct of research, decisions on funding and investments, and regulation and performance assessment. • Policies and practices that recognize the importance of aligning technology development and use with equity.

TABLE 5-1 Continued

Recommendation	Actions	Desired Outcomes
Incentivize Equity (Recommendation 3)	• Draw on available governance levers to incentivize stakeholders to incorporate ethics and equity-focused assessments more fully into the process of emerging science, technology, and innovation in health and medicine. • Based on the results of such assessments, incentivize stakeholders to make decisions and take action to address misalignments that arise.	• Governance of emerging science, technology, and innovation in health and medicine that addresses barriers to effective alignment with equity and supports actions and accountability to mitigate misalignments and inequities within and across institutions and actors.
Expand Participation in Innovation (Recommendation 4)	• Identify best practices and lessons for engaging with underserved and marginalized communities throughout the innovation life cycle. • Where relevant to the research, identify aims and methods and establish sustained, bidirectional partnerships with affected and traditionally underrepresented communities. • Incorporate policies and practices that recognize and value a community's contributions to and participation in research. • Support the capacity of underserved and marginalized communities to engage in innovation.	• Practices and tools for addressing decision making across the innovation life cycle. • Substantive participation in the innovation system from a wider range of users and communities, driven by enhanced trust, engagement, and capacity.
Develop Equity Science (Recommendation 5)	• Catalyze the development of equity science and the validation of qualitative and quantitative methods, metrics, and benchmarks. • Develop associated data collection and reporting systems and data quality standards. • Adopt resulting equity science methods, metrics, and benchmarks to assess and monitor technology implications.	• An expanded set of evidence-based methods, metrics, and benchmarks for assessing the alignment of emerging science, technology, and innovation with equity while supporting informed decision making and action throughout the technology life cycle.
Create and Promote Context-Relevant Equity Playbooks (Recommendation 6)	• Develop and disseminate specific guidance targeted to particular roles in the technology life cycle, types of inequity, or particular areas of emerging science and technology.	• Enhanced implementation of a governance framework for aligning emerging science, technology, and innovation with equity through actionable guidance on key questions, practices, and strategies in specific contexts.

GALVANIZING NATIONAL LEADERSHP AND SETTING PRIORITIES

Important federal and private efforts are ongoing to address some of the issues raised in this report, including efforts aimed at diversifying the science, technology, engineering, and mathematics (STEM) innovation workforce; increasing community and patient engagement in research; and targeting inequities associated with particular types of emerging medical technologies, such as artificial intelligence (AI). Given the scope of innovation in health and medicine, the significance and breadth of ethical principles that must guide it, and the importance of context, many efforts must flourish, targeting a range of needs and conducted in ways that best address a given issue and situation. But the dynamic and diverse nature of these activities and the number of groups with important roles to play can lead to potential confusion or misalignment of goals, duplication or contradiction of efforts, and lack of coordination.

Recent language around equity often emphasizes achieving equitable *outcomes*. While ensuring equitable access to new technologies and achieving equitable health outcomes remain important targets, this report and the framework it describes emphasize a complementary focus: how to establish an equitable *process* for the conception, development, and governance of emerging science, technology, and innovation, applying the framework imperatives described in Chapter 4 across the full life cycle to analyze where and how forms of inequity arise and shift choices and decisions to better align the process with more equitable innovation.

Harnessing this array of efforts to achieve a shared vision for enhancing the biomedical innovation ecosystem will help align current activities and inform the development of new ones targeted toward needs, challenges, and opportunities that remain, as well as those that will continue to emerge as science and technology advance. While multiple avenues of guidance and the efforts of agencies, offices, and other key stakeholders are making crucial progress, coordination and coherence are required to build and sustain maximum impact. Establishing such a system-wide vision can provide clarity on how multiple actors and their efforts fit together in an equity-aligned innovation process as groups make progress in tackling different goals and accelerating implementation. Federal leadership is needed to provide this system-wide view, help institutionalize the framework described in this report, and drive systemic change. This federal leadership must in turn be combined with extensive consultation beyond the federal government through a multistakeholder, public–private coalition of stakeholders in the ecosystem of emerging science, technology, and innovation. National leadership can also enhance engagement around equity in innovation in international settings, bringing together policy makers, researchers and developers, members of affected communities, private-sector actors, and government stakeholders through such venues as the World Health Organization, World Trade Organization, World Intellectual Property Organization, and Organisation for Economic Co-operation and Development, among others.

RECOMMENDATION 1. Galvanize national leadership for aligning emerging science, technology, and innovation in health and medicine with principles of equity. To focus attention on establishing equitable, holistic, sustainable, and cross-sectoral innovation in health and medicine:

- **The White House Office of Science and Technology Policy (OSTP) should lead the cohort of federal departments and agencies that fund and oversee science and technology in their efforts to translate and operationalize the governance framework for equitable innovation laid out in this report in accordance with their specific mission and life-cycle phase (i.e., from ideation to postmarket use).**
- **OSTP should convene a multistakeholder, cross-sectoral Equity in Biomedical Innovation (EBI) Task Force to galvanize action in the areas recommended in this report. The EBI Task Force should:**
  - **— Diagnose how and where inequities arise throughout the biomedical innovation ecosystem.**
  - **— Articulate near-, intermediate-, and long-term priorities for aligning emerging biomedical science, technology, and innovation with the governance framework for equity. To inform the White House Steering Committee on Equity, the EBI Task force should issue annual reports describing progress toward achieving these priorities, challenges encountered, adjustments made, new opportunities, and resources needed.**
  - **— Work with department or agency equity teams and the White House Steering Committee on Equity to translate priorities for emerging biomedical science,**

technology, and innovation into an initial set of goals to be accomplished over the next decade.

- **— Partner with the broader community of stakeholders in biomedical innovation to engage proactively with underserved communities to identify specific actions that address identified goals and provide insight on equity benchmarks, measures, and metrics (see Recommendation 5), including how to incorporate them at each phase of the innovation life cycle and how they can be used to achieve greater equity.**

- **Federal, state, and local policy makers should upgrade existing or create new policy and oversight mechanisms to drive the alignment of emerging biomedical science, technology, and innovation with the priorities and goals identified by OSTP, relevant departments and agencies, and the EBI Task Force.**

The ecosystem of emerging biomedical science, technology, and innovation involves a wide range of federal and nonfederal stakeholders whose engagement is needed in these efforts. Relevant federal departments and agencies include, but are not limited to, the White House National Science and Technology Council (NSTC) and the U.S. Department of Health and Human Services (HHS) and its agencies (e.g., the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, the FDA, the Health Resources and Services Administration, the Indian Health Service, NIH, and the Substance Abuse and Mental Health Services Administration). The OSTP can also draw on its relationships with the Office of Management and Budget and advisory bodies such as the President's Council of Advisors on Science and Technology. Additional agencies funding research or programs relevant or contributing to science and technology in health and medicine, such as NSF; the Department of Energy; the National Institute of Standards and Technology; and other agencies involved in decision making and oversight relevant to biomedical innovation, including the FTC and the U.S. Patent and Trademark Office, are also important to this ecosystem. In addition, the VA provides health care to a substantial population and conducts key biomedical research, thus offering a key opportunity to pilot changes in practices, incentives, or other governance levers that could drive more equitable outcomes.

Similarly, many nonfederal partners and stakeholders should be involved in activities to establish an equitable biomedical innovation ecosystem. These groups include biomedical innovators from academia and industry; scholars and experts from such disciplines as economics, science education, social sciences, and humanities; numerous professional societies in relevant disciplines; public and private organizations that conduct research and development; venture capitalists; health insurers and other payers; state and territorial health departments; and health care professionals and delivery organizations. This array of cross-sectoral stakeholders should also include patient and consumer advocacy groups; advocacy groups concerned about data privacy and use; and community organizations, including those representing historically marginalized and underserved communities.

IMPLEMENTATION GUIDANCE

Convening to Advance This Recommendation

The Equity in Biomedical Innovation (EBI) Task Force should have among its members or consult with the full range of relevant stakeholders, including federal and state agencies that fund and oversee the medical innovation system; organizations representing communities historically underserved by the current system; philanthropic foundations; local and regional organizations addressing research and innovation in health and medicine; leaders of research universities and relevant scientific and technical professional societies; technology investors; companies developing and marketing emerging technologies in health and medicine; and health care payers, insurers, and care delivery organizations.

In formulating priorities and goals, the EBI Task Force should solicit input from additional stakeholders in emerging science, technology, and innovation through calls for input, listening sessions, virtual discussions, or other mechanisms. Potential topics for the EBI Task Force to discuss include

- how to better incorporate equity science developed under Recommendation 5 into science and technology assessment across all phases of the innovation life cycle;
- how to better support and implement the significant and sustained community partnerships in emerging science, technology, and innovation called for in recent Executive Order 14091 and Recommendation 4; and
- which information is most useful and effective to collect as input for the annual progress reporting called for in this recommendation, how to collect it, and how to implement the reporting.

Additional Actions that Can Advance This Recommendation

- The Office of Science and Technology Policy (OSTP) and the Office of Management and Budget (OMB) can include the 10-year priorities and goals developed under this recommendation in their annual letter providing research and development (R&D) guidance to federal agencies, with a directive that relevant agencies consider them in formulating budget submissions.
- The director of OSTP can issue policy guidance for all relevant agencies on actions they can take to implement the priorities and goals developed under this recommendation.
- OSTP and the EBI Task Force can engage in dialogues at the international level on models, practices, metrics, and lessons learned for advancing equitable innovation.

ENHANCING THE CULTURE OF ETHICAL INNOVATION

Foundational to the practice of responsible science, technology, and innovation in health and medicine is alignment with ethical principles, the understanding of which has evolved over time. Achieving the vision described in this report of a system able to consider and address the needs of all users more equitably will require that those who undertake innovation conceive of their responsibilities as broader than such issues as patient safety, data privacy, and informed consent, although this is by no means to diminish the vital importance of these issues as manifestations of the core ethical principles of autonomy and individual good. Indeed, innovation must be guided by the full set of ethical principles identified in Chapter 1, which include justice, fairness, and collective good (recognizing that equivalent

ethical concepts are identified in the literature using different terms). This report focuses on equity as one key expression of alignment with these principles and with the foundational principles of the U.S Constitution to promote the general welfare and affirm the equal rights of all persons. The report thus provides a framework for enhancing development and governance in health and medicine guided by five core imperatives:

- broadening participation and sharing responsibility to empower a wider range of stakeholders;
- aligning incentives to encourage equitable decision making;
- determining how inequities develop along technology innovation life cycles and taking responsibility for mitigating them;
- crafting timely guidance for pursuing equitable ends; and
- sharpening ongoing, iterative oversight and evaluation along innovation life cycles.

Incorporating these imperatives into the ecosystem of emerging science, technology, and innovation will require a culture that reflects the values, expectations, and norms guiding how those involved in the innovation ecosystem understand their roles and responsibilities—in the conception of new research ideas, the design and conduct of research, the development and scale-up of resulting products and technologies, performance assessment, and patient and consumer use. This culture and the operationalization of the five governance imperatives within the many organizations that make up the ecosystem of health and medicine critically influence how innovation is carried out, how impacts are assessed, and whether and what actions are taken in response to information learned during these processes. Recommendation 2 therefore focuses on the culture of innovation, affirms that members of the system should be mindful of how their choices affect equity, and aims to help foster a shared understanding of equity and why and how it is relevant in innovation. Progress toward Recommendations 5 and 6 below will also provide key information about the equity considerations, concerns, opportunities, and types of actions that are most relevant to a given area of advancement in science and technology, thereby assisting organizations across the life cycle in implementing the aims of this recommendation.

RECOMMENDATION 2: Enhance a culture of innovation that incorporates equity as an ethical concept in technology development and integrates it into organizational practice. The research and development enterprise in health and medicine should more fully incorporate the concept of equity into the foundational ethical principles that guide innovation. Achieving this shift will require a culture of innovation that takes responsibility for incorporating ethical principles across the innovation enterprise and leverages expertise in such fields as bioethics; science and technology studies; and the history of science, technology, and medicine. In particular, organizations that conduct research and technology development in health and medicine and organizations that train and fund researchers and technology developers should:

- **Mandate ethics training that addresses the core ethical principles, five governance imperatives, and awareness of multiple forms of equity identified in this report. Such training should draw on practical guidance that enables researchers and developers to identify how equity intersects with innovation in their particular field and provides them with tools to help identify and address inequities that may arise in their own work, recognizing that specific issues and responsibilities differ substantially with the nature and type of research and phase of development (see also Recommendations 5 and 6).**

- **Demonstrate a commitment to these ethical principles and framework imperatives in their operations and processes. This commitment should include the ability to assess the extent to which the organization's overall portfolio reflects alignment with forms of equity, whether any misalignments might be anticipated for a particular technology, and with what implications for decision-making processes (see Recommendation 6).**

IMPLEMENTATION GUIDANCE

Convening to Advance This Recommendation

Different fields and sectors face as challenging areas for debate and agreement how to strike the most effective balance among advancing substantive action toward equity; incorporating the other ethical, social, legal, scientific, and financial considerations that affect progress in science and technology; and minimizing undue restrictions on innovation. Coalitions of universities, professional societies, and academic experts play key roles in developing and promulgating disciplinary norms for fields of emerging science and technology. These groups can come together to develop further guidance and standards for academic and professional training and sample training modules that integrate information on forms of equity and dynamics of inequities and the governance imperatives identified in this report, and incorporate cultural practices into normative practices for translational, clinical, and population research; professional development; and institutional accreditation.

Coalitions of university technology transfer offices, law firms, philanthropic organizations, and investment companies can convene with science and technology innovators, patient and community organizations, and social science and humanities experts to develop further normative guidance on practices in technology licensing that could be applied in assessing ethical and equity considerations associated with new intellectual property and in making use of enhanced equity and public benefit provisions in licensing and start-up agreements.

Actions by Multiple Stakeholders to Advance This Recommendation

Incorporation into Training

- The convening activities identified above can create a module on equity for all stages of innovation in health and medicine for incorporation into existing training programs. Creation, updating, or use of such training modules on equity in biomedical innovation can also be reported on by the Equity in Biomedical Innovation Task Force (see Recommendation 1).
- Training in responsible conduct of research required by such agencies as the National Institutes of Health (NIH) and the National Science Foundation (NSF) can address equity, justice, and fairness as core bioethical principles, fostering broad awareness among the research and development (R&D) community.
- Departments and other academic units can assess students on awareness of ethical principles, including concepts of equity and the imperatives described in this report, at appropriate benchmarks (e.g., as part of qualifying exams).
- Departments and other academic units can train innovators to understand the equity implications of their work and to become aware of and incorporate best practices in minimizing research biases, drawing on guidance most relevant to their context or discipline (see also Recommendation 6).
- Faculty and instructors can incorporate relevant case studies into curricula to raise awareness of the consequences of the misalignment of innovation and equity.
- Departments and other academic units can provide training on the use of inclusive design principles to account for the needs of the full range of anticipated users in technology development.
- Clinical research training programs can discuss how to spot unquestioned assumptions in research plans, situations likely to lead to data biases, and research or delivery models likely to be nonfunctional in underresourced settings.

- R&D companies in health and medicine can establish training standards beyond those addressing legal compliance issues to encompass awareness of the forms of equity, framework imperatives, context-relevant guidance, and equity-aligned practices described in this report, including how to identify any misalignment between their technology and equity.

Promulgation of Professional Norms

- Professional societies and other groups that hold regular meetings can ensure that ethical principles and equity considerations are explicit items in meeting agendas.
- Research journals and other publishers can ensure the inclusion of articles that assess or provide commentary on the role of equity in emerging science, technology, and innovation in health and medicine.

Funding and Research Approvals

- Where relevant to the type and topic of research, managers of grant and research review processes can require investigators to discuss equity considerations associated with the proposed work and steps taken to enhance alignment or mitigate concerns.
- Reviewers of funding and research proposals can be asked to identify and comment on potential equity considerations in the proposed work.
- Funders of clinical and applied research (agency and philanthropic) can refer awardees to appropriate resources, such as field-specific playbooks, and raise awareness of these resources (see also Recommendation 6).
- Peer review committees, advisory councils, institutional review boards (IRBs), and other oversight committees can include diverse perspectives and expertise and can consider whether research designs might unfairly benefit or burden particular groups.
- Organizations that approve the design and conduct of research can incorporate a diverse range of academic, cultural, and stakeholder perspectives on review panels (e.g., IRBs, ethics committees, community advisory boards).
- In situations requiring effective partnerships with affected or underserved community organizations, federal, private, and philanthropic funders can be flexible in evaluating and supporting substantive participation by such organizations, which may not currently have the same levels of research experience, capacity, and infrastructure as universities or companies yet need to be empowered to engage as equal partners.

Technology Transfer

- Technology transfer and licensing offices can establish enhanced processes for engaging with researchers, social science experts, and other organizational units to understand the potential ethical and equity considerations associated with new intellectual property.
- Technology transfer and licensing offices can develop additional equity provisions in licensing and start-up agreements, and can develop additional template data use agreements (DUAs)/memoranda of understanding (MOUs) that include provisions recognizing the contributions of communities that contributed data. Although adherence to such provisions is difficult to monitor and enforce, they nonetheless raise awareness of equity as an important consideration.

Periodic Technology and Portfolio Assessments

- Stakeholders throughout the innovation process can adopt equity science methods, metrics, benchmarks, and data systems to assess the implications of a given technology and/or an overall portfolio of technologies, and use these assessments to inform decision making (see Recommendation 5). For example, investors in the prototype stage of a technology can engage in horizon scanning to link current design choices to downstream equity implications that would have financial or logistical implications across the populations of intended users. Innovation stakeholders can also assess whether their research, development, or investment portfolio represents an equitable distribution of investigators, institutions, and anticipated risks/benefits.
- Stakeholders developing emerging medical technologies, such as drug or device manufacturers, can incorporate input from a wider range of end users at earlier stages of design and decision making to identify and mitigate any misalignments with equity that can be anticipated.

MAKING TARGETED USE OF GOVERNANCE INCENTIVES

As stressed throughout this report, a governance framework for emerging science, technology, and innovation should establish policies and practices that foster an innovation system with the capacity to address the needs and concerns of all of the system's users, including those who have historically been marginalized or underserved. Yet the U.S. innovation system results in gaps and negative consequences, including disparities in opportunities to be included in the system and substantial inequities in health outcomes. Multiple levers are available to redress these inequities by changing incentives and disincentives and influencing the decisions of innovation stakeholders. These levers include federal and state laws and regulations; professional standards and best practices; the use of targeted funding; requirements for research design, funding, approval, publication, and evaluation; market incentives; and many others. These various levers can be applied to produce both "pushes" leading to further innovation, such as new and transformational science developments, and "pulls," such as offers of patent exclusivity or advance purchase commitments.

Achieving a more equitable system of emerging technology and innovation will require both individual and collective actions to create positive feedback loops that shift the system toward a sustained focus on equitable benefit. While policy and regulatory changes or new funding will be needed in some cases to achieve a more equitable health ecosystem, many essential elements are already in place and require only the necessary political and professional will.

RECOMMENDATION 3: Incentivize the alignment of innovation with equitable benefit. Those who fund and oversee innovation in health and medicine should incentivize their grantees, researchers, and partners to assess periodically an emerging technology's alignment with equity, focusing on choice points during the technology life cycle and on governance actions that can be taken to mitigate any misalignments that may arise. Assessment areas should include the following:

- **Funding and research approvals: Whether research and analysis methods mitigate biases and incorporate a diverse range of relevant expertise and perspectives, including input from and partnerships with directly affected communities.**
- **Patenting, licensing, investment, and scale-up: Whether intellectual property and licensing decisions have been informed by alignment with ethical principles. Specific considerations include whether the contributions of people and communities to the research through participation and the provision of bodily materials and data have been recognized and valued, whether patent scope and description are appropriate for a claimed invention, and whether to make use of enhanced provisions on unmet need and public benefit in licensing agreements.**
- **Assessment and approval for widespread use: Whether a technology's performance has been evaluated in populations that meaningfully reflect the full range of the technology's intended users, and whether evaluation and approval processes included diverse representation and input from relevant experts and populations.**
- **Cost and coverage decisions: Whether purchasing, coverage, and use decisions have taken equity measures and anticipated impacts into account (see Recommendation 4).**
- **Postmarket analyses: Whether new information on inequitable impacts has emerged following widespread use, what can be done to mitigate impacts, and whether such analyses include sufficient input from affected communities and members of the public.**

IMPLEMENTATION GUIDANCE

Incentivizing the alignment of innovation with equitable design will require substantive engagement with underserved communities, as well as increased agency flexibility and resources, such as those mandated under recent Executive Orders advancing equity.

Actions by Multiple Stakeholders to Advance This Recommendation

Funding and Research Approvals and Research Design

- Funders can support ongoing efforts to diversify the science, technology, engineering, mathematics, and medicine (STEMM) workforce and broaden views on who innovators are and where innovation occurs.
- Funders can require researchers to partner with relevant communities; create funding opportunities focused on community engagement; and support communities through funding, capacity building, and training to enhance their ability to participate in such partnerships.
- Funders can include equity-focused proposal requirements and scoring elements where appropriate to the nature and type of research. For example, funders can hold grantees accountable for the diversity of research teams, and value contributions to equitable science in addition to scientific output.
- State and federal government agencies can provide funding, guaranteed loans (analogous to those made under the 2005 Energy Policy Act), and/or tax incentives for targeted investment in new technologies or retrofitting of existing technologies to expand access and usefulness for historically marginalized or underserved populations.
- Peer review committees, advisory councils, institutional review boards (IRBs), and other oversight groups can ensure that marginalized and underserved communities are included in the design and patient/subject selection processes for relevant research projects, and that the work proactively addresses knowledge and access gaps among these populations.
- Funders and publishers can require that research recognize community contributions, including by acknowledging community participation, listing community leaders as coauthors, and/or returning relevant study results to participants.
- Funders and innovators, in partnership with historically underserved and/or marginalized communities, can take up the challenge of designing a technology to help address an identified need or inequity.

Patenting, Licensing, Investment, and Scale-up

- Research institutions, technology offices, and other relevant organizations can examine how informed consent practices intersect with the recommendation to recognize and value bodily materials, data, and other contributions made by research participants, and can pilot new models and practices for benefit sharing that support innovation while building community trust.
- The U.S. Patent and Trademark Office (USPTO) can incentivize examiners to maintain patent "quality" so that claims do not go beyond the actual invention, and can require patent descriptions to be transparent about the data, population, and, where relevant, algorithms on which an invention is based, which will shape its utility.
- State and federal governments can create new avenues or expand existing ones (such as Small Business Innovation Research [SBIR]/Small Business Technology Transfer [STTR] programs) for public–private partnerships in which government investment serves to derisk private investment in equity-focused ventures.
- Technology transfer offices can use terms and provisions in licensing and start-up agreements that facilitate public benefit and equity in biomedical innovation (e.g., requirements for nonexclusive or royalty-free licensing; triggers for compulsory licensing; provisions for discounted or free use of some applications; and model provisions related to benefit sharing, such as for communities that contributed biological materials and data).

- Philanthropic and nonprofit funders can encourage or mandate intellectual property and licensing arrangements for the grants they support that align with public benefit and equity provisions.
- Social impact investors, private philanthropy, and other stakeholders can develop reputational incentives for investors and funders to prioritize investment in technologies that focus on access and usefulness for marginalized or underserved populations with unmet needs. Such incentives could take the form of "LEED [Leadership in Energy and Environmental Design] certification" or "Good Housekeeping seal of approval" types of designations, prizes, and other rewards.

Assessment and Approval for Widespread Use

- Premarket approval processes can consider whether study designs, results, and underlying data adequately reflect the full population of intended postmarket users and contexts, including alignment with emerging federal guidance on diversifying clinical trials and testing data.
- Oversight and regulatory agencies can expand when and how decisions are made requiring postmarket evaluations (such as Phase 4 studies and Risk Evaluation and Mitigation Strategies [REMS]) to assess real-world access and performance for the range of intended postmarket users and contexts, and to evaluate this information to determine whether unanticipated inequities have arisen.
- These efforts should draw on the robust equity science methods, metrics, benchmarks, and data systems developed under Recommendation 4.

Cost and Coverage Decisions

- Public and private purchasers and health care insurers can conduct or require equity analyses to inform their decision making.

Postmarket Analyses

- State and federal governments can amend state product liability laws and federal preemption of state tort law to include failure to equitably consider all relevant populations as a form of actionable defect when causation and other tort law requirements are met.
- Government agencies and sponsors can use postmarket surveillance to identify and understand any inequitable distribution of medical benefits and risks. Warning letters and label changes can be used to alert providers and patients more quickly to adverse events or lack of effectiveness in affected subpopulations (see Recommendation 5).
- Public and philanthropic funders can create dedicated funding streams for exploring alternative designs and delivery systems that might better or more proactively address any inequities and barriers to access that have been identified (analogous to the development of in vivo genome editing while work continues on scientifically more attainable in vitro systems for treating target conditions such as sickle cell disease).

EXPANDING WHO PARTICIPATES IN INNOVATION

The concept of being an innovation "stakeholder" or "rights holder" carries assumptions about deriving benefits and having power to influence decisions and trade-offs. The report's framework and recommendations are aimed at broadening who sees themself as being (and who is empowered to be) a stakeholder or rights holder in this system, and at identifying avenues for historically underserved and marginalized communities to play expanded roles in the technologies that have consequences for their health and well-being.

While various efforts have sought to prioritize the perspectives and needs of patients, research subjects, underserved communities, and other groups in innovation, equitable

innovation requires expanding and rethinking which groups participate in innovation and how. All interested parties should have opportunities to inform the process and governance of innovation in health and medicine, including through sustained, bidirectional engagement that expands the participation of historically underserved populations throughout the process, including at early stages.

A more equitable health innovation ecosystem will require redesign to be more accountable and responsive to the interests and needs of patients and underserved communities. To this end, it can draw on patient and community advocacy organizations as research and innovation drivers that can help build trust and broaden and diversify research to characterize diseases and design solutions more accurately so they are most applicable to community needs. Indeed, some funders are already recognizing patients and underserved communities as central stakeholders in the ecosystem. Models include those operationalized by the Patient-Centered Outcomes Research Institute (PCORI) and some NIH programs, in which community partnerships are required as a condition for funding in certain research areas. For example, the NIH ComPASS (Community Partnerships to Advance Science for Society) program focuses on innovations designed to address social determinants of health and requires that the community partner serve as the lead applicant, with an appropriate academic research partner as a subrecipient. Other opportunities for action include incorporating varied perspectives and backgrounds on the panels that review proposals (see also the implementation guidance box for Recommendation 4 below). Such models providing targeted funding help recognize community members as coproducers of knowledge and true partners in the innovation pipeline. Ongoing efforts can also support diversifying the workforce in science, technology, and innovation and investing in diverse innovators, including those from underrepresented communities.

Who, specifically, represents a "marginalized or underserved community" and how to better center the interests of patients, users, and members of affected communities in the innovation ecosystem will depend on careful assessment of whether and how a technology could potentially produce misalignments with the forms of equity described in this report (see Recommendation 2). The individuals and communities that should be engaged in a particular area of emerging technology development will vary with the research topic, intended uses, and other critical contextual factors.

RECOMMENDATION 4: Empower diverse communities to participate in the innovation system. Conveners appropriate to stages of the innovation life cycle in health and medicine should bring together experts and practitioners in effective community engagement, participatory research and codesign, inclusive design principles, and participatory technology assessment, along with leaders of model engagement partnerships, to analyze lessons learned from these efforts and identify best practices, standards, and tools for designing and maintaining bidirectional engagement with members of marginalized or underserved communities. Such convening should:

- **Address decision-making issues encountered during the technology development life cycle, including how to empower substantive input during research priority setting and funding; research conception, design, and conduct; data access, management, and ownership; intellectual property identification and management; technology performance evaluation; coverage and use determinations; and monitoring of a technology's impacts and implications.**
- **Identify policies and practices that recognize and value a community's contributions to and participation in research.**
- **Center the interests of patients and affected communities in the innovation ecosystem.**

IMPLEMENTATION GUIDANCE

Convening to Advance this Recommendation

No single actor is responsible for convening across the suite of issues relevant to different phases of emerging science, technology, and innovation in health and medicine, although critical roles can be played by the Equity in Biomedical Research (EBI) Task Force proposed in Recommendation 1; federal agencies carrying out their respective activities in research, technology development, and innovation; and philanthropic organizations. Multiple, focused opportunities are likely needed to delve deeply enough into lessons, models, tools, and best practices on specific topics (such as research codesign or community data ownership). The resulting guidance from these efforts would provide critical information for the context-specific equity playbooks developed under Recommendation 6 below. At the same time, although topically focused convening and guidance are needed, implementing this recommendation will collectively expand the network of leaders active in this area. Dedicated and systematic efforts should enable members of historically underserved populations to participate in the innovation process, including by

- supporting historically underserved communities in expanding their capacities to participate in innovation, such as by identifying problems of interest and establishing and engaging in community-based and external partnerships, including serving as co–principal investigators on projects and authors on research papers;
- encouraging researchers to recognize the contributions of affected communities in the development of intellectual property, and helping them identify tangible models and practices for doing so;
- incorporating diverse voices in program prioritization and in the development of equity science methods, metrics, and benchmarks (see Recommendation 5); and
- supporting the leadership and participation of affected and underserved communities in the development of context-specific equity playbooks (see Recommendation 6).

Actions by Multiple Stakeholders to Advance This Recommendation

Research Conceptions and Design, Including Agenda Setting.

- Organizations conducting research can strengthen inclusiveness through the use of community engagement boards and the inclusion of relevant community members and experts on research teams.
- Research funders can include plans for community engagement in advisory bodies that help set program directions and priorities and in grant evaluation and review.
- Research teams can use best practices for codesigning goals, plans, and methods with affected communities, including crediting them on resulting publications and intellectual property.
- Research teams can develop agreements with affected communities, particularly those actively participating in projects, to ensure that they benefit from intellectual property resulting from the project.

Funding and Conduct of Research

- Federal, state, and nonprofit research funders can adopt and require best practices for community engagement in research conception, codesign, and implementation emerging from recent initiatives.
- Research funders can ensure the inclusion of diverse voices on panels that review proposals and make funding decisions.
- Research funders can support the inclusion of diverse clinical research participants consistent with the topic being investigated.
- Clinical research funders, research organizations, and investigators can emphasize the importance of developing a shared vision for engagement for a given scenario or project; work with participating communities to identify local needs, concerns, and meaningful outcomes; identify ways to share tangible benefits, such as equipment, infrastructure, nonexclusive licensing, and the use of revenue sharing, with the community; and identify ways to foster nonfinancial benefits, such as skill and capacity-building and career development.

- Funders can provide support to affected underserved and marginalized communities through funding, capacity building, and training to enhance their ability to participate in innovation.

Evaluation of Performance

- Premarket consultations, advisory committee discussions, and review processes, such as those undertaken by the Food and Drug Administration (FDA), can include representatives of historically marginalized or underserved populations.
- Initial market approvals can require consideration of whether focused Phase 4 trials are needed to detect performance, access, or other disparities in order to help address potential initial difficulties in detecting lack of effectiveness in a marginalized or underserved population.

Monitoring Impacts and Implications

- Regulatory authorities such as the FDA can require that postmarket safety assessments include specific attention to whether adverse event reports are disproportionately from patients from marginalized or underserved populations or settings.
- Regulatory agencies can respond to such reports by investigating possible causes and responses, ranging from changes in Risk Evaluation and Mitigation Strategies (REMS) to warnings (via dear doctor letters or more formally through labeling changes).

DEVELOPING EQUITY SCIENCE

A governance framework for more equitable development and governance of emerging science, technology, and innovation in health and medicine requires credible methods, metrics, and benchmarks for assessing equity throughout the system in a purpose-driven, contextually sophisticated manner, enabling both anticipatory analysis of inequities that may arise and retrospective analysis of efforts to mitigate inequities. Having such measures can help in identifying and understanding sources of inequity, assessing the extent to which trade-offs occur (or not) between considering equity and advancing innovation and commercialization, encouraging members of the system to implement practices that enhance alignment with equity or deimplement negative practices, and supporting accountability and iterative system improvement.

Methods for measuring equity encompass steps, processes, and analytical tools by which dimensions of equity can be assessed; qualitative and quantitative equity metrics are the specific indicators or measures that can be gathered; and benchmarks represent the goals or targets against which progress toward greater equity can be envisioned. A robust field of equity science needs all three of these elements. Systematic and iterative progress will require establishing target benchmarks, developing suitable conceptual and methodologic strategies, and collecting and analyzing identifiable metrics, and then using the resulting information to make decisions, assess the results of those decisions, and revise them as needed within the context of a learning system.

No single measure will capture the multiple equity dimensions and issues associated with the innovation life cycle in health and medicine. The equity methods, metrics, and benchmarks that are developed will need to have clear purpose and meaningful content and to be modifiable, meaning that knowable actions by identified actors can be taken to shift the value of a metric in the desired direction. The equity methods, metrics, and bench-

marks also will need to support inquiry and analysis at three levels—individual people, social groups, and the entire population. Examples of types of metrics that could be considered for further development include those providing greater transparency in intellectual property decisions and outcomes and measures of equity that can inform clinical decision making.

Public and private efforts are ongoing to improve the measurement of equity and develop equity-relevant metrics. Examples include the federal equitable data vision from the interagency Equitable Data Working Group ("Equitable data are those that allow for rigorous assessment of the extent to which government programs and policies yield consistently fair, just, and impartial treatment of all individuals" [White House, 2022]), NSF's Analytics for Equity Initiative,[1] state activities such as the COVID-19 health equity metrics reported by the California Department of Public Health,[2] academic programs such as the Equity Metrics program at the University of California-Berkeley,[3] philanthropic efforts such as the Robert Wood Johnson Foundation's report on *Chartering a Course for an Equity-Centered System* (RWJF, 2021), and others. In addition to key agencies such as NIH and NSF, other partners that will need to be engaged in the development and deployment of new equity science metrics for innovation in health and medicine include PCORI, the FDA, the Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare & Medicaid Services (CMS), and the VA (for the development of metrics relevant to health system performance and health equity); and the USPTO and Department of Commerce through the National Institute of Standards and Technology (NIST) (for the development of metrics addressing such areas as patenting and licensing). Equity-relevant metrics are also being developed in specific areas of emerging science and technology, such as algorithmic fairness and data representativeness.[4]

This report calls for developing a robust and comprehensive field of equity science, building on current efforts in equity metrics; maturing this field of knowledge; and applying it to the biomedical innovation system. Building the field of equity science is not a short-term goal; it will require sustained commitment to produce value over a multiyear timeline. Equity science for biomedical innovation will require a multistakeholder and multidimensional approach guided by the governance imperatives described in this report and able to account for the many dimensions and factors involved.

Ideally, the field of equity science developed under this recommendation will support enhanced efforts to assess and monitor developing technologies against equity considerations and revisit governance actions and innovation choices in light of the results of these efforts. As described in this report, U.S. federal agencies, private-sector actors, payers, and others may not systematically conduct such equity assessments now. Although holistic technology assessment remains a need, equity science can build a foundation for future efforts and discussions aimed at enhancing system capacity.

RECOMMENDATION 5: Invest in developing equity science for technology innovation. The National Institutes of Health and the National Science Foundation should partner with philanthropic organizations to support the development of a robust, multidisciplinary equity science that builds on current efforts to develop equity-relevant metrics while establishing a wider range of qualitative and quantitative methods,

[1] https://beta.nsf.gov/od/oia/eac/analytics-equity-initiative (accessed June 30, 2023).
[2] https://covid19.ca.gov/equity/ (accessed June 30, 2023).
[3] https://belonging.berkeley.edu/equity-metrics (accessed June 30, 2023).
[4] For example, see https://www.ibm.com/docs/en/cloud-paks/cp-data/3.5.0?topic=openscale-fairness-metrics-overview (accessed June 30, 2023).

metrics, and benchmarks encompassing the forms of equity and governance imperatives laid out in this report. The equity science thus developed should

- **enable better assessment of how inequities arise, in which contexts, and for which communities across all phases of emerging science, technology, and innovation in health and medicine;**
- **yield greater understanding of how success is measured and how innovation systems and processes can change in response to the evidence obtained, including better understanding and evaluating the impacts of different stakeholder actions and choices; and**
- **include metrics, measures, and benchmarks suitable for assessing both near-term and longer-term changes.**

IMPLEMENTATION GUIDANCE

Convening to Advance This Recommendation

Setting a research agenda for developing the field of equity science will require the participation of public and philanthropic agencies and organizations; academic and professional expertise from such areas as the social and behavioral sciences and humanities; experts in scientific and technical disciplines and economics; and representatives of the lived expertise of historically marginalized and underserved groups. Groups already active in developing equity-relevant metrics can discuss current efforts and examples; identify relevant methods that can be used and metrics that can be collected; prioritize gaps; and identify promising strategies for the development of new methods, metrics, and benchmarks aimed at addressing the key gaps.

Equity science methods, metrics, and benchmarks developed through these programs should

- incorporate the development of associated data collection and reporting systems and data quality standards;
- enable iterative review of the effectiveness of governance policies that have been implemented, the shifting landscape of technology, and the potential for new implications and impacts to have emerged; and
- support responsive course correction of governance decisions, including incentives and disincentives.

As equity science is developed:

- Stakeholders throughout the innovation process can support system-wide change by adopting the resulting methods, metrics, benchmarks, and data systems to assess equity-relevant implications of technology innovation decisions. Evaluation of impacts and implications using equity science can also be incentivized over longer timelines to help identify and mitigate inequities or disparities that arise over time.
- Scientific fields that traditionally have not considered equity in research and development can integrate equity science methods, metrics, and benchmarks into their policies and practices. Equity science should not stand apart or be siloed from the traditional research, development, and innovation community.
- Federal science and regulatory science agencies can establish, resource, or empower mechanisms to support decision making, program improvement, and continuous learning based on equity science methods, metrics, and benchmarks, in accordance with the Government Performance and Results Act (GPRA) of 2010, the Office of Management and Budget's Circular A-11, and the Foundations for Evidence-Based Policymaking Act of 2018 (Evidence Act).

Actions by Multiple Stakeholders to Advance This Recommendation

- Stakeholders developing the quantitative methods, metrics, and benchmarks for a robust multidisciplinary equity science need to include expertise from the humanities, social science, and history to augment and contextualize the development of this science.
- As equity science methods, metrics, and benchmarks are developed and validated, the Office of Management and Budget (OMB) and federal agencies can use them in evaluating agency activities and in making decisions about whether changes to resource allocations may be warranted to address gaps.

CREATING CONTEXT-SPECIFIC PLAYBOOKS

Equity playbooks can serve as important guides for stakeholders on the strategies, key questions, and specific suggestions that can translate the governance framework in this report into practice, providing tools to advance equity in the innovation life cycle. To be sufficiently specific given the breadth of science, technology, and innovation in health and medicine, these playbooks would need to be technology- or stakeholder-specific and be subject to recurring review. They would also need to be developed with input from a broad and inclusive group of stakeholders. The committee recognizes that not all stakeholders in all areas of emerging science, technology, and innovation will find it equally useful to develop and disseminate equity playbooks, but concludes that all stakeholder groups should consider the value of such playbooks as practical tools for setting norms and standards, and advancing discussion and action to address equity.

Efforts to develop equity playbooks for emerging science, technology, and innovation in health and medicine can draw conceptually on model playbooks that have been developed for particular challenges and communities. Examples of such models include the Equity Playbook from Chicago United for Equity (CUE Fellows, 2019); the COVID-19 Health Equity Playbook for Communities from the California Department of Public Health (CDPH, 2020); the Playbook for New Rural Healthcare Partnership Models of Investment (Thomas-Squance et al., 2022); the Funders Guide to diversity, equity, and inclusion from the Ford Foundation (Ford Foundation 2023a,b,c); and the Algorithmic Bias Playbook, developed through the University of Chicago Booth School of Business by researchers in artificial intelligence to provide guidance on algorithm development and oversight targeted toward health care leaders, technical teams, and regulators (Obermeyer et al., 2021). Federal agencies and philanthropic foundations can provide key support to such efforts.

RECOMMENDATION 6. Develop context-specific guidance on translating the governance framework for emerging science, technology, and innovation into practice. Innovation stakeholders in professional, government, and community settings should strongly consider developing equity playbooks providing strategies, key questions, and advice targeted to particular roles in the technology life cycle, types of inequity, or specific areas of emerging science and technology, including context-specific guidance on incorporating equity science into technology assessment (see Recommendation 5).

- **Federal, philanthropic, and private funding organizations in the innovation system for health and medicine should support the development and dissemination of such playbooks by their stakeholders.**

- **Consistent with Recommendation 4, federal and philanthropic funders should support the development of model community-focused playbooks that articulate community-specific ideals for how technology should be aligned with context-specific equity goals. Such playbooks should be developed in partnership with affected historically marginalized and underserved communities to provide them with guidance, strategies, and tools that can enhance their participation in the innovation system.**
- **Professional associations, particularly those that govern norms and standards for a field of science, technology, and innovation, should coordinate the development and dissemination of the resulting equity-aligned playbooks as a professional norm.**

IMPLEMENTATION GUIDANCE

This report provides a starting toolkit for better aligning the development, use, and governance of emerging biomedical technology with principles of equity, justice, and fairness. The resources previously developed by the National Academy of Medicine's (NAM's) standing Committee on Emerging Science, Technology, and Innovation in Health and Medicine (CESTI) and those provided in this report provide a basis for further development of the context-specific paybooks called for in Recommendation 6. These resources include the following:

- *Case Studies:* Published by members of CESTI, illustrative case studies that explore history, development, and governance in areas of regenerative medicine, neurotechnology, and telehealth (see Appendix A for further information).
- *Forms of Equity*: Explanation of the different forms of equity relevant to emerging science, technology, and innovation identified in this report (see Chapter 2).
- *Governance Framework:* The framework provided in this report that applies five core imperatives to enhance the alignment of the life cycle of emerging science, technology, and innovation with equity (see Chapter 4).
- *Illustrative Examples and Tables:* Examples and boxes provided throughout this report illustrating the impacts of failures to consider equity implications sufficiently and highlighting some of the organizations, efforts, and strategies that can be used to advance equity in the innovation life cycle (throughout the report).
- *Heatmap:* Developed by CESTI, this tool illustrates potential ways in which a particular stakeholder could look at the alignment of a given technology or portfolio of technologies with ethical principles of justice, autonomy, fairness, collective good, and individual good. Questions that might be posed range from "Does the technology interfere with individuals' ability to make decisions about their bodies or lives?" (autonomy) to "Is there an inclusive, transparent process for resolving tensions between ethical demands?" (fairness) (see Appendix A).

AN ACTION AGENDA FOR STAKEHOLDERS IN THE INNOVATION SYSTEM

Reimagined governance for emerging science, technology, and innovation in health and medicine will need to involve an array of approaches, including enhanced engagement; targeted use of incentives to prioritize equity, justice, and fairness at phases along the technology development life cycle; regulation and oversight from key federal, state, and local agencies; the deployment of soft governance through awareness raising; and the promulgation of professional norms and creation and dissemination of practical guidance through context-relevant playbooks, along with enhanced coordination, interactive review,

and revision in light of information learned. To operationalize equity in biomedical innovation and implement the six recommendations presented above will thus require commitments from multiple stakeholders across multiple sectors. To encourage stakeholders to act, Table 5-2 provides a high-level summary of actions and desired outcomes for major stakeholder groups.

TABLE 5-2 An Action Agenda for Stakeholders

Actors	Actions	Desired Outcomes
White House Office of Science and Technology Policy (OSTP) and Equity in Biomedical Innovation Task Force	• Identify priorities for aligning emerging biomedical science, technology, and innovation with the report's governance framework for equity. • Work with department and agency equity teams and White House Steering Committee on Equity to translate these priorities into goals to be accomplished over the next decade. • Partner with biomedical innovation stakeholders to engage proactively with underserved communities.	• An innovation system that catalyzes the discovery, translation, and use of emerging science and technology in health and medicine and leads to innovation aligned with ethical principles, including equity. • Federal and multistakeholder leadership to advance equitable innovation.
Funders of emerging science, technology, and innovation	• Mandate ethics training that incorporates an understanding of equity. • Support efforts that broaden views of who is part of the innovation workforce and where innovation occurs, including by supporting underserved communities to enhance their ability to participate in innovation. • Where appropriate, require applicants to address types of equity associated with proposed work, including community engagement plans, and/or to reassess a technology's alignment with equity periodically. • Include diverse perspectives on funding panels and periodically undertake portfolio analyses for alignment with equity aims, to inform decision making. • Support the development of equity science and enhanced equity measures and benchmarks usable at multiple points throughout the technology life cycle.	• Expanded methods, metrics, and benchmarks for assessing alignment with equity to inform decision making by stakeholders throughout the innovation system. • Policies that recognize the importance of alignment with equity and evaluation criteria for undertaking assessments. • Integration of ethical concerns, including stakeholder needs and values, into the formulation, funding, and conduct of research.
Researchers and organizations, from academia and industry, that conduct research and development	• Demonstrate organizational commitment to equity in biomedical innovation, including in training programs and technology assessments. • Develop guidance and standards for academic and professional training incorporating equity. • Use best practices for codesigning research with affected communities, and implement designs that mitigate biases and consider the full range of anticipated users. • Include diverse perspectives on review panels, and consider whether research designs are likely to benefit or burden particular groups unfairly.	• Integration of ethical and equity concerns, including stakeholder needs and values, into the formulation and conduct of research and development. • Policies that recognize the importance of alignment with equity and evaluation criteria for undertaking assessments. • Substantive partnerships, synergies, and collaborations that address needs and opportunities.

TABLE 5-2 Continued

Actors	Actions	Desired Outcomes
U.S. Patent and Trademark Office, technology transfer and licensing offices, law firms, and venture capital and other investors	• Expand engagement with research and social science experts to understand ethical and equity considerations associated with new intellectual property. • Incorporate ethics and equity assessment more fully into licensing and technology transfer practices, including developing and making use of enhanced equity provisions in licensing and start-up agreements. • Make use of models and practices for recognizing the contributions of research participants to resulting intellectual property. • Require patent descriptions to be transparent about the data, populations, and algorithms on which they are based. • Periodically undertake portfolio analyses for alignment with equity aims, to inform decision making.	• Enhanced use of provisions in IP identification, management, licensing, and start-up agreements that facilitate public benefit and equity.
Affected communities, including those that are historically marginalized and underrepresented	• Identify questions and research areas that would address areas of community interest and need. • Participate in developing a shared vision for engagement for a given research project. • Participate in developing equity science.	• Sustained, bidirectional participation and engagement in the innovation system. • Expanded methods, metrics, and benchmarks for assessing alignment with equity.
Regulatory stakeholders	• Require testing and analyses that meaningfully reflect the full range of intended users and contexts. • Incorporate mechanisms for engaging with affected communities, considering input received, and explaining how the information will be used in decision making. • When relevant, require postmarket analyses to identify whether inequities have arisen, and take action to address them.	• Policies that recognize the importance of alignment with equity and evaluation criteria for undertaking assessments. • Governance that is responsive to changes in equity impacts.
Health care payers and delivery stakeholders	• Include equity science metrics and analysis in purchasing, use, and coverage decisions. • Use postmarket analyses to identify whether inequities have arisen, and take action to address them. • Periodically conduct or require portfolio analyses for alignment with equity aims, to inform decision making.	• More equitable access to new technologies and more equitable health outcomes.

continued

TABLE 5-2 Continued

Actors	Actions	Desired Outcomes
All stakeholders	• Promulgate a culture of emerging science, technology, and innovation that includes awareness of equity as a normative principle. • Consider how information learned from the development and use of a technology provides new conceptual understanding or new problem formulations or identifies future research needs. • Consider whether a fuller understanding of the technology's impacts through the life cycle reveals a need for governance changes (to oversight mechanisms, incentives, or other actions). • Support and take part in the development and dissemination of context-specific equity playbooks.	• A learning system that fosters equitable innovation in health and medicine. • Context-specific guidance on equity tools and strategies targeted to particular fields, roles in the innovation life cycle, or equity considerations.

Reorienting innovation to advance equity is a vital and challenging imperative for 21st century science, medicine, and technology. The coordinated, cross-sectoral governance framework and six recommendations in this report represent important steps to be taken by actors and stakeholders across the ecosystem. These steps aim at achieving the vision for a system of emerging science, technology, and innovation in health and medicine that is equitable, responsive to the needs of a broader range of individuals, and more capable of recognizing and addressing inequities as they arise.

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Thomas-Squance R., A. Hernandez, C. Flynn, and D. Jutte. 2022. *A playbook for new rural healthcare partnership models of investment*. Build Healthy Places Network. San Francisco. https://buildhealthyplaces.org/downloads/Build-Healthy-Places-Network-Rural-Playbook.pdf (accessed June 30, 2023).

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Appendix A

Information Sources and Methods

The Committee on Creating a Framework for Emerging Science, Technology, and Innovation in Health and Medicine was tasked with developing a governance framework for considering potential benefits and risks that emerging science, technology, and innovation in health and medicine can bring to society, informed by prior work of the National Academy of Medicine (NAM) standing Committee on Emerging Science, Technology, and Innovation (CESTI). The committee was asked to produce a framework founded on core ethical principles with a focus on equity.

COMMISSION COMPOSITION

The National Academies of Sciences, Engineering, and Medicine and the National Academy of Medicine appointed a committee of 19 experts to undertake the statement of task. The committee was composed of members with expertise in such areas as biomedical research and development in academia and industry; health equity and justice; bioethics of emerging science and technology; governance, policy, and innovation; technology assessment, economics, and behavioral economics; and community engagement. Appendix D provides biographical information for each committee member. Two National Academy of Medicine fellows also participated in the study; their biographical information is also provided in Appendix D.

MEETINGS AND INFORMATION-GATHERING ACTIVITIES

The committee deliberated from approximately May 2022 to February 2023 to gather and discuss information and draft its report. To address its task, the committee analyzed information obtained from reviewing current literature and other publicly available resources and undertook information-gathering activities, such as inviting stakeholders to share perspectives during several virtual sessions and soliciting public input online.

Input from NAM CESTI

Materials developed by CESTI and information presented during an April 2022 workshop, at which the study was announced, served to inform the study committee. The workshop included sessions on lessons learned about emerging technology governance, technology assessment models, public engagement, and overviews of CESTI's work. Materials developed by CESTI articulated essential elements and ethical principles to inform governance of emerging science, technology, and innovation, drawing on preparation and analysis of three case study discussion papers, in the areas of regenerative medicine, neurotechnology and noninvasive neuromodulation, and telehealth and mobile health. Each case study opened with hypothetical vignettes to illustrate potential ethical issues, identified key stakeholders and how governance developed within and across sectors, and concluded with a "visioning" section on possible evolutionary trajectories the example may take that would need to be accounted for in a governance system. Publications arising from CESTI have been referenced in relevant chapters:

- Mathews, D. J. H., C. A. Balatbat, and V. J. Dzau. 2022a. Governance of emerging technologies in health and medicine: Creating a new framework. *New England Journal of Medicine* 386:2239-2242.
- Mathews, D. J. H., R. Fabi, and A. C. Offodile II. 2022b. Imagining governance for emerging technologies. *Issues in Science and Technology* 38(3):40-46.
- Mathews, D., A. Abernethy, A. Butte, J. Enriquez, B. Kocher, S. Lisanby, T. M. Persons, R. Fabi, A. C. Offodile II, J. S. Sherkow, R. Sullenger, E. Freiling, and C. Balatbat. 2023a. Neurotechnology and noninvasive neuromodulation: Case study for understanding and anticipating emerging science and technology. *NAM Perspectives*. Discussion Paper, National Academy of Medicine, Washington, DC. Forthcoming.
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- Mathews, D., A. Abernethy, A. Butte, P. Ginsburg, B. Kocher, L. Levy, C. Novelli, L. Sandy, J. E. Smee, R. Fabi, A. C. Offodile II, J. S. Sherkow, R. Sullenger, E. Freiling, and C. Balatbat. 2023c. Telehealth and mobile health: Case study for understanding and anticipating emerging science and technology. *NAM Perspectives*. Discussion Paper, National Academy of Medicine, Washington, DC. Forthcoming.

CESTI also developed a heatmap to serve as a visual representation of a consideration of a technology's alignment with guiding ethical principles at a point in time. This heatmap is intended as a flexible tool that can be further customized in multiple contexts and by multiple types of stakeholders and decision makers (see Table A-1).

Finally, in conjunction with CESTI, a public survey was conducted in 2022 by Johns Hopkins University on the implications raised by emerging technologies, conducted in compliance with the University's policies and procedures. The survey drew on two brief stories in areas of the case study perspectives mentioned above—focusing on genetically modified stem cells as a treatment for sickle cell disease and on the use of a noninvasive brain stimulation device—and asked participants about their views on risks and benefits associated with these areas of technology.

Commissioned Papers

The committee commissioned two white papers to inform its analysis: a historical analysis of the intersection of equity with U.S. innovation (authored by Michael McGovern and Keith Wailoo, Princeton University) and an exploration of how the National Institutes of Health and Federal Trade Commission have addressed equity (authored by Alexis Walker, Columbia University). These papers are provided in Appendixes B and C, respectively.

Literature Review and Additional Information Gathering

To supplement the expertise of committee members and information gathering through other sources, members and staff also drew on relevant articles from peer-reviewed journals, reports, statements, websites, and other literature sources. Committee members also analyzed federal agency equity action plans and gathered information on how selected federal agencies, including the National Science Foundation, the U.S. Department of Veterans Affairs, the Office of Science and Technology Policy, and others, are attending to equity.

Public Meetings and Webinars

Sessions at meetings held over the course of the study enabled the committee to obtain input from a range of additional experts. The committee's first meeting was held virtually in May 2022 and provided an opportunity for the committee to discuss the focus, goals, and timeline of the study. The committee held additional information-gathering meetings in June, August, and October 2022. Sessions with invited speakers and experts included:

- Discussion of study context and goals with sponsoring organizations (June 2022)
- Presentation and discussion on the development and governance of emerging science, technology, and innovation in health and medicine (June 2022)
- Panel discussion on equity in emerging science, technology, and innovation (June 2022)
- Presentation and discussion on issues at the intersection of emerging technologies, ethics, and equity (August 2022)
- Opening presentation and panel discussion on the example of artificial intelligence and algorithmic fairness (August 2022)
- Opening presentation and panel discussion on university technology transfer and licensing (October 2022)
- Opening presentation and panel discussion on decision making by investor communities (October 2022)

At a fifth meeting in January 2023, the committee discussed the conclusions and recommendations presented in this report and prepared its draft report for external review following National Academies policies and procedures.

Public Comments and Call for Input

To inform its deliberations, the committee invited responses to a public call for input released in summer 2022, which posed the following questions:

- What are key gaps and needs in the current system of governance for emerging science, technology, and innovation in health and medicine? How do the gaps and needs lead to ethical or societal consequences such as inequities or unfairness?
- In what ways does the current governance system succeed? What governance elements or strategies work well and should be preserved or built upon?
- What is most critical stage to act, and who are the most impactful actors for enhancing governance of emerging science, technology, and innovation (STI) in health and medicine to promote societal benefits and align with ethical principles such as equity and justice?
- What approaches or incentives are most useful for improving governance of emerging science, technology, and innovation to mitigate potential risks, enhance societal benefits, and increase alignment of emerging technologies with ethical principles?
- Are there practical ways to enhance coordination among potential actors and at various stages in the emerging S&T life cycle?
- Which governance pathways, emerging developments, or topics should be the focus of the study report to enable it to have the greatest impact?

We welcome any other comments relevant to the study's task that you think the committee should consider, including relevant governance models, tools, practices, and resources of which the committee should be aware.

Approximately 80 submissions were received. Respondents commented on the context of emerging science, technology, and innovation in health and medicine and identified a variety of potential gaps and needs, including expanding stakeholder participation, the role of leadership and organizational culture, workforce considerations, issues involving data use and access, and balance and influence in the current innovation ecosystem, including access and cost issues. Submissions also noted areas in which the current U.S. system is successful, shared examples of potential models and approaches, and noted areas in which interventions in the system may be useful, including during research and early phases of technology development, when considering premarket approvals, during postmarket deployment, and in clinical care and use. The committee thanks all of the individuals and organizations that shared input as part of this process.

Information provided to the committee from outside sources or through online comment is available by request through the National Academies' Public Access Records Office.

Website and Communications

The committee worked to make its activities transparent and accessible. The study website hosted by the National Academies was periodically updated to reflect recent and planned committee activities. Study outreach included an email address for comments and questions. A subscription to email updates was available to share further information and solicit additional comments and input to the committee.

Consulted Experts

The following individuals were invited speakers at information-gathering sessions of the committee.

Ruha Benjamin, Princeton University
Fred Cohen, Monograph Capital Partners
I. Glenn Cohen, Harvard University
Robert Cook-Deegan, Arizona State University
Regina Dugan, CEO, Wellcome Leap
Kadija Ferryman, Johns Hopkins University
Michelle Groman, Greenwall Foundation
Andrea Hodgson, Schmidt Futures
Priti Krishtel, Initiative for Medicines, Access & Knowledge (I-MAK)
Katharine Ku, Wilson Sonsini Goodrich & Rosati
Holly Fernandez Lynch, University of Pennsylvania
Laura Maher, Siegel Family Endowment on behalf of the Public Interest Technology Infrastructure Fund
Aisling McMahon, Maynooth University, Ireland
Bradley Malin, Vanderbilt University
Lori Melichar, Robert Wood Johnson Foundation
Michelle Shevin, Ford Foundation
Susan Song, Gordon and Betty Moore Foundation
Sabriya Stukes, IndieBioNY
Herman Taylor, Morehouse School of Medicine
Kush Varshney, IBM Research
Alice Xiang, Sony AI
Ruqaiijah Yearby, St. Louis University

Draft Heatmap Developed by CESTI as a Potential Tool

As noted above, the NAM CESTI standing committee also developed the concept of a heatmap as a type of flexible visual tool that could be further adapted by stakeholders or decision makers to help characterize the alignment of a technology with foundational ethical principles. A draft of this tool is reproduced in Table A-1.[1] In this draft, a particular technology at a given stage of development and in the context of specific stakeholder activities (top columns) could be evaluated against example questions (rows on the right). The specific stakeholders/rights holders, innovation activities, and other features could be adapted as relevant. This type of tool aims to provide a visual snapshot to inform governance discussions.

[1] The heatmap tool is also available as a supplementary online resource (Excel file) at https://nap.nationalacademies.org/catalog/27184/.

TABLE A-1 Draft Heatmap for Characterizing the Alignment of Technology with Ethical Principles

Technology Lifecycle Stage	(heatmap to be completed for a given technology and stage of development)

Benefit Level				Risk Level			
High benefit			Low benefit	Low risk			High risk

Example Marker of Alignment with Principles		SECTOR OF DEPLOYMENT										
		Academia		Healthcare		Private sector			Government			Nonprofit/consumer
Within the context of the listed activity/decision process:		Clinical research disease targets	Clinical research recruitment	Availability of geographically distributed trials	Insurance coverage	Investment in translational applications	Targeted markets	Planned business model	CMS coverage	Privacy protections	Regulation	Education/Outreach
Justice	How equitable is individual access to benefits? (e.g., do marginalized groups have same access as priviliged groups?)											
	How equitable is distribution of burdens across individuals?											
	Impact on existing health disparities?											
	Impact on existing economic disparities?											
Autonomy	Does the technology interfere with an individual's ability to make decisions about their bodies or lives?											
	Are individuals given the information they need to make informed decisions about their bodies and lives?											
	Does the technology pose risks to an individual's personal privacy?											
Fairness	Is there a mechanism for stakeholder engagement and incorporation of public interests and values?											
	Is there an inclusive, transparent process for resolving tensions between ethical demands?											
Collective Good	How equitable is group access to benefits?											
	How equitable is distribution of burdens across groups?											
	What is the environmental impact of the research/technology?											
Individual Good	Is the technology when used in this way safe?											
	Does the known and estimated benefit of the technology outweigh the potential harm to an indiviudual?											
	Is foreseeable harm being avoided or sufficiently mitigated?											

Appendix B

Technology Governance and Equity in the United States from the Cold War to COVID-19

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Summary

Introduction

- The paper argues that if there was a high point in the federal government's commitment to equity in technology access, it occurred in the late 1960s and early 1970s, but that commitment has eroded over time.
- A substantial and sweeping commitment to equity in technology governance has yet to be pursued as a matter of federal policy; however, such a commitment is not entirely without precedent.

I. Innovation without Guardrails: The Inequities of Science as an "Endless Frontier"

- As federal funding for science, technology, and medicine rose dramatically in the post-World War II years, considerations of equity—how benefits would be distributed, or how technological progress or failures might address or exacerbate existing social inequities—were not evident in policy discussions.
- In Vannevar Bush's report, *Science: The Endless Frontier*, science itself was understood as a fundamental general good, with little attention to equity, fairness, or justice in its practices or outputs.
- Central to the report's vision for public welfare was the potential for "scientific capital" to further the goal of full employment.

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- Of course, there were many limitations in the vision of science and social progress laid out in *Science: The Endless Frontier*. It downplayed both the destructive potential of innovation and the threat that technological developments might generate social harm like mass unemployment.
- One shocking example of the price paid for the government's laissez-faire approach to science was the Cutter incident in 1955, in which supplies of polio vaccine mistakenly containing an active disease-causing virus were distributed and caused multiple cases of polio.
- Innovation policy produced inequities in the post-World War II era not only because it ignored the downsides of technology, but also because policy makers were inattentive to the fact that scientific innovation generated harms by itself relying upon social inequities in the generation of new knowledge.
- In the decades that followed, these routine exploitative practices, such as the use of institutionalized persons as research subjects (practices that were elemental parts of scientific innovation), would be subject to scathing social criticism, policy critique, and expanding oversight.

II. Pursuing Equity in Science, Medicine, and Technology Governance in the 1960s: Ideals and Limitations

- A fundamental driver of policymaking in the 1960s was the growing conviction that science, technological innovation, and applications required greater oversight in order to serve the common welfare.
- Early in the 1960s, a confluence of factors shaped a new commitment to "technology assessment" that would dramatically attenuate Vannevar Bush's idea of the endless frontier of scientific innovation.
- Several types of inequity came into view, along with new governance systems for managing innovation, first among which was consumer protection.
- In a similar vein, science and technology oversight expanded to address inequities that had built up over previous decades: protecting research subjects and patients and expanding equitable access to medicine and health technologies.
- Medicare and Medicaid legislation also created new institutions to oversee, regulate, and guide coverage, albeit institutions that continued the existing trend of using funding as leverage to shape the socially, geographically, and demographically equitable application of innovation to health care. Attention to certain vulnerable groups—research subjects, consumers, the elderly, the poor—exposed one face of social inequity during the 1960s; at the same time, deep-seated racial and ethnic inequalities in science, technological, and medical innovation also came into focus.
- The convergence of Medicare reform and civil rights showed how the federal government could use funding leverage to advance health equity, making large advances in rapid and dramatic fashion.
- The turmoil of the era informed new approaches to governance in the name of justice, fairness, and equity in science.
- Anti-technology skepticism flourished in many of the movements of the era, from the rise of environmentalism in the wake of the publication of *Silent Spring* in 1962 to protests over chemical weapons used in Vietnam to concerns over the threat of nuclear technology.
- A new idea of "technology assessment" emerged in this context.
- Attention to racial inequities were rarely part of these new debates over technology assessment, an omission that mirrored conversations in the medical realm.
- Henry Beecher's 1966 essay in the *New England Journal of Medicine* highlighted a growing divide between the interests of researcher and subject and doctor and patient, exacerbated by the growth of the research enterprise.
- Importantly, Beecher's exposé had one glaring blindspot: it never mentioned the racial and ethnic minority inequities at the center of the ongoing exploitation of research subjects.
- Beecher's exposé fell in the middle of a decade of dramatic reforms in science and technology governance, in which new social values grounded in patients' rights and accountability of experts and government were reshaping the ecosystem of science.

III. Disciplining Technological Innovation in the 1970s: Promises and Pitfalls

- The 1970s were a high-water mark of commitments to equity. Many of these advances came in the guise of new professional norms, while others were achieved through government programs enacted to ensure equity. However, without universal programs or equivalent expansions of government authority, the latter advances rested on unstable ground.
- The case of access to kidney dialysis highlighted the continuing power of direct federal government funding of new entitlements to enhance social equity in access to life-saving science and technology.
- Passage of the Kidney Dialysis Entitlement in Medicare represented a high point in the federal government's attempt to remedy market inequity with regard to a single life-saving technology.
- Amid the discussions about how to implement a national health insurance, health policy scholar Rashi Fein indicated that better measures of equity were needed.
- If dialysis legislation continued to build on the 1960's model of government addressing equity through financing, to a large extent, the Health Maintenance Organization (HMO) Act of 1973 and the creation of the Office of Technology Assessment (OTA) represented a break in this form of technology governance. These emerged not from pressures to ensure equity or fairness in the development of technologies, but from policy actors who valued efficiency as they expanded the role of economic analysis in governmental affairs.
- Senator Ted Kennedy's failed effort to establish a national health insurance and the passage of the HMO Act of 1973 highlights how the tide was shifting away from global equity-based arguments for expanding access and toward specific market incentives that advanced more limited equity ideals—specifically, rural and urban health.
- The HMO Act of 1973 provides a case in point of the new focus on incentives in health and technology governance.
- The rise of the OTA in these years, along with its fraught history and ultimate demise in the 1990s, would symbolize the promise and limitations of this new type of technology governance in the 1970s.
- A multitude of environmental and scientific concerns, from oil spills to the implications of supersonic aircraft and sonic booms to pesticide use and air pollution, suggested the need for an advisory body to assess technology.
- For policy makers, the need for expertise was a driving force behind the OTA; issues of equity and the disparate social effects of technology did not figure at all in the vision for the office.
- Meanwhile, the energy crisis of the 1970s raised particular concerns about energy needs, social equity, and government policy regarding the energy sector.
- These limitations of technology assessment, including its inattention to inequities or inability to mitigate unequal impact, did not go unnoticed by insightful critics.
- Whenever equity concerns did appear in the OTA, they appeared in a limited and circumscribed way.
- From the outset, supporters of the OTA sought to distance technology assessment from regulation and positioned the office as an information provider above all else.
- The 1970s began with faith, carried over from the 1960s, that new institutions—Medicare, HMOs, and the OTA—might fulfill a broader mission of science for the common good. Over the course of the decade, these ideals confronted significant limitations: ideological opposition, fiscal limitations, and growing skepticism about the use of government powers to advance social equity.

IV. Piecemeal Equity in Technology Governance: The Reagan Era and Beyond

- In the 1980s, three pieces of legislation highlighted a conservative political turn in the federal government's approach to addressing inequities that arose in science, technology, and medicine. In the increasingly pro-business, deregulatory climate defined by market-oriented drug and technology development, the piecemeal approach to equity prevailed.
- The ideal of governing science and technology innovation to promote equity—that is,

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greater fairness in the distribution of benefits from innovation—did not disappear entirely, but the governance philosophy behind it adapted to more conservative times, with increasing attention paid to the idea of incentivizing for equity.
- Even prior to the Reagan revolution, throughout the Carter administration a pro-business, regulation-wary climate was growing in government.
- The establishment of special vaccine courts to compensate people injured by vaccines exemplified the new ecosystem for dealing with science and technological harms in this era. Like the Orphan Drug Act and the Bayh-Dole Act, it offered an industry-friendly incentive, in this case by reducing industry liability when vaccine technologies proved harmful.
- The result of these laws—incentivizing drug production, reducing liability, and speeding technology transfer from universities to the private sector—was a new ecosystem that prioritized technology development above other ideas about the public good.
- These policies promoted speed and innovation in the technology development ecosystem, limiting government oversight that had expanded through efforts to mitigate harm.
- Perhaps not surprisingly, the Reagan revolution also saw intensifying criticism of the goals of "technology assessment," and the demise of the OTA when Republicans gained legislative power in 1992.
- The policies of the 1980s and 1990s created a new set of ground rules, a profound shift in the ecosystem of technology governance. Promoting—not disciplining—innovation made financial incentives, rather than careful assessment and regulation, the instrument of choice, as equity considerations moved to the background.

V. The Growing Crisis of Access, Accountability, and Calls for Equity-based Policies

- In the last two decades, as economic trends have increased social inequalities, the topic of equity and technological innovation has figured ever more prominently in academic policy discussions regarding technological, scientific, and medical innovation.
- One example of a law that subjected one area of science and technology innovation to extraordinary market constraints in the name of social equity and preventing discrimination stands out: the Genetic Information Nondiscrimination Act (GINA) enacted in 2009.
- Over the past two decades, other problems with the innovation-oriented, deregulatory, pro-business ecosystem have emerged, leading to calls for accountability and improved regulation, including through post-market surveillance.
- The wave of lawsuits against drug companies brought by pregnant women, children, and others harmed by illegal marketing over the past twenty years highlights the heavy toll that deregulation has had on public health. These cases raise sweeping questions of governance and regulatory failure, with only hints at the underlying inequities in the users affected by the malfeasance.
- New technological developments in a range of fields, from genetics to cryptocurrency to new modalities of transportation, as well as long-standing questions of access and consumerism, have kept the question of equity and science governance in the forefront of policy discussion.
- Against the backdrop of history, the years 2020–2022 mark a sea change, with equity emerging as a new governance ideal. Historically speaking, the Biden administration's decision in 2021 to prioritize racial equity in an "ambitious whole-of-government equity agenda" is unprecedented, although some of its ideals and features certainly resonate with equity commitments of the past, particularly the 1960s and 1970s.
- The one area in which federal and state governments have sought to translate equity concerns into practice is the distribution of COVID-19 technologies.

Paper Conclusions

- Learning lessons from the past, we must continue the unfinished equity work of the 1960s and 1970s: There is ample precedent for equity-based governance of technology, most notably in the 1960s and early 1970s. However, a substantial and sweeping commitment to equity in technology governance has yet to be pursued as a matter of U.S. federal policy. Since the 1960s and 1970s, even as policy makers accept that science, medical, and tech-

nological innovation, and their applications require greater oversight to serve the common welfare, robust governance for fair distribution of the benefits of science and technology has lagged as a policy commitment.

- Absence of governance and laissez-faire approaches to regulation produce inequities: The price paid for abdicated governance of technologies is severe and lasting, with the burden often borne by the most vulnerable members of the population. Prior to the 1960s, for example, policy makers were inattentive to the prospect that scientific innovation generated harms—most notably by unregulated use of human subjects, institutionalized persons, and other vulnerable groups. This practice produced deep social inequities in the process of generating new knowledge. Laissez-faire governance in later eras similarly fostered inequities via neglect.
- Build on successful models of using federal powers for equity: Several important federal programs such as Medicare have exercised power to ensure equity. The convergence of Medicare reform and civil rights, for example, showed how the federal government could use funding leverage to advance health equity, making large advances in rapid and dramatic fashion. Medicare and Medicaid legislation (as well as kidney dialysis legislation) created new institutions of government to oversee, regulate, and guide coverage; such institutions also continued the important trend of using funding as leverage to shape the socially, geographically, and demographically equitable application of innovation to health care.
- In some times and contexts, outright restrictions of technology use and dissemination are necessary to prevent inequities: Even with the increasing reliance on incentives to promote equity in technology governance since the 1980s, the example of the GINA Act stands out, representing an instance in which the government restricted an entire industry from accessing information in service of preventing inequities. Fear of curtailing innovation extends back to *Science: The Endless Frontier*, but a proper balancing of interests can allow scientific research to advance while restricting its potentially harmful applications.
- Incentives can work for remedying inequities, but they can also fail: The Orphan Drug Act remains a powerful model of incentives for equity in drug development. The HMO legislation provides a case in point of how incentives in health and technology governance (originally aimed in part at increasing access in underserved areas) have, in subsequent years, strayed far from these stated ideals. Though they gradually became the default over the course of the 20th century, this history reminds us that incentives are simply one tool among many policy options.
- A new, expanded model of technology assessment is needed to meet the challenges of technology governance in the 21st century: Going forward, a commitment to comprehensively assess the disparate social effects of technology is an important goal, but any new model of technology assessment in the 21st century must not repeat historical errors and blind spots. For example, attention to racial inequities were rarely part of debates over technology assessment in the 1970s. These limitations in technology assessment (its inability to consider inequities or to act to mitigate unequal impact) did not go unnoticed by insightful critics. Policy scholar Lenneal Henderson's critique that the dominant "models and techniques rarely include the economic and political conditions, dynamics and aspirations of black urban communities," as well as his call for more black involvement in the field, ring as true today as they did in 1974. Going forward, technology assessment can be updated for the 21st century through a commitment to studying inequities and an expansion of its keystone values and tenets to include broadening participation and sharing responsibility.
- Learning from the past, the promoting of fairness and equity in technology governance must expand beyond the governance policies developed in the 1980s—the Bayh-Dole Act, vaccine courts, the Orphan Drug Act—that shape today's ecosystem. That governance model prioritized the speed and efficiency of technology transfer and patenting for innovation and profit and relied on incentives to promote fairness, justice, and equity. These latter values, however, remained minor concerns. An important step toward advancing fairness and equity in technology/science innovation in the 21st century should involve supplementing the incentives approach with a more robust commitment to other governance practices used in the past. These include: (a) using federal funding, priority-setting, and other leverage to advance equity; (b) expanding and developing a new equity-based

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model of technology assessment; and (c) encouraging more robust engagement between innovators and the groups and communities that have been poorly served by the current innovation system.

Technology assessment models and techniques rarely include the economic and political conditions, dynamics and aspirations of Black urban communities. Marginal impacts of technologies such as transit systems, water and solid waste techniques...on the political economy of particular and aggregate Black metropolitan neighborhoods are neither known nor included in the planning and evaluation of these technologies. And yet there is evidence to indicate both the positive and negative impacts of technology on Blacks. How such evidence is conceptualized and related to Black goals and values needs more attention from those involved in technology assessment and decisions. (Henderson, 1974, pp. 9–18)

Abstract: A review of the past eight decades of U.S. science, health, and technology policy reveals that federal government efforts to promote equity and fairness in technology development have been piecemeal and unsystematic. This investigation finds that policy makers have embraced equity—defined as attention to justice, proportional fairness, and inclusion—as a value only in particular social contexts and instances: in the early 1970s, for example, to ensure equitable access to new technologies such as kidney dialysis, in the 1980s to incentivize industry to develop "orphan drugs" to benefit disease populations whose small numbers attracted little private sector research and development (R&D), and in the 2000s to restrict insurance-based discrimination aimed at people on the basis of their genetic conditions. These actions in the name of equity and fairness in science and technology governance have been sporadic, often contested, and uneven. Nonetheless, identifiable trends in equity and technology governance have emerged as government policies shifted over the decades. The 1950s marked an era promoting innovation without guardrails, and inequities in the system were widespread; the 1960s and 1970s witnessed important attempts to govern innovation with modest attention to removing system-wide inequities, for example, in the exploitation of vulnerable subjects and to using the lever of government programs to equalize access to technology products; and the decades since the 1980s have seen both rollbacks on these commitments as well as specific targeted piecemeal efforts to advance equity in science, technology, and medicine. One finding of this report is that over the past 80 years, equity concerns have never been a primary commitment in technology policy and assessment. Nor has the U.S. government undertaken a systematic approach to equity in technological development. Another finding is that the goal of incorporating equity into technology innovation has been contentious and difficult to sustain. Small progress in specific areas has been vulnerable to rollbacks. For most of the past eight decades, other values have guided innovation governance: namely, a commitment to laissez-faire innovation, deference to pursuit of profit and speed in innovation, and willingness to allow market and consumer forces to play leading roles in determining who benefits from science and technological innovation. The result of this policy history has been persistent and sustained large-scale inequity, punctuated by specific narrow crises and zones (protection of subjects, health insurance access, genetic discrimination, orphan drugs, kidney dialysis access, and so on) in which equity ideals have surfaced and shaped laws, procedures, and policies.

INTRODUCTION

This white paper explores technology governance in the United States from the period following World War II to today. In particular, it examines milestone policies and controversies within the U.S. technology governance ecosystem[1] during this period. Such touchstones include the dialysis entitlement within Medicare, the creation and demise of the congressional Office of Technology Assessment (OTA), the National Vaccine Injury Compensation Program (VICP), and important legislation such as the Genetic Information Nondiscrimination Act (GINA) and laws supporting adaptive technology following the passage of the Americans with Disabilities Act (ADA). The review examines the language of legislation, regulation, and enactments, as well as social commentary, in order to document changes over time in the underlying values and principles that have guided technology governance.

The report argues that if there was a high point in the federal government's commitment to equity in technology access, it occurred in the late 1960s and early 1970s, but that this commitment has been slowly eroded over time. The apex of that commitment to equity was passage of dialysis legislation in 1972, in which explicit principles of fair distribution of a life-saving technological good was the focal point of technology governance. Such a commitment was the outgrowth of an era of intense focus on civil rights, social welfare, and sweeping health legislation. Another milestone development of the era was a bold and sweeping interest in technology assessment that led to the creation of the OTA in 1974. Yet, even in this era of heightened concern for distributive questions, equity in technology access was often an afterthought rather than the impetus for major policy initiatives.

In subsequent years, owing to transformations in American political culture, fiscal conservatism, and shifting pro-market ideologies, there has been a great deal of backsliding in regard to these equity commitments. Later decades have been defined by sporadic and piecemeal efforts, like the passage of the Orphan Drug Act (1983) and GINA (2008), which have targeted specific sectors and interest groups to curb inequities that have developed in the health marketplace. On the whole, however, efforts to promote equity in technology governance—whether by incentivizing industry or restricting discriminatory applications—have been piecemeal. In recent decades, such efforts have largely sought to fix problems of maldistribution in the market. For the most part, in U.S. technology policy, equity has become a minor value. Concerns for efficiency and speed of innovation, alongside risk mitigation, play more central roles in technology governance.

A substantial and sweeping commitment to equity in technology governance has yet to be pursued as a matter of federal policy; however, such a commitment is not entirely without precedent. Here, we consider how equity has often been an *implicit* value associated with broader ideas about "the public good." Making equity concerns *explicit* is an important step toward a technology governance that will work for all.

INNOVATION WITHOUT GUARDRAILS: THE INEQUITIES OF SCIENCE AS AN "ENDLESS FRONTIER"

As federal funding for science, technology, and medicine rose dramatically in the post-World War II years, considerations of equity—how benefits would be distributed, or how

[1] By "technology governance," we refer to the broad array of strategies through which the federal government has addressed itself to the benefits and harms—actual and projected—of technological developments. These might include obligations tied to federal grants, market incentives and intellectual property protection, safety regulations and standards, compensation programs, and more. Only a capacious definition such as this can capture the multiple ways that equity concerns become manifest.

technological progress or failures might address or exacerbate existing social inequities—were not evident in policy discussions. Using vulnerable people as experimental subjects in scientific research was the norm; informed consent did not exist in any formal sense. Nor did researchers spend much effort considering how the fruits of scientific research would be distributed equitably. The United States in the wake of World War II was a fragmented society where racial segregation was perfectly legal in many states. In other words, inequities in science, innovation, and society were a norm, and not often considered to be connected.

Despite these inequities, policy makers were silent on the question of whether technology innovation should advance social equity. It was simply not a question worth asking. Indeed, as historian David Rothman has argued, laissez-faire policies prevailed.

The values driving government investment in science gestured toward the role of scientific innovation in advancing social welfare and economic progress. On November 17, 1944, President Roosevelt wrote to Vannevar Bush, director of the wartime Office of Scientific Research and Development, seeking recommendations on how to put military research to civilian ends, wage further war against disease, aid research activity, and nurture future scientific talent. Bush responded with the report *Science: The Endless Frontier*, often hailed as laying the foundation for U.S. science and technology policy. The report articulated a vision of science and technology innovation that would result in a lifting of all boats, with government funding of science serving as a catalyst for social progress, jobs, and a generalized commitment to public welfare. Notably, the report remained largely silent about exactly how basic research would be translated into applications and who would have a say in the process.

Science itself was understood as a fundamental general good, with little attention to equity, fairness, or justice in its practices or outputs. The report's centerpiece was a proposal for a new agency—later partially realized in the National Science Foundation—guided by a set of five principles that elevated scientific autonomy above utility. The agency would provide stable funds for long-range programs doled out by citizens who understood and valued the research process over any potential outcomes. Moreover, it would neither operate its own laboratories nor attempt to impose its own rules upon the operation of universities and research institutes. Nonetheless, this scientific research organization would seek to "maintain the proper relationship between science and other aspects of a democratic system" through "[the] usual controls of audits, reports, budgeting, and the like," adjusted to "the special requirements of research" (Bush, 1945, p. 33). It would be accountable, but only on its own terms. These principles articulated what subsequent commentators have referred to as a "social contract of science": the government provides money to scientists and gets out of the way, since the results of research will eventually translate into beneficial technologies (Guston, 1994).[2] There was no discussion of justice, fairness, equity, or ethics that should underpin or inform the expansion of research funding, let alone concern for inequities in how the eventual goods flowing from research would be distributed.

The principles of *Science: The Endless Frontier* are fundamentally products of their time and place. The report is suffused with Bush's confidence in a compact between government and the market. In this light, the report related to equity in two ways: (1) it sought to expand science education; and (2) it envisioned basic research as promoting application by others, which then was intended to support full employment and advance the public welfare. Science was understood merely as the catalyst for social changes that would occur elsewhere,

[2] "Crudely, it holds that the federal government provides funds for basic research in academia and agrees not to interfere with scientific decision making, in exchange for unspecified technological benefits that could ultimately flow from such research." (Guston, 1994, p. 215)

in steps labeled "applications." The public good imagined in *Science: The Endless Frontier* was an aggregate good.

The report, and its commitments to expanding access to university education and building "scientific capital," emerged in an era in which specific class, racial, and gender assumptions prevailed about who did science (Bush, 1945).[3] Although studies showed that "talented individuals [could be found] in every part of the population," higher education remained a realm of the wealthy. Bush appealed to ideals of equal opportunity, proposing merit scholarship programs as a counterbalance to economic inequality. If racial equality of opportunity was absent as a goal in this report, so too was equality of opportunity for women in the sciences. Although the report mentions women explicitly, the judgment of history does not bear favorably on what came to pass. In these post war years, passage of the GI Bill, which expanded access to college and science education, would benefit almost exclusively white, straight, male veterans. Jim Crow segregation and funding practices continued to prevent Black K–12 students from accessing science education (Katznelson, 2005; Malcolm, 2022).

Central to the report's vision for public welfare was the potential for "scientific capital" to further the goal of full employment. Bush's assumption was that this "capital" of basic research could then generate dollars and national welfare. All that was needed was for the government to clarify tax deductions for research expenditures in industry and strengthen intellectual property protections. The market would do the rest (Bush, 1945, p. 7).

Of course, there were many limitations in the vision of science and social progress laid out in *Science: The Endless Frontier*. It downplayed both the destructive potential of innovation and the threat that technological developments might generate social harms like mass unemployment. Bush's report was released in July of 1945, just a month before the atomic bombings of Hiroshima and Nagasaki. Indeed, the report's biggest shortcoming was its apparent lack of concern for the consequences of scientific innovation, assuming that science would lead inexorably toward undifferentiated social good. Critics of Bush's view of innovation were quick to emerge in the postwar years. In a 1947 letter to the *Atlantic Monthly*, published as "A Scientist Rebels," Norbert Wiener wrote that in the wake of the bomb, "to provide scientific information is not a necessarily innocent act, and may entail the gravest consequences" (Wiener, 1947, p. 46). He refused to participate in further military research, raising new questions that would continue throughout the years of the Korean War and into the era of the Vietnam War about unethical and socially beneficial uses of science. Further, Weiner cast aspersions on Bush's neat equation between scientific progress and full employment, writing to the head of the American Auto Workers Union in 1949 to warn that automation could lead to "large scale industrial unemployment" (Michael et al., 2017). These criticisms suggested that technological innovation needed to be regulated carefully, and watched closely, lest its effects generate new social inequities.

One shocking example of the price paid for the government's laissez-faire approach to science was the Cutter incident in 1955, in which supplies of polio vaccine mistakenly containing an active disease-causing virus were distributed and caused multiple cases of polio. As historian Allan Brandt has noted, "By abdicating a more active role" in the testing and distribution of the vaccine, "the government invited the possibility of crisis." Pharmaceutical companies like Cutter Laboratories were trusted to manufacture safe products under intense pressure, with neither regulation nor incentives to secure that obligation. This avoidable

[3] "Two great principles have guided us in this country as we have turned our full efforts to war. First, the sound democratic principle that there should be no favored classes or special privilege in a time of peril, that all should be ready to sacrifice equally; second, the tenet that every man should serve in the capacity in which his talents and experience can best be applied for the prosecution of the war effort. In general we have held these principles well in balance." (Bush, 1945, p. 24)

incident compounded with troubling ethical oversights in the testing of the vaccine on human subjects (Brandt, 1978, p. 268).

Innovation policy produced inequities in the post-World War II era not merely by ignoring the downsides of technology, but also because policy makers were inattentive to the fact that scientific innovation generated harms by itself relying upon social inequities in the generation of new knowledge. Innovators at the time also *relied upon inequities* and the absence of ethical guardrails in conducting research (see Box B-1). Research was routinely conducted among vulnerable populations without their consent, including prisoners, institutionalized patients with mental illness, nursing home residents, soldiers, and patients at academic health centers. Some of the leading researchers of the era, such as Jonas Salk, relied on institutionalized children with mental illness in testing polio vaccines. Scientific research thus embodied a profound paradox: the promise of public goods for all was often built upon exploitation of vulnerable people, whose bodies were crucial to the testing of drugs and new technologies.

BOX B-1

ABDICATION OF GOVERNANCE: INNOVATION WITHOUT GUARDRAILS

"The twenty years between the close of World War II and the appearance of Henry Beecher's exposé witnessed an extraordinary expansion of human experimentation in medical research... Utilitarian justifications that had flourished under conditions of combat and conscription persisted, and principles of consent and voluntary participation were often disregarded. This was, to borrow a phrase from American political history, the Gilded Age of research, the triumph of laissez-faire in the laboratory. Yet between 1945 and 1965 very few investigators or their funders took note of the changed circumstances. The thrust of public policy was not to check the discretion of the experimenter but to free up the resources that would expand the scope and opportunity for research." —David Rothman. 1991. *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making*. Basic Books.

"The ethical aspects involved in the development and distribution of the Salk vaccine are varied and complex...Testing with human subjects presented a series of problematic considerations, from the suspect use of mentally defective children to the use of healthy, parent-volunteered youngsters...The federal government [played a] minimal role in...[the] scientific advance...By abdicating a more active role, the government invited the possibility of crisis. The Salk episode [the Cutter incident in which tainted vaccines caused polio in a group of vaccinated children] seems to indicate a less than complete commitment by the government to the public welfare." —Allan Brandt. 1978. Polio, politics, publicity, and duplicity: Ethical aspects in the development of the Salk vaccine. *International Journal of Health Services* 8(2):257–270.

"In the case of the Tuskegee Study, in which some 400 poor, mostly illiterate African American sharecroppers became the unwitting objects of investigation, the seeds of ethical disaster were planted in the selection of such vulnerable subjects, so easily exploited by the combined power of government and science." —Larry Churchill and Allan Brandt. 2000. Preface to *Tuskegee's Truths: Rethinking the Tuskegee Syphilis Study*, edited by Susan M. Reverby. Chapel Hill: University of North Carolina Press.

In the decades that followed, these routine exploitative practices, such as the use of institutionalized persons as research subjects, practices that were elemental parts of scientific innovation, would be subject to scathing social criticism, policy critique, and expanding oversight. But the fundamental tensions of the "Endless Frontier" era remained, pitting the laissez-faire governance approach to innovation, along with the assumption that the advance of science would naturally foster social welfare, against an emerging contrary perspective: the argument that technology innovation, whether in drug development, military applications, private enterprise, or academic research, needed some degree of oversight in order to fulfill those ideals. Moreover, this emerging criticism contended that the system of scientific innovation itself was founded on deep inequities.

These tensions over governing scientific and technological innovation would animate U.S. science and technology policy in the decades to come.

PURSUING EQUITY IN SCIENCE, MEDICINE, AND TECHNOLOGY GOVERNANCE IN THE 1960S: IDEALS AND LIMITATIONS

A fundamental driver of policy making in the 1960s was the contention that science, technological innovation, and their applications required greater oversight in order to serve the common welfare. In a decade defined by civil rights activism and legislation, consumer consciousness, advancements for women in the academy, deinstitutionalization of the mentally ill and hopes of their integration into society, public insurance reform expanding health insurance access for the elderly and poor, burgeoning antiwar protest, and the "war on poverty," the definition of the public good was changing rapidly. Scientific and technological innovations became subject to unprecedented scrutiny. The decade would see sweeping reforms in scientific innovation and technology governance, many of which sought to reduce or remove vexing inequities.

Several high-profile failures of governance had already become glaring as early as the late 1950s. At the time, congressional hearings focused on the pharmaceutical industry's failures to disclose drug side effects, but it would take the thalidomide scandal in 1960 to drive major reform. Congress, previously hesitant to expand oversight, enlarged the authority of the Food and Drug Administration (FDA) to require proof that a drug was both safe and effective. New governance systems for innovation emerged slowly over the next two decades, with new practices of informed consent, new institutions to govern ethical conduct, and laws mandating disclosure of side effect risks to consumers and imposing other requirements on researchers and manufacturers in the name of protecting the public health. This episode was indicative of the mood of the decade, in which the government was increasingly held accountable for the harms of technological development.

Early in the 1960s, a confluence of factors shaped a new commitment to "technology assessment" that would dramatically attenuate Vannevar Bush's idea of the endless frontier of scientific innovation. Two developments stand out. First, the political economy of Cold War spending led to a vast expansion of research and higher education. That decade produced new prosperity and rapid growth in domestic consumption, such that it was christened as "the decade of the consumer." Second, the 1960s was also a decade of social turmoil. Antiwar and civil rights movements aimed to hold the government accountable for inequity and unjustified violence. President Johnson's "Great Society" programs aimed to address gaps in the New Deal's provisions for economic citizenship in ways that were sensitive to problems of equity and structural disadvantage. These trends birthed a new regulatory climate by promoting the rights of consumers, minorities, and conscientious

objectors, which spurred a broader conversation about civilian participation in technological decision making.

Several types of inequity came into view, along with new governance systems for managing innovation, first among which was consumer protection. Described by President Kennedy in 1962 as "the only important group in the economy who are not effectively organized, whose views are often not heard," consumers moved to the center of the policy stage (Browne Ittig, 1983). Endowing consumers with rights—to safety, choice, information, and a voice at the table—empowered new legislation and administrative oversight of technological development. Most visible were the efforts of Ralph Nader, whose 1965 book *Unsafe at Any Speed* led to the passage of the Highway Safety Act the following year and served as inspiration for a group of law and graduate students, known as "Nader's Raiders," who brought his research-led model to other regulatory agencies.

In a similar vein, science and technology oversight expanded to address inequities that had built up over previous decades: protecting research subjects and patients and expanding equitable access to new technologies. In many of the reforms undertaken, racial inequities remained subsidiary concerns, lagging in importance behind general questions of *safety*—wholesale protections of consumers, research subjects, patients, and other disadvantaged categories of persons from the harms that scientific innovators had visited upon them (Cohen, 2003).[4]

First, there was the problem of how vulnerable subjects and consumers were exploited or harmed by scientific innovation in academic and non-academic research. In the early 1960s, for example, FDA authority over drug approval expanded dramatically in the wake of public shock over revelations that thalidomide, a drug prescribed for morning sickness, was tied to deaths and birth defects in thousands of infants. Protecting consumers and research subjects required a different kind of governance altogether. "From a policeman of safety," explained William Curran, "the FDA was transformed into an arbiter of value, quality, and success in scientific achievement" (Curran, 1969, p. 552). New practices emerged, including informed consent, the creation of Institutional Review Boards (IRBs), and consumer protection laws that aimed to hold innovators accountable and empower vulnerable research subjects and consumers. The FDA oversaw an expansive set of new requirements on industry, including proof of therapeutic efficacy for drugs, comprehensive requirements for clinical testing, controls on drug advertising, labeling to disclose contraindications and harmful side effects, and the elimination of a loophole that led to automatic approval of an application after a passage of time.

Second, there were also inequities in access to beneficial medicines and health technologies. Pressures to create a national health insurance program led to the establishment of Medicare and Medicaid in 1965. Ever since President Truman's call for a Fair Deal for Americans via a national health insurance program, the proposal had faced stiff opposition. As Theodore Marmor argues, by the mid-1960s Medicare was conceived to be a first step toward that broader goal (Marmor, 2000). As a program targeted at the elderly, the problem that Medicare and Medicaid sought to address was truly one of social inequity because of the yawning gaps between an employer-based private health insurance system and those left behind by age or poverty, thus lacking access to insurance and to health care.

Medicare and Medicaid legislation also created new institutions to oversee, regulate, and guide coverage, albeit ones that continued the existing trend of using funding as leverage to

[4] Consumption was itself an arena for civil rights activism. Historian Lizabeth Cohen has shown how "Don't Buy Where You Can't Work" efforts that began during the Great Depression fed into a mass movement geared toward direct action in the consumer marketplace. In turn, Cohen argues, "[the] legal and commercial right to participate drew more attention than the economic right to a fair share," stealing the spotlight from questions of redistribution and equity (Cohen, 2003, p. 190).

shape the socially, geographically, and demographically equitable application of innovation to health care. The use of government leverage to accomplish equity goals—along lines of race but also regional access—would become the topic of ongoing political debate (Cohen et al., 2015; Katz Olsen, 2010; Oberlander, 2003). The evenness of Medicare's implementation across U.S. states contrasted with the unevenness of Medicaid coverage, prompting critics in the 1970s to observe that "although it is well known that Medicaid eligibility varies among states, very little effort has been made to implement the program more equitably" (Okada and Wan, 1978, p. 343).

Attention to certain vulnerable groups—research subjects, consumers, the elderly, the poor—exposed one face of social inequity during the 1960s; at the same time, deep-seated racial and ethnic inequalities in science, technological, and medical innovation also came into focus. The Black Freedom movement brought stark racial inequities to center stage with demands for the freedom to vote, freedom from employment discrimination, and equal access to educational and housing opportunities. Passage of the Civil Rights Act, Voting Rights Act, and Housing Rights Act helped to chip away at entrenched racism and the legacies of legalized segregation. When coupled with litigation or other legislation aimed at undoing segregation and racism, these acts turned a language of rights that had previously worked *against* regulation (for example, state's rights) into a formidable tool (civil rights) for addressing institutional harms.

The convergence of Medicare reform and civil rights showed how the federal government could use funding leverage to advance health equity, making large advances in rapid and dramatic fashion. On the eve of passage of Medicare and Medicaid, racial inequities in health care were deeply entrenched. Most blatantly, many medical institutions remained segregated, but the mid-1960s saw a sea change in the federal government's use of funding to advance racial equity. The 1963 federal court ruling in *Simkins v. Cone* opened the door for the federal government to use funding for hospitals as leverage to compel hospitals to reform, integrate, and remedy persistent inequities in access to care. For decades since the 1945 passage of the Hill-Burton Act, also known as the Hospital Survey and Construction Act, federal dollars had flowed to states, many of which used the funds to build and sustain segregated facilities. The passage of Medicare in 1965 created a convergence of forces. A new stream of funding to hospitals, along with commitments to equity, provided extraordinary leverage to a new agency charged with implementing Medicare to compel hospitals to desegregate. As Historian David Barton Smith notes, "The most controversial section of the civil rights bill, Title VI, prohibited the provision of federal funds to organizations or programs that discriminated on the basis of race." In early 1966, the Surgeon General's Office created the Office of Equal Health Opportunity (OEHO), a unit delegated with the specific responsibility of certifying hospitals to become Medicare providers. The process was politically contentious, but, as Smith explains, by the time Medicare was implemented "hospitals became the most racially and economically integrated private institutions in the nation" (Smith, 2015). See Box B-2 for quoted material regarding these new systems.

The turmoil of the era informed new approaches to governance in the name of justice, fairness, and equity in science. The idea that scientific, medical, and technological innovation needed robust oversight also expanded, inspiring new laws, new administrative agencies and powers, new exercises of funding leverage, new rights recognized for subjects and patients, and new professional norms. Across areas of technological, science, and medical innovation, investigators were confronted with shocking allegations of persistent mistreatment of research subjects, misaligned incentives in research, and the need for ethical reform.

Anti-technology skepticism flourished in many of the movements of the era, from the rise of environmentalism in the wake of the publication of *Silent Spring* in 1962 to protests over

BOX B-2 THE DISCOVERY OF INEQUITY IN THE 1960S: NEW SYSTEMS FOR GOVERNING RESEARCH, TECHNOLOGY, AND HEALTH CARE

"In many respects, what the civil rights movement and those implementing the Medicare program were able to accomplish together was the most significant legacy of both. American hospitals went from being the nation's most racially and economically segregated institutions to its most integrated." —David Barton Smith. 2015. Civil Rights and Medical Care: Historical Convergence and Continuing Legacy. In *Medicare and Medicaid at Fifty*, edited by A. Cohen et al. New York: Oxford University Press. Pp. 21-38.

"Viewed from the perspective of 1965, the enactment of Medicare and the first years of its implementation resulted in a tremendous forward thrust of insured hospital and related coverage on an equitable and non-discriminatory basis to all aged persons," —Arthur E. Hess. 1976. A Ten-Year Perspective on Medicare. *Public Health Reports* 91:299-302.

"This enhanced sensitivity and expanded range of alternatives does not necessarily imply that the deleterious side effects of technological change are worse today and they were a century or two ago—although some obviously are. It does imply that our visions and capacities have so broadened and deepened that we can now, for the first time in human history, realistically aspire to have it both ways: to maximize our gains while minimizing our losses. The challenge is to discipline technological progress in order to make the most of this vast new opportunity." National Research Council. 1969. *Technology: Processes of Assessment and Choice*. Washington, DC: The National Academies Press. P. 12

"One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition." —Office for Human Reserarch Protections. 1979. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

chemical weapons used in Vietnam to concerns over the threat of nuclear technology. One scholar of the decade, Matthew Wisnioski, notes that by 1968 these strands became woven together within the burgeoning counterculture: "Never before had technological power appeared simultaneously so autonomous and so inextricable from political power, and not since the machine-breaking uprisings of the early nineteenth century had so many citizens perceived technology as a force to be resisted" (Wisnioski, 2012, p. 5).[5]

[5] "By 1968, strands of critical thought provided commonality between countercultural, environmental, civil rights, and antiwar movements in what historian Theodore Roszak characterized as 'a cultural constellation that radically diverges from values and assumptions that have been in the mainstream at least since the Scientific Revolution of the seventeenth century.'" (Wisnioski, 2012, p. 5)

A new idea of "technology assessment" emerged in this context. Many academics were chastened by the political mood, balking at their colleagues' eagerness to join picket lines. Others, Wisnioski shows, sought to carve out a middle ground and reclaim the narrative of scientific progress, albeit one attenuated by social forces. Harvard University led an IBM-sponsored Program on Technology and Society, which supported numerous reports, books, and articles on how to "understand and control technology to good social purpose" (Wisnioski, 2012, pp. 52-54). Democratic congressman Emilio Daddario, a member of its bipartisan, multisector steering committee, was instrumental in bringing its findings to the federal government. The idea of "technology assessment" crystallized around a perceived need to "discipline technological progress," to carve out a "middle ground" of regulation that would allay the anti-technology sentiment threatening a key front of the Cold War. *Technology: Processes of Assessment and Choice*, the 1969 report by the National Academy of Sciences to Congress, spoke of systemic risks, while only gesturing toward "potentially injurious effects upon sectors of society" as a major issue for technology governance (NRC, 1969, p. 13).

Attention to racial inequities were rarely part of these new debates over technology assessment, an omission that mirrored conversations in the medical realm. As many scholars have documented, the field of bioethics emerged and expanded amid the tensions of the 1960s. "Medical schools and university hospitals are increasingly dominated by investigators," wrote Henry Beecher in his shocking 1966 *New England Journal of Medicine* exposé on widespread medical experimentation without informed consent. Beecher's review of the literature revealed routine and dangerous procedures conducted without patient consent, from liver biopsies to cardiac catheterization and injection of live cancer cells. In other cases, standard procedures were withheld for the sake of a scientific study. In Beecher's assessment, the interests of science and the interests of patients were diverging. His careful documentation helped inspire efforts to reform scientific innovation, to establish guardrails around innovation, and to make science not only more ethical and just but also less inequitable in the risks borne by unwitting research subjects and patients.

Beecher's essay highlighted a growing divide between the interests of researcher and subject and doctor and patient, exacerbated by the growth of the research enterprise. Decades of funding geared toward innovation and global competitiveness in science, medicine, and technology had produced a culture that routinely harmed patients and subjects, even as it produced many new products and lifesaving interventions. The incentives of the system had warped researchers' values, Beecher suggested. Anyone seeking promotion to a medical professorship had to "[prove] himself as an investigator," and the availability of research funds placed extreme pressure on ambitious young physicians. This professional dynamic, along with "the great power for good and harm in new remedies," Beecher warned, "can lead to unfortunate separation between the interests of science and the interests of the patient" (Beecher, 1966, pp. 1354-1360).

Importantly, Beecher's exposé had one glaring blindspot: it never mentioned the racial and ethnic minority inequities at the center of the ongoing exploitation of research subjects. One example was the use of women in Puerto Rico for testing high estrogen birth control pills in the 1950s. Within a few years of Beecher's exposé, the topic of racial exploitation would become unavoidable. It burst into the open in the early 1970s with public disclosure of the ongoing Tuskegee study of untreated syphilis in African American men in Macon County, Alabama, a U.S. Public Health Service study that stretched from the 1930s until 1970. It would not be until the late 1970s that the Belmont Report on human subjects research noted that these specific groups constituted a "special instance of injustice" and vulnerability to research exploitation, because "racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their

ready availability in settings where research is conducted" (OHRP, 1979). Statements like this confirmed that racial exploitation had been a key facet of research abuses, all made easier by socioeconomic conditions, geographic isolation, the illiteracy of the research subjects, compromised capacities, administrative convenience, and manipulation of existing power dynamics (OHRP, 1979).

By the end of the 1960s, new social values and a heightened awareness of potential abuses of power were reshaping the ecosystem of science. Government was called upon to reduce exploitation and to police the harms inherent to scientific innovation, though the means of doing so varied. Legal obligations of equal protection made funding a lever to enforce equal access to medical services. Yet the larger question of how to "discipline technological progress" and ensure equitable distribution of its harms and benefits remained on the table as the 1970s began.

DISCIPLINING TECHNOLOGICAL INNOVATION IN THE 1970S: PROMISES AND PITFALLS

The 1970s were a high-water mark of commitments to equity. Many of these advances came in the guise of new professional norms, while others came through government programs enacted to ensure equity. However, without universal programs or equivalent expansions of government authority, the latter advances rested on unstable ground. The regulatory constraints on innovation in the 1960s had dramatically expanded the role of government beyond merely funding innovation, and there was little credibility left in the assumption that social and medical benefits would be equitably distributed without explicit guidance. Where this system of science governance would go in the 1970s was subject to heated debate, with arguments for continued government oversight facing stiff new opposition. Indeed, as the gains of the prior decade became manifest, the groundwork was laid for opposition and limits upon that vision of governance. This shift was reflected across several policy spheres, from expansion of Medicare to cover access of dialysis, to passage of the 1973 Health Maintenance Organization (HMO) Act, to a new congressional Office of Technology Assessment (OTA).

The case of access to kidney dialysis highlighted the continuing power of direct federal government funding of new entitlements to enhance social equity in access to life-saving science and technology. In 1972, Congress expanded Medicare to include two new provisions. One ensured that people with disabilities were covered under the program, not only the elderly. The second expanded the program to ensure that patients with end-stage renal disease would have access to dialysis. The dialysis entitlement was a specific example of how concern for market-created inequities continued to drive health legislation.

Passage of the Kidney Dialysis Entitlement in Medicare represented a high point in the federal government's attempt to remedy market inequity with regard to a single life-saving technology. The market for patients with kidney failure was ridden with stark inequities, with patients with insurance more likely to be able to afford dialysis, and other patients with kidney failure who lacked financial means being denied access to the critical life-saving technology. As the influential Congressman Wilbur Mills explained, equity within this class of patient was the policy maker's concern: "to assure that any individual who suffers from chronic renal disease will have available to him the necessary life-saving care and treatment for such disease and will not be denied such treatment because of his inability to pay for it" (Rettig, 1991, pp. 189-190). As analyst Richard Rettig has explained, these considerations over dialysis disparities—the glaring fact that life and death hinged on access to a single technology—were central to the passage of the legislation (Rettig, 1991).

Amid the discussions about how to implement a national health insurance, health policy scholar Rashi Fein indicated that definitions and measures of equity needed to be sharpened: Some forms of equity should focus on creating a common baseline of services that equalize access for people in the same economic circumstances, while other definitions of equity would work to reduce disparities across people in different economic circumstances, and that better measures of equity were needed (Fein, 2005).[6] Fein pointed to the inherent limitations of cost-benefit analysis for dealing with distributive questions and suggested that overall, the difficulty of quantifying equity often led to its neglect. The technology-specific dialysis legislation also raised the specter that government actions were introducing new inequities while attempting to remedy others (Berman, 2022).[7] Why, after all, was this specific patient group and this single technology singled out for Medicare coverage?

If dialysis legislation continued to build on the 1960s model of government addressing equity through financing, to a large extent the HMO act and the creation of the OTA represented a break in this form of technology governance. These emerged not from pressures to ensure equity or fairness in the development of technologies, but from policy actors who valued efficiency as they expanded the role of economic analysis in government affairs. In this era, policy makers who were tasked with administering these programs adopted principles of budgeting and systems analysis developed for the military, what historical sociologist Elizabeth Popp Berman calls an "economic style of reasoning" that elevated efficiency over equity as a keystone value. In practice, this economic logic and attention to budgets would limit the ideals of the 1960s Great Society programs. Budgetary concerns undermined efforts to expand programs like Medicare universally, even if they also allowed for adding specific new entitlements to the program in the name of equity.

Senator Ted Kennedy's failed effort to pass national health insurance and the passage of the HMO Act of 1973 highlights how the tide was shifting away from global equity-based arguments for expanding access and toward specific market incentives that advanced more limited equity ideals—specifically, rural and urban health. In 1971, Kennedy introduced a Health Security bill that proposed replacing Medicare and Medicaid with federally-run, universal insurance. Its opening salvo declared that adequate health care should be recognized as a right, not a privilege, a view endorsed by civil rights leaders and feminists in addition to public health experts (Berman, 2022). Few in the Nixon administration opposed the idea. However, growing interest in cost control through market incentives held greater appeal, which led them to embrace legislation establishing health maintenance organizations (HMOs) as an alternative to universal insurance.

The HMO legislation provides a case in point of the new focus on incentives in health and technology governance. The law exemplified a flawed idea: that incentives for new health organizations could address ongoing problems of rural and urban "ghetto" access. As Clark Havighurst wrote in 1970, Nixon saw the HMO concept as "altering incentives in health care delivery to induce efficiencies and reduce overutilization," proposing $22 million in

[6] "We can distinguish between horizontal and vertical equity. By horizontal equity we mean that the health care system shall provide essentially the same set of health services (or a distribution of services that equalize outcomes) for persons in approximately the same economic circumstances…Vertical equity, 'fairness,' in the provision of services for persons in different economic circumstances, is more difficult to define." (Fein, 2005, p. 9)

[7] The significance of the dialysis entitlement becomes clearer in the context of the 1970s debate over national health insurance. In response to Kennedy's Health Security bill, the Nixon administration solicited a proposal from the RAND Corporation for a Health Insurance Experiment to evaluate whether the fully insured would "overuse" care compared with those on cost-sharing programs. The study took 15 years and cost $80 million, but paid dividends. Economist John Nyman argued in 2007 that this early work on moral hazard "provided the intellectual justification for transforming the health care delivery system of the 1960s and 1970s into the one we have today." (Berman, 2022, p. 122).

subsidies for HMOs that would serve rural and urban areas where medical resources were in particularly short supply (Havighurst, 1970, p. 725). Among other justifications, the HMO model was rooted in a genuine belief that such incentives could fix inequities in access to care—specifically, the geographic maldistribution of health care institutions. It thus represented a shift in approach to Great Society "welfare" programs that aimed to advance equity (Berman, 2022, p. 117).[8] The program was founded on a technocratic ideal: providing for "an ongoing quality assurance program for its health services which [stressed] health outcomes." As health policy scholars Steven Schroeder and Molla Donaldson noted, "This provision followed in the wake of congressional testimony criticizing proprietary HMOs serving the urban poor in California…and represented an attempt to protect consumers by mandating quality assurance procedures" (Schroeder and Donaldson, 1976, pp. 49-56). HMOs were an effort to innovate in equity and health governance, one that pitted the idea that incentives, quality assessment, and new structures could reduce inequities against the government-run programs of the Great Society era (see Box B-3).

The rise of the OTA in these years, and its fraught history and ultimate demise in the 1990s, epitomizes the promise of this new type of technology governance in the 1970s and its limitations. Writing in 1971, physician Lewis Thomas observed that technology assessment had become a new idea. It was now "a routine exercise for the scientific enterprises on which the country is obliged to spend vast sums for its needs…committees are continually evaluating the effectiveness and cost of doing various things in space, defense, energy, transportation and the like, to give advice about prudent investments for the future" (Thomas, 1971, pp. 1366-1368). Though such evaluations were on the rise, the groups that conducted them were, by design, limited in their authority.

A multitude of environmental and scientific concerns, from oil spills to the implications of supersonic aircraft and sonic booms to pesticide use and air pollution, suggested the need for an advisory body to assess technology (Assessing U.S. Technology, 1970.) The OTA, promoted by Congressman Emilio Daddario, sought to create an "early-warning system—a means of identifying the probable consequences, either good or bad, of technological developments before they reach widespread use." What the mechanisms of that system would be, "who should operate it, and how the findings should be implemented," remained an open question in 1970. The goal for such an office was formidable—to advise Congress on the consequences of emerging technologies, and "in the case of detrimental technologies, it would seek and foster alternative approaches" (Clauser, 1970, pp. 315-317). Nonetheless, responsibility to act would be left to the executive and legislative branches.

For policy makers, the need for expertise was a driving force behind the OTA; issues of equity and the disparate social effects of technology did not figure at all in the vision for the office. As one Senate aide explained, the primary concerns hinged on the need for experts to envision consequences. In the lead-up to the law establishing the OTA, "two recent battles helped sell Congress" on the need for such an office, the aide explained: the ABM [anti-ballistic missile system] and the SST [supersonic transport]. Without authoritative expertise of its own, Congress's ability to act was limited (Cohn, 1972). Understanding inequities and variations in technology's effects was not front and center in this vision of technology assessment.

The OTA's early reports reflected the controversies that gave rise to it, and even its proponents pointed to limitations in the model early on. For its first few years, the Office was

[8] For example, Social Security, which in principle benefited both the needy and well-off, came under increased scrutiny. Debating the economist Milton Friedman on whether Social Security should be means-tested rather than universal, Department of Health, Education and Welfare secretary Wilbur Cohen argued in 1972 that "[a] program for the poor will most likely be a poor program."

BOX B-3

DISCIPLINING TECHNOLOGICAL INNOVATION: PROMISES & PITFALLS

"The battle of equity and equality has not yet been fought in the field of health in the United States. One can predict that, at some point in the future, it will be fought...If society were to conclude that it would not finance kidney dialysis for all who need it, will it finance it for some (and, if so, how will it select the "some")?" —Rashi Fein. 1972. "On Achieving Access and Equity in Health Care." *Milbank Memorial Fund Quarterly* 50(4):157-190.

"Technology assessment models and techniques rarely include the economic and political conditions, dynamics and aspirations of black urban communities. Marginal impacts of technologies such as transit systems, water and solid waste techniques...on the political economy of particular and aggregate black metropolitan neighborhoods are neither known nor included in the planning and evaluation of these technologies. And yet there is evidence to indicate both the positive and negative impacts of technology on blacks. How such evidence is conceptualized and related to black goals and values needs more attention from those involved in technology assessment and decisions." —Lenneal J. Henderson. 1974. "Public Technology and the Metropolitan Ghetto." *The Black Scholar* 5(6):9-18.

"The OTA's [Office of Technology Assessment] deficiency was not in conducting value-informed analysis but in failing to explain that it was doing so, and in arbitrarily favoring certain values over others that can arguably be defended as meriting attention. Why, for instance, should a TA [Technology Assessment] organization routinely consider how technological change affects economic growth and productivity but not, for example, its effects on work satisfaction, parenting, gender and race relations, and corporate power relative to that of workers and local communities? Social values of one kind or another are inescapable and necessary to conducting sound analysis....Partly as a consequence of striving to appear objective, OTA reports were not consistently successful in elucidating the ethical and social implications of new technologies." —Richard E. Sclove. 2010. "Reinventing Technology Assessment." *Issues in Science and Technology* 27(1):34-38.

largely devoted to the assessment of transit projects, natural gas, and the procurement of raw materials, reflecting the overwhelming influence of the energy crisis of the time. When it did consider other topics, like the development of medical technology, the limitations of the framework seemed to almost outweigh the opportunities. Authors of a 1976 report cited prohibitive costs, in addition to a lack of standard methods, "weaknesses in the tools and techniques of social science," and a difficulty coordinating among experts as obstacles for effectively implementing technology assessment for medical innovation (OTA, 1976, p. 47).[9] Objective measurement of social consequences, perhaps unsurprisingly, was an elusive goal.

Meanwhile, the energy crisis of the 1970s raised particular concerns about energy needs, social equity, and government policy regarding the energy sector. Following the Organization of the Petroleum Exporting Countries (OPEC) oil embargo of the early 1970s and the ensuing national energy crisis, observers like Ellis Cose, in a book titled *Energy and Equity*, noted that

[9] In fact, one of the report's recommendations was not to implement any technology assessment processes at the National Institutes of Health.

minorities and the poor were particularly vulnerable to energy crises. Such observations did have modest impact in reshaping technology policy. For example, in 1978 a National Energy Conservation Policy Act, Public Law 95-619, created an Office of Minority Economic Impact within the Department of Energy. Its role was to "advise the Secretary on the effect of energy policies, regulations, and other actions of the Department and its components on minorities and minority business enterprises" (Equity in energy, 1979, p. 7; Poyer, 1990, p. 10). Minority was defined as "Negro, Puerto Rican, American Indian, Eskimo, Oriental, or Aleut or… Spanish speaking individual of Spanish descent." As one policy scholar, David Poyer, later noted, the law "affirmed the fact that American society is pluralistic and that the enactment of policy can without care adversely affect certain population groups relative to others." But the office remained merely advisory to the Secretary, with no directives to pursue equity in energy policy. Looking back in lament on the 1970s, Poyer observed "the development of a comprehensive national energy policy, let alone one in which equity issues were addressed, has been difficult and in the view of many unsuccessful (Poyer, 1990, p. 7).

These limitations of technology assessment, including its inattention to inequities or inability to mitigate unequal impact, did not go unnoticed by insightful critics. Writing in *The Black Scholar* in 1974, for example, policy scholar Lenneal Henderson called for "more black involvement in the emerging discipline of 'technology assessment,' the attempt to analyze and make informed decisions about the implications of technological developments." From his perspective, "technology assessment models and techniques rarely include the economic and political conditions, dynamics and aspirations of black urban communities," not to mention that the impacts of transit, water, and sewage systems "on the political economy of particular and aggregate black metropolitan neighborhoods are neither known nor included in the planning and evaluation of these technologies." The answer was not merely to collect more data, but to reevaluate how "such evidence is conceptualized and related to black goals and values [and this] needs more attention from those involved in technology assessment and decisions." Henderson called for assessment to consider "the needs, goals and conditions of black metropolitan dwellers and the capabilities and limitations of these technological systems in providing for black people," as well as "a multidimensional plan for black participation in technological decision-making and technological assessment," and "black participation…in the inchoate Office of Technology Assessment" (Henderson, 1974, pp. 9-18).

Whenever equity concerns did appear in the OTA, they appeared in a limited and circumscribed way. For example, in 1977 the OTA initiated a long-range program on R&D policies and priorities with an expansive scope. One of the many items for further consideration, true to its technocratic origins, was "the development of objective criteria for assessing health and performance of the science and technology enterprise." Another was "the equity of access to the career opportunities provided by scientific and technological systems," reflecting attention to professional norms that was on the rise even as other equity commitments diminished (Brooks, 1977). In 1980, the OTA conducted its own extensive study of cost-benefit analysis, concluding that while the common practice had "the potential to be very helpful to decision makers," cost-effectiveness had "too many methodological…weaknesses to justify relying solely or primarily on the results of formal studies in making decisions." One of the weaknesses in this type of assessment was "the inability of analysis to adequately incorporate equity and political considerations" (Banta and Behney, 1981, pp. 445-479).

From the outset, supporters of the OTA sought to distance technology assessment from regulation, and positioned it as an information provider above all else. Its ultimate aim was to regulate the balance of power between branches of government through information: "to lessen [Congress's] dependence on executive branch agencies and special-interest groups for

scientific and technical information and analysis" (Stine, 1998, pp. 815-816). It was shaped by a particular set of values and commitments that prevented it from being an effective ally in the environmental justice movement, one of the initial visions for the office. Despite this emphasis on neutrality, during the 1980s the office would wade into controversy surrounding defense spending, ultimately leading to its demise.

The 1970s began with faith, carried over from the 1960s, that institutions—Medicare, HMOs, and the OTA—might fulfill a broader mission of science for the common good. Over the course of the decade, these ideals confronted significant limitations: ideological opposition, fiscal limitations, and growing skepticism about the use of government powers to advance social equity. For a host of reasons, the OTA never really grew into the office it was originally envisioned to become. Nor was it capable of responding to the call from scholars like Lenneal Henderson to incorporate Black concerns and perspectives into technology assessment. The vision of technology governance would become even more circumscribed in the pro-business and deregulatory climate of the 1980s. The rise of conservative approaches to governance would limit earlier ambitions, undermining the idea that government should continue to use its leverage to advance racial and economic equity.[10]

PIECEMEAL EQUITY IN TECHNOLOGY GOVERNANCE: THE REAGAN ERA AND BEYOND

In the 1980s, three pieces of legislation highlight a conservative political turn in the federal government's approach to addressing inequities that arose in science, technology, and medicine. In the increasingly pro-business, deregulatory climate defined by market-oriented drug and technology development, the piecemeal approach to equity prevailed (see Box B-4 for policy examples). Whenever problems of inequity in science and technology innovation appeared in this era, the solutions would be largely (but not exclusively) pro-business. These included incentives to help the private sector redress market inequities and injustices, incentives for universities to share in innovation, and reforms to limiting industry liability for innovations that produced harms.

The ideal of governing science and technology innovation to promote equity—that is, greater fairness in the distribution of benefits from innovation—did not disappear entirely, but the governance philosophy behind it adapted to more conservative times, with increasing attention paid to the idea of incentivizing for equity. This was not a return to the gilded age of the "endless frontier," nor was it a full-scale rejection of activist governance. Rather, this era in some ways extended a formula for governance that had begun in the Nixon years, echoing ideas that created the HMO Act of 1973. The 1980s policy makers embraced attempts to balance innovation and equity in specific sectors where the injustices had become most politically problematic: for example, the Orphan Drug Act of 1983.

In an atmosphere of deep hostility to the idea of government oversight, the programs that had become associated with equity—Medicare, Social Security, Medicaid, Head Start, and so on—were subject to harsh criticism. Opponents of Medicare, for example, framed their opposition to the program as a matter of "generational equity," a sly rhetorical effort to highlight that in an insurance system, the elderly benefited at the cost of the young. As health policy scholar Theodore Marmor noted, for critics "the prospective retirement of the baby boomers beginning in 2010 figured prominently in the picture of an American government

[10] In education policy, opposition to school bussing to achieve equality of access came under attack; opposition to affirmative action grew. In social welfare policy, skepticism and outright hostility expanded toward programs from Head Start to Aid to Families with Dependent Children.

BOX B-4

PIECEMEAL EQUITY: GOVERNING AND INCENTIVIZING INNOVATION IN THE 1980S AND BEYOND

"The [establishment in 1986 of the National Vaccine Injury Court] compensation system…was most specifically intended to achieve the goal of fair compensation. At the same time, most members of Congress hoped it would also contribute to stabilizing vaccine supplies and prices and to improving immunization rates. The basis for this hope was the assumption that potential liability was a disincentive to manufacturers to enter or stay in the vaccine business. The program intended to remove that disincentive by serving as a substitute for litigation against vaccine manufacturers."

"This legislation [the Orphan Drug Act] will rescue millions of Americans who suffer from rare diseases…They are in a tragic situation because our drug development system has failed us." — Henry Waxman. Quoted in Paul Houston. December 19, 1982. "Orphan Drug Act Wins Approval in Congress." *Los Angeles Times*: A22.

facing a tidal wave of expenses from programs directed at the growing number of elderly citizens…[an] apocalyptic conception of the future" (Marmor, 2000, p. 140). In this cynical portrait, government action in the name of equity was cast not only as costly but also as inequitable.

Even prior to the Reagan revolution, throughout the Carter administration a pro-business, regulation-wary climate was growing in government. The Patent and Trademark Act Amendments of 1980 (also known as the Bayh-Dole Act) created new incentives for commercialization by allowing universities to benefit financially from patenting innovations, facilitating technology transfer and industry spin-offs. Social equity was an afterthought. Three years after the Bayh-Dole Act came passage of the Orphan Drug Act, which explicitly acknowledged that incentives in drug development were heavily skewed toward large markets and profit potentials, and against "orphan diseases"—that is, rare disorders where industry had no incentives to conduct drug research and development because there were so few patients and such meager profits. In this era, enhanced business incentives became the guiding strategy for addressing social inequities stemming from technology development.

The establishment of special vaccine courts to compensate people injured by vaccines exemplified the new ecosystems for dealing with science and technological harms in this era. Like the Orphan Drug Act and Bayh-Dole, it offered an industry-friendly incentive: reducing industry liability when vaccine technologies proved harmful. Signed into law as part of the 1986 National Childhood Vaccine Injury Act, the National Vaccine Injury Compensation Program was intended to promote fairness. As health law scholar Wendy Mariner observed, "Most members of Congress hoped it would also contribute to stabilizing vaccine supplies and prices and to improving immunization rates." The basis for this hope was "the assumption that potential liability was a disincentive to manufacturers to enter or stay in the vaccine business," one that government was in a position to remove by creating an alternative to the traditional tort system (Mariner, 1991, p. 422). As political scientist Anna Kirkland explains in her book, *Vaccine Court*, the new program was the product of an elaborate compromise:

"In the end, the parents got a route to compensation and an open if not unimpeded path to a tort suit, the manufacturers got stability and protection from litigation, and pediatricians were reassured that the nation would have an uninterrupted supply of childhood vaccines" (Kirkland, 2016, p. 72).

The result of these laws—incentivizing drug production, reducing liability, and speeding technology transfer from universities to the private sector—was a new ecosystem that prioritized technology development above other conceptions of the public good. Dialing back on equity commitments had consequences. After 25 years of Bayh-Dole, for example, financial benefits to universities skewed heavily toward a small number of powerful universities. According to a government study, out of 141 universities with licensing income, 22 accounted for 80 percent of the patent licensing income. This skew would lead some universities to take "a broader view of the appropriate metrics of technology transfer activity to emphasize more regional economic development." The Association of American Medical Colleges and several universities, led by Stanford, generated "nine points" to guide technology transfer, including one equity guideline. Point 9 suggested that licensing "consider provisions that address unmet needs, such as those of neglected patient populations or geographical areas, giving particular attention to improved therapeutics, diagnostics, and agricultural technologies for the developing world" (House of Representatives, Committee on Science and Technology, Subcommittee on Technology and Innovation, 2007).

These policies promoted speed and innovation in the technology development, limiting government oversight that had expanded through efforts to mitigate harm and advance social equity. In many respects, this era witnessed a fundamental rethinking of the existing ecosystem. The fast-tracking of AIDS drug approval and other FDA innovations aimed at speeding experimental medicines to the market attracted praise, as well as concern about drugs that needed to be removed from the market after detrimental effects appeared postapproval. As George Annas observed in 1989, "The politics of AIDS has produced strange political alliances. The anti-regulatory Reagan and Bush administrations and the gay community probably have only one interest in common: deregulating the drug approval process" (Annas, 1989, p. 778). The result was new drugs, as well as new surrogate marker measurements for speeding drug approval, and the blurring of lines between experimental drugs and therapy. The market in pain drugs was another case in point of market booms that began in the 1980s, with slowly emerging calamities in later decades, leading to calls for stiffer post-market accountability and liability law figuring more and more prominently in pursuing accountability in this new ecosystem (Wailoo, 2015).[11]

Perhaps not surprisingly, the Reagan revolution also saw intensifying criticism of the goals of "technology assessment" and the demise of the Office of Technology Assessment (OTA) when Republicans gained legislative power in 1992. As with the ABM controversy under the Nixon administration, the OTA waded into controversy when it came out in opposition to President Reagan's Strategic Defense Initiative. The administration fired back that the office had exposed defense secrets, and while it weathered these charges, it would not survive for long. As part of Congressman Newt Gingrich's sweeping "contract with America," the OTA budget was eliminated as excessive spending. For some, it was a wonder that the

[11] For example, Eli Lilly's Oraflex was approved in 1981; annual sales totaled $1.9 billion; by 1982, the drug was linked to multiple deaths; by mid-1982, the drug was off the market. In 1985, the company pled guilty to misdemeanor charges, admitting to mislabeling the drug and failing to inform the FDA about adverse reactions in the approval process. In some cases, the court system was left to assess the damage and provide relief. One Alabama man whose mother had died after taking Oraflex won a jury award for $6 million in federal court. Other painkiller drugs, such as Syntex's Toradol, attracted similar controversy (Wailoo, 2015, p. 192).

office lasted at all; others lamented that the office had sacrificed authority and influence for the sake of stability (Bimber and Guston, 1997).

The policies of the 1980s and 1990s created a new set of ground rules, a profound shift in the ecosystem of technology governance. Promoting—not disciplining—innovation made financial incentives, rather than careful assessment and regulation, the instrument of choice, as equity considerations moved to the background. The passage of the Orphan Drug Act revealed the ways in which even conservative lawmakers embraced federal laws (using the mechanism of incentives) to restore fairness in a drug development system where markets created large inequities.

THE GROWING CRISIS OF ACCESS, ACCOUNTABILITY, AND CALLS FOR EQUITY-BASED POLICIES

In the last two decades, as economic trends have increased social inequalities, the topic of equity and technological innovation has figured ever more prominently in academic policy discussions regarding technological, scientific, and medical innovation. One aspect of the equity discussion addresses *equitable access* to the fruits of science, technology, and medical innovation—that is, building systems for ensuring equity in access to the products of scientific and technological innovation. Another related aspect of the equity discussion addresses preventing inequities in technology development, or ensuring that scientific research processes, human subjects research, researchers' engagement with communities, and technological development do not exacerbate existing inequities. The urgency of these concerns has been widely recognized in policy discussions, even if there are few concrete steps proposed for addressing these equity challenges.

One example of a U.S. law that subjected one area of science and technology innovation to extraordinary market constraints in the name of social equity and preventing discrimination stands out: GINA, passed in 2008. Policy makers in the 1990s had grown increasingly aggressive about regulating insurance companies, banning them from denying coverage to people with preexisting conditions. Developments in genetics resulting from the sequencing of the human genome and identification of genes linked to diseases added a new concern for lawmakers. These advances promised new medicines, but they also prompted fears that insurance companies might unfairly discriminate against patients on the basis of genetic information.

The result was sweeping legislation banning the use of this innovative technology and an entire class of biological data from use by the health insurance industry. These restrictions showed that even conservative government was not above placing outright restrictions on the use of technologies when those uses were understood to foster new forms of discrimination and social inequities. In a shift away from the incentive-based ecosystem of technology governance, GINA saw the government taking a proactive role, restricting the use of genetic information in anticipation of social inequities that might arise if genetic data became part of the insurance business model. These definitions of inequity, however, focused on specific, even speculative vulnerable groups—people with genetic disorders—rather than federally recognized minorities who have historically been singled out by governments and businesses alike.[12]

Over the past two decades, other problems with the innovation-oriented, deregulatory, pro-business ecosystem have emerged, leading to calls for accountability and improved regulation, including postmarket surveillance (see Box B-5 for a range of examples). The opioid

[12] There have also been proposals to overturn GINA (Zhang, 2017).

BOX B-5

THE GROWING CRISIS AND CALLS FOR EQUITY-BASED POLICIES

"Johnson & Johnson has agreed to pay more than $2.2 billion in criminal and civil fines to settle accusations that it improperly promoted the antipsychotic drug Risperdal to older adults, children and people with developmental disabilities, the Justice Department said on Monday. The agreement is the third-largest pharmaceutical settlement in United States history and the largest in a string of recent cases involving the marketing of antipsychotic and anti-seizure drugs to older dementia patients. It is part of a decade-long effort by the federal government to hold the health care giant—and other pharmaceutical companies—accountable for illegally marketing the drugs as a way to control patients with dementia in nursing homes and children with certain behavioral disabilities, despite the health risks of the drugs." —Katie Thomas. November 4, 2013. "J&J to Pay $2.2 Billion in Risperdal Settlement." *New York Times*.

"Given the legacies of inequality, injustice, and discrimination that have undermined the health and well-being of certain populations in the United States for centuries, considerations of equity should factor into plans for allocating and distributing COVID-19 treatments and vaccines to the population at large" (NASEM, 2020, p.29).

"Our country faces converging economic, health, and climate crises that have exposed and exacerbated inequities, while a historic movement for justice has highlighted the unbearable human costs of systemic racism. Our Nation deserves an ambitious whole-of-government equity agenda that matches the scale of the opportunities and challenges that we face...Because advancing equity requires a systematic approach to embedding fairness in decision-making processes, executive departments and agencies (agencies) must recognize and work to redress inequities in their policies and programs that serve as barriers to equal opportunity." —The White House. January 20, 2021. "Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government."

"Although equity in access and allocation has been a proclaimed principle of the organ transplantation system for decades, and appears in federal regulations directing allocation policy, equity has, until recently, been absent as a stated goal or vision in the strategic plans of many organizations working in organ transplantation." —NASEM. 2022. Realizing the promise of equity in organ transplantation. Washington DC: The National Academies Press, p. 87.

crisis provides one example of how and why calls for better governance have grown louder in recent decades. The drug OxyContin was approved in the late 1990s and charted a path through market approval toward wider prescription and use. By the mid-2000s, a social crisis of addiction and overdoses (seen in the early years as prevalent in white rural areas such as Appalachia) began to emerge. The side-effects of other drugs, like Vioxx, were also attracting lawmaker concern. By 2006, critics of both the FDA and the industry, such as Senator Charles Grassley, saw the removal of Vioxx from the market as a reason to consider stronger reforms: "Vioxx was like a dead canary in the coal mine," he explained, "a warning that worse may come…there's no question left that we need to strengthen postmarket surveillance in order to improve drug safety and save lives" (Wailoo, 2015, p. 192).

The wave of lawsuits against drug companies brought by pregnant women, children, and others harmed by illegal marketing over the past 20 years highlights the heavy toll that deregulation has had on the public health. These cases raise sweeping questions about governance and regulatory failure, only hinting at the underlying inequities in the users affected by the malfeasance. Examples are numerous. In 2009, Eli Lilly agreed to pay $1.4 billion to settle in response to off-label allegations involving the drug Zyprexa (DOJ, 2009). That same year, Pfizer paid $2.3 billion for a health fraud settlement. In 2013, Johnson & Johnson paid $2.2 billion for illegal off-label marketing of Risperdal to children, among others, and in 2022, Purdue Pharma reached an $8.3 billion settlement with the Justice Department, pleading guilty to three felonies relating to the marketing and distribution of OxyContin (OPA, 2009a,b, 2013; Thomas, 2013). The opioid settlements have been wide ranging, involving not only the drug manufacturer but other industries—including consulting firms and pharmacies—in the drug market ecosystem who were strongly incentivized to build painkiller markets without concern for public welfare (Forsythe and Bogdanich, 2021).

In this context, a number of National Academies studies have sought to push equity to the foreground in technology governance—even if implementation remains a challenge. For example, a 2021 Study, "Racial Equity Addendum to Critical Issues in Transportation," acknowledged that "transportation has…contributed to racial inequalities" in freeway development, rail transit infrastructure, and other ways. Though light on policy solutions, the report insisted that innovation in the transportation industry provided an opportunity to "build more equity into the system" and to ensure that the "equity chasm does not widen" (NASEM, 2021). In a similar vein, a 2022 NASEM study, titled "Realizing the Promise of Equity in the Organ Transplantation System" is one of a few studies of science, technology, and medicine that has pushed concerns about equity to the foreground. Its authors noted the fact that despite years of rhetorical attention to equity, implementation of those ideals has lagged: "Although equity in access and allocation has been a proclaimed principle of the organ transplantation system for decades, and appears in federal regulations directing allocation policy, equity has, until recently, been absent as a stated goal or vision in the strategic plans of many organizations working in organ transplantation." The study concluded that new governance and oversight of the transplantation system was needed in order to achieve these goals, specifying that oversight should begin before patients are placed on waitlists, at the level of referrals and evaluations (NRC, 2022, p. 87). New technological developments, in fields from genetics to cryptocurrency to new modalities of transportation, as well as long-standing questions of access and consumerism, have kept the question of equity and science governance in the forefront of policy discussion.

Against the backdrop of history, the years 2020–2022 mark a sea change, with equity emerging as a new governance ideal. Historically speaking, the Biden administration's decision in 2021 to prioritize racial equity in an "ambitious whole-of-government equity agenda" is unprecedented, although some of its ideals and features certainly resonate with equity commitments of the past, particularly those of the 1960s and 1970s. The administration called for "a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality." Though it made no mention of science, medical, and technology innovation, the report drew together a number of familiar as well as new steps relevant for equity-based technology innovation: Identifying Methods to Assess Equity; Conducting an Equity Assessment in Federal Agencies; Allocating Federal Resources to Advance Fairness and Opportunity; Promoting Equitable Delivery of Government Benefits and Equitable Opportunities; Engagement with Members of Underserved Communities; and Establishing an Equitable Data Working Group (White House, 2021).

The one area in which federal and state governments have sought to translate equity concerns into practice is the distribution of COVID-19 technologies. Amid the COVID-19 pandemic, the development of tests and vaccines raised anew and in sweeping fashion the need for coordinated governance in the name of equity. In its 2020 Framework for Equitable Allocation of COVID-19 Vaccine, one National Academies report explicitly asked, "What criteria should be used in setting priorities for equitable allocation of vaccine?" In addressing which groups should be in the first tier when vaccines became available, the report made explicit that the government must play an active role in these distributional questions, lest the market reproduce existing disparities. Matters of equity that came forcefully into view included prioritizing distribution among the elderly, people with underlying health conditions, and those at higher occupational risk and prioritizing "populations at higher risk (e.g., racial and ethnic groups, incarcerated individuals, residents of nursing homes, and individuals who are homeless.)" In establishing equity-based plans for COVID-19 mitigation, it was also clear that communicating about equity was essential. As the report asked, "How can we communicate to the American public about vaccine allocation to minimize perceptions of lack of equity?" (NASEM, 2020; Tai et al., 2020).[13]

In many respects, the pandemic crisis and its disparities in infection rates, hospitalizations, and mortality along lines of racial and socioeconomic difference pushed equity discussions into the foreground. Moreover, the rapid development of vaccines presented an opportunity to translate longstanding discussions and promises to prioritize equity into policy guidance and action.

CONCLUSION

The history of technology governance in the United States since the 1950s is characterized by a fundamental tension between a *laissez-faire* approach to innovation and a conviction that active government is necessary to ensure that the fruits of innovation are equitably distributed. Though the basic tenet that innovation contributes to social welfare has rarely been called into question, the tension between these two approaches manifests in shifting ecosystems of technology governance: from a "gilded age" era of robust science funding without oversight to an era in which government programs embraced the idea that funding and financing provided crucial leverage to advance equity, toward a more pro-business era in which government scaled back on the promise of equity, and finally a pivot to using softer incentives to balance equity and innovation.

U.S. policies have aimed at governing technology innovation with attention to specific equity concerns. At times, the focus has been on redressing inequities of harms to subjects and enhancing governance of research; at times, attention turned to redressing inequities caused the market and by government's laissez-faire approach to inequalities in who benefits from science. At other times, policies have used new federal institutions, power, and funding (for example in Medicare) to leverage equity in access to science and technological services. At yet other historical junctures, policies have focused on incentivizing the private sector to prioritize more equitable development of products.

[13]A range of social inequities lay the groundwork for COVID-19 disparities. The report (NASEM, 2020) cited numerous instances, including, for example, that "minority groups also comprise a greater percentage of essential workers—only 20 percent of African Americans are able to work from home, for example—and many rely on public transportation to travel to work, which increases their likelihood of exposure to SARS-CoV-2" (NASEM, 2020 p. 31; Tai et al., 2020).

The gaps in this approach to technology, science, and medicine governance are glaring. Technology policy in the name of equity has been largely reactive—responding to crises, growing inequities in the private sector. While the OTA focused initially on the problem of anticipating the social impact of technology, little attention was given to analyzing disparate social impact. In science funding, technology design, and early-stage development, there has been little attention to equity considerations in granting. In cases where technologies produce egregious harms, lawsuits and legal action have functioned as a retroactive check, imposing a price on innovation that goes wrong. Little attention has been paid over the years to the goal of postmarket assessment or to building system-wide efforts to incorporate equity considerations into the funding, development, assessment, and deployment of technological and scientific innovation.

Several conclusions may be drawn from this history.

First, the unfinished work of the 1960s and 1970s provides clear lessons for today. There is ample precedent for equity-based governance of technology, most notably in the 1960s and early 1970s. However, a substantial and sweeping commitment to equity in technology governance has yet to be pursued as a matter of U.S. federal policy. Since the 1960s and 1970s, even as policy makers accept that science, medical, and technological innovation, and their applications, require greater oversight to serve the common welfare, robust governance for fair distribution of the benefits of science and technology has lagged as a policy commitment.

Second, using federal powers for equity has often yielded significant results. Several important federal programs, such as Medicare, have exercised power to ensure equity. The convergence of Medicare reform and civil rights, for example, showed how the federal government could use funding leverage to advance health equity, making large advances in rapid and dramatic fashion. Medicare and Medicaid legislation (as well as kidney dialysis legislation) created new institutions of government to oversee, regulate, and guide coverage; such institutions also continued the important trend of using funding as leverage to shape the socially, geographically, and demographically equitable application of innovation to health care.

Third, policy makers should consider the precedent for restricting technology. Even with the increasing reliance on incentives to promote equity in technology governance since the 1980s, the example of GINA stands out—an instance in which government restricted an entire industry from accessing information in service of preventing inequities. Fear of curtailing innovation extends back to Science: The Endless Frontier, but a proper balancing of interests can allow scientific research to advance while restricting its potentially harmful applications.

Fourth, it is abundantly clear that lack of governance produces inequities. The price paid for abdicated governance of technologies is severe and lasting, with the burden often borne by the most vulnerable members of the population. Prior to the 1960s, for example, policy makers were inattentive to the prospect that scientific innovation generated harms—most notably by unregulated use of human subjects, institutionalized persons, and other vulnerable groups. This practice produced deep social inequities in the process of generating new knowledge. Laissez-faire governance in later eras similarly fostered inequities via neglect.

Fifth, incentives can work for remedying inequities, but they can also fail. The Orphan Drug Act remains a powerful model of incentives for equity in drug development. The HMO legislation provides a case in point of how incentives in health and technology governance (originally aimed in part at increasing access in underserved areas) have, in subsequent years, strayed far from these stated ideals. Though they gradually became the default over the course of the twentieth century, this history reminds us that incentives are simply one tool among many policy options.

Finally, the history recounted here evidences the need for a new model of technology assessment. Going forward, a commitment to comprehensively assess the disparate social effects of technology is an important goal, but any new model of technology assessment in the twenty-first century must not repeat historical errors and blind spots. For example, attention to racial inequities were rarely part of debates over technology assessment in the 1970s. These limitations in technology assessment (its inability to consider inequities or to act to mitigate unequal impact) did not go unnoticed by insightful critics. Policy scholar Lenneal Henderson's critique—that the dominant "models and techniques rarely include the economic and political conditions, dynamics and aspirations of black urban communities"—as well as his call for more Black involvement in the field, rings as true today as it did in 1974. Going forward, technology assessment can be updated for the twenty-first century through commitment to studying inequities and expansion of its keystone values and tenets to include broadening participation and sharing responsibility.

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Appendix C

Equity in Innovation within NIH and FTC: Examination of Agency Approaches and Implementation

A white paper for the Committee on Creating a Framework for Emerging Science, Technology, and Innovation in Health and Medicine

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This paper describes how two U.S. government agencies—the National Institutes of Health (NIH) and the Federal Trade Commission (FTC)—have approached "equity in innovation"[1] in recent years, including successes and barriers, as well as potential remedies. It is based on a literature and legal review, as well as interviews with 19 current and former leaders within these agencies. After an executive summary and a background section, the report covers each of the two agencies separately, first addressing the agency's approaches and test cases of how it is responding to an emerging technology (polygenic risk scores at NIH and artificial intelligence at FTC), and then addressing successes and barriers, plus potential improvements.

EXECUTIVE SUMMARY

Although of late there has been increasing attention to "equity" outcomes in American policy making, within the U.S. federal government, the term is not well defined. A recent Executive Order[2] focuses on equity in the federal government and provides one definition of the term, but this definition is neither well known nor universally accepted across govern-

[1] As tasked by the National Academies Committee on Creating a Framework for Emerging Science, Technology, and Innovation in Health and Medicine.

[2] EO 13985, "On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government," 2021.

ment agencies, especially by individuals doing equity work (see the section on Definitions, below). Different genealogies of the terms "equity" and "equality," as well as political battles over these terms and related goals, have led different groups and individuals to operate with different definitions—or none at all. And while the 2021 Executive Order referenced above also required agencies to develop Equity Action Plans (EAPs), these plans have not been broadly publicized within NIH and FTC. NIH does not have its own EAP; administratively NIH left the obligation of developing an EAP to its umbrella agency the Department of Health and Human Services (HHS), whose plan makes little mention of NIH.

At FTC, equity work has been controversial, with commissioners from different political parties disagreeing on whether and how this goal ought to be pursued. There is explicit opposition by some of the agency's commissioners, who argue that such work "unfairly privileges" some groups and is a form of government overreach. The latter framing is a technocratic construal of an issue that has long been the object of strong party divides: the size and role of the federal government. These debates create major barriers to equity work at FTC, but individuals working on these issues at FTC have nonetheless advanced significant and innovative approaches to equity in innovation and emerging technology, especially regarding artificial intelligence (AI) and algorithmic bias.

As an agency, NIH has attempted to focus its equity work on ostensibly apolitical scientific approaches, which makes it difficult for NIH to address the social dynamics of equity that are integral to science.[3] For example, NIH has relied far more on the "scientific" stage of its grant review (in terms of resources, time, weight in decision making, etc.) than on the parts of its review and award process that could make equity more central (e.g., existing processes of council review and discretion of institute directors, adding new and revised processes). There are clear disparities in grant funding (by race as well as other features of applicants) at NIH, but there is disagreement within the agency as to the cause of these disparities, making it difficult to address the underlying issues. The institutes and centers (ICs) that make up NIH have great autonomy, which can make it hard to introduce common equity approaches across the agencies and push all ICs forward. On equity, the National Human Genome Research Institute (NHGRI) has been among the leading ICs in implementing extensive stakeholder involvement, as well as engaging with alternative forms of knowledge and expertise.

NIH has focused primarily on health disparities and workplace diversity rather than equity per se. And while NIH has made a great deal of resources available in these arenas, an explicit focus on equity (including a formal definition) would help equity workers advance these efforts, as would a shift toward approaching equity as part of the scientific process rather than treating it as an "add on" or even as an element that is at odds with objective science (e.g., the distinction some parties make between equity and excellence, which NIH has tried to address through a focus on "inclusive excellence").

See Table C-1 for an overview of approaches that NIH and FTC have taken to advancing equity in the scientific process as well as barriers those organizations have faced.

[3] That is, science is inherently a human endeavor, and the funding, design, implementation, analysis, etc., of any scientific project is shaped by social assumptions and priorities, and thus these assumptions and priorities also shape the dynamics that drive equity and inequality (what projects matter, who has relevant expertise, etc. [see the *Science Studies Reader* (Biagioli, 1999) for more on this]).

TABLE C-1 NIH and FTC's Approaches Taken and Barriers Faced to Promoting Equity in Science

	NIH	FTC
How does this agency approach equity?	Mostly focused on health disparities and workplace diversity. NHGRI is a leader re: attention to equity (e.g., stakeholder engagement, engaging with alternative forms of knowledge and expertise).	Many within the agency (including commissioners and other leadership) are explicitly hostile to equity work. A small group of innovative equity workers are leading significant and innovative efforts on equity in AI, etc.
Barriers to equity	(1) Divergence among ICs re: equity understandings and approaches, (2) focus on scientific stage of review with little resources or process for prioritizing equity concerns in later stages of review and awarding, (3) definitional and goal confusion	(1) Extremely limited financial and human resources for equity work, (2) perception of equity as a progressive/liberal agenda item, (3) debates over FTC jurisdiction and overreach (a technocratic framing of explicitly party politics on government size and scope)

NOTES: AI = artificial intelligence; FTC = Federal Trade Commission; IC = institutes and centers; NHGRI = National Human Genome Research Institute; NIH = National Institutes of Health.

BACKGROUND: "EQUITY" LANGUAGE IN FEDERAL GOVERNMENT

Legal scholar Martha Minow argues that, in recent years, debate over the terms "equality" and "equity" has become a battleground of American politics, where equality refers to uniform or "equal" treatment versus "equity," which focuses on equality of *outcomes*—addressing past oppression through compensatory justice and remedies for those who have been most discriminated against (Minow, 2021). The Biden administration's use of the term "equity" in several Executive Orders[4] breaks with the language primarily used in Executive Orders, laws, regulations, and other official communications of the U.S. federal government in this area over the last several decades; on related topics, such statements have previously used terms such as "equal" and "fair," or "discrimination" and "disparity."

With regards to labor practices, for example, President Truman's Executive Order of 1948 ("Regulations Governing Fair Employment Practices Within the Federal Government") prohibited discrimination in federal employment on the basis of race, color, religion, or national origin and required all federal government departments to appoint a Fair Employment Officer (emphases added); the Equal Employment Opportunity (EEO) Act of 1972 (emphasis added) extended broader antidiscrimination employment provisions of the Civil Rights Act to federal employees (Hadden and Gallegos, 2008), following on the EEO in the Federal Government Executive Order (11478) of 1969. These led to regulations directing federal agencies to establish Special Emphasis Programs (SEPs) promoting employment from underrepresented groups (Office of Civil Rights), which were subsequently defined by the Federal Equal Opportunity Recruitment Program (established by the Civil Service Reform Act of 1978). Today, three of these SEPs are still required of federal agencies[5]: the

[4] See EO 13985, EO 14035, EO 14031, and EO 14036.

[5] There were at least two additional government-wide SEPs in the past: the Minority Outreach and Upward Mobility Program and the Veterans Employment Program, as noted by a 1980 General Accounting Office report, *How to Make Special Emphasis Programs an Effective Part of Agencies' EEO Activities*. But by 1982, a congressional investigation on federal EEO activities found that the budgets of SEPs had been eviscerated, especially those of the Minority Outreach and Upward Mobility Program, whose budget was cut by all reporting agencies, and slashed by 76.2 percent at HHS between fiscal years (FY) 1981 and 1982; these actions "effectively emasculate the programs," according to the chairwoman of the House Subcommittee on the Civil Service (Schroeder, 1982, p. 86).

Hispanic Employment Program,[6] the Federal Women's Program,[7] and the People with Disabilities Program.[8]

Apart from such terms as "fair" and "equal," equity as a legal doctrine has a long history, where it differs significantly from colloquial use. In law (other than in the financial sense), "equity" refers to the authority to impose sentences that are nonmonetary; this is how it is used in the U.S. Constitution (Harrison, 2022). But with today's sense of equity as social justice, the term does not appear to have been in frequent use by the federal government in the years immediately prior to the Biden administration. The Department of Defense's 1969 Human Goals Charter used the term, describing its goal "to provide *equity* in civilian employment regardless of race, color, sex, religion, national origin, disability, age, or sexual orientation, and to provide an environment that is accessible to and usable by all," but by the late 1990s, a subsequent secretary of defense had removed the term "equity" from the charter's discussion of diversity (emphasis added; Military Leadership Diversity Commission, 2011).

The Reagan administration, however, made several Executive Orders focused on equity in this sense of justice (including one establishing the Task Force on Legal Equity for Women to identify discriminatory federal laws and work toward "equal treatment from Federal activities"); President Reagan also signed into law several bills focusing on "equity," including the Educational Opportunity and Equity Act of 1982 (which provided a federal income tax credit for private school tuition) and the Retirement Equity Act of 1984 (which focused on ensuring "that working women are receiving their fair share of private pension benefits"; Donovan, 1985).

Education has been a primary battleground over "equity" versus "equality"; the federal Elementary and Secondary Education Act of 1965 focused explicitly on "equity" as redistribution (Thomas and Brady, 2005), although federal government approaches in the 1990s shifted toward a focus on "adequacy" of education rather than "equity" therein (Houck and Debray, 2015). In spite of this trend, in 2016, the Department of Education changed the title of the "Desegregation Assistance Centers" mandated by the 1964 Civil Rights Act (to aid in the processes of school integration) to "Equity Assistance Centers."

DEFINITIONS

The term "equity" is not well defined within the federal government. The 2021 Executive Order "On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government"[9] provides one definition of "equity":

> Equity means the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treat-

[6] Federal Personnel Manual Letters (FPM) 713-23 of 1974; renamed as such in FPM 713-41 of 1978.

[7] EO 11478 of 1969; codified in 5 U.S.C. 7201; 38 U.S.C. 4214; Title 5 CFR, Subpart B, 720.204.

[8] Rehabilitation Act of 1973, renamed from "Handicapped" in an Amended Act of 1992. These have all been reinforced by subsequent Executive Orders and laws focused on the federal workplace: EO 13583, "Establishing a Coordinated Government-wide Initiative to Promote Diversity and Inclusion in the Federal Workforce" (August 2011); EO 13548, "Increasing Federal Employment of Individuals with Disabilities" (July 2010); EO 13171, "Hispanic Employment in the Federal Government" (October 2000), EO 13163 "Increasing the Opportunity for Individuals With Disabilities to be Employed in the Federal Government" (July 2000). These are in addition to Executive Orders and laws focused on the broader U.S. workforce, such as EO 13078, "Increasing Employment of Adults With Disabilities" (March 1998). And while the Veterans Employment Program does not appear to be a federally mandated SEP any longer, EO 13518 (November 2009) established the Veterans Employment Initiative, which requires most agencies to employ at least one full-time officer for a Veterans Employment Program.

[9] EO 13985.

> ment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.

However, some at FTC have argued that this definition is closer to the notion of "equality" than "equity" (Interview C). Many leaders at NIH had not heard of any NIH-wide definition of "equity" or even "health equity," and those doing equity-focused work emphasized that an NIH-wide definition of equity would be extremely helpful in their efforts. Currently, many NIH institutes and centers use a definition of health equity drawn from the U.S. Centers for Disease Control and Prevention (CDC, 2022):

> [Equity is] the state in which everyone has a fair and just opportunity to attain their highest level of health...
>
> Achieving this requires focused and ongoing societal efforts to address historical and contemporary injustices; overcome economic, social, and other obstacles to health and healthcare; and eliminate preventable health disparities.

This language is drawn from the National Partnership for Action to End Health Disparities, a 2007–2011 stakeholder engagement program of the HHS Office of Minority Health that conducted widespread community conversations in order to produce the National Stakeholder Strategy for Achieving Health Equity (OMH, 2011).

These recent definitions of "health equity" may be of use in developing an updated definition of equity at NIH as well as other agencies. Recently, many scholars of health and equity have come to believe that there is no such thing as "health equity" independent of broader social and economic equity—only the latter would allow for real equity in health (Creary, 2021). Based on this scholarship, definitional work would likely be better focused on *equity* than on health equity.

Through EO 13985, the Biden administration tasked the heads of all executive departments and agencies (referred to thereafter collectively as "agencies") with identifying barriers to "full and equal" participation in federal programs "for people of color and other underserved groups." The Executive Order also requires each agency head to develop a plan for addressing those barriers, as well as barriers in procurement opportunities, and makes reference to "advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality…[a]ffirmatively advancing equity, civil rights, racial justice, and equal opportunity." It does not make any reference to "protected classes" or to the "special emphasis" programs per se, instead calling attention to "equity with respect to race, ethnicity, religion, income, geography, gender identity, sexual orientation, and disability."

NATIONAL INSTITUTES OF HEALTH

Within the U.S. federal government, NIH is a mid-size agency, with approximately 19,000 employees and a FY2022 budget of $45 billion (NIH Office of Budget, n.d; NIH Workforce Demographics, 2022).[10] An agency's size and budget impact its ability to main-

[10] Compare with the U.S. Postal Service's 580,000 employees, Office of Management and Budget's 450 employees, Department of the Air Force's FY2021 budget of $204 billion, the Small Business Administration's FY2021 budget of $0.8 billion, and NASA's FY2021 budget of $23.3 billion (CRS, 2022, 2023; DoD 2021; OMB 2021).

tain personnel for portfolio analysis, for recruitment and retention of employees from various demographics, and for other work toward improving the equity focus and efforts of the agency. NIH has much more expansive resources for this as compared with smaller agencies, such as FTC (see below).

Each of NIH's 27 ICs operates largely autonomously, with separate congressional budget appropriations (excepting rare cases; NIH Office of Budget, n.d.), and able to set its own research agenda—although NIH Director Francis Collins did expand the Office of the Director (OD) substantially during his tenure from 2009 to 2021, and centralized more activities there (Interview A, Interview E). The autonomy of ICs means that they vary significantly in how they understand and approach equity issues. Institutes set their own priorities, sometimes guided by directives from Congress. So the National Institute on Deafness and Other Communication Disorders, for example, decides whether it will continue to see deafness as an impairment and fund work that addresses deafness as pathophysiology (as it does currently on the latter point), even if some other institutes have increasingly adopted the idea that deafness, at its heart, is part of human richness and variation rather than inherently an impairment.

As noted above, there is little clarity at NIH as to what "equity" means exactly. NIH has much more frequently focused on research to address "health disparities" (including creating the National Institute on Minority Health and Health Disparities) and efforts to increase workforce diversity. NIH's Equity Committee, founded in 2017, focuses entirely on issues in the workforce (diversity metrics including those regarding hiring and promotion). It was established in response to a report that year by NIH's Gender Inequality Action Task Force, which highlighted gender inequities in tenure and promotion, salary, and the like.

NIH Grant Review

NIH's Center for Scientific Review (CSR), which implements approximately 75 percent of peer review for NIH's extramural programs across ICs, has a two-stage process for reviewing grant applications from academic and other nonfederal scientists and scholars: (1) a scientific review by a panel of non-NIH academic scientists (coordinated by scientific review officers [SROs]), and (2) further review by the funding IC's national advisory council or board. This system is rooted in the original 1944 text of the Public Service Act, which vastly expanded NIH's grants program across the ICs (NIH, 2004; NIH Central Resource for Grants and Funding Information, 2021; NIH CSR, 2023).

For nearly 40 years, NIH has had some form of public involvement in grant review. In 1985, an amendment to the Public Health Act formalized the advisory council system by requiring that each IC have such a council, with one-third of the membership drawn from the "general public"—to include "leaders in fields of public policy, law, health policy, economics, and management."[11] The amendment authorized these councils to conduct additional review of grant proposals and to make recommendations regarding the institute's research priorities and programs. More recent regulations on federal peer review, such as the 2004 rule on "Scientific Peer Review of Research Grant Applications and Research and Development Contracts" (69 FR 275), likewise make no mention of demographics of peer reviewers, nor do they mention other social positioning as part of requirements for peer-review participants, beyond technical expertise and conflict-of-interest issues. Notably, the example categories for public representation given in the 1985 amendment do not include patient advocates, health equity activists, tribal leaders, or members of underserved or marginalized communities. It

[11] 42 U.S.C. 284(a).

may be important to update guidelines for participation in IC advisory councils and their role in review.

Scientific Review

NIH's scientific review is based on an overall "impact score," meant to take into account five criteria[12]: significance (how important is the problem it addresses or the knowledge it will produce), innovation, approach (appropriateness and feasibility), environment, and investigator team (strength and appropriateness). NIH established these categories in 1997, based largely on a report by the agency's Committee on Improving Peer Review (specifically the subcommittee on the Rating of Grant Applications), itself a response to perceptions that peer review had become overly focused on "details of technique and methodology" rather than broader impact (NIH, 1997).[13] NIH has an extensive process for engaging non-NIH scientists in reviewing each grant application in detail.

Advisory Council Review

After reviewers score all applications, advisory councils in each IC (with "public representation") then make funding recommendations based on impact scores from the scientific review. However, they do not generally review the full pool of applications (which is typically large, so advisory councils do not have capacity to review all applications fully). And as noted before, the public representation is drawn from a narrow set of stakeholders.

Directors' Discretion

Leadership of each institute makes final decisions on what applications are funded, and they have authority to fund grants "out of order"—that is, not based simply on the scores from scientific review or even from the advisory council. Directors of some ICs have used this authority to choose grants to fund because they align with the ICs priorities, including for diversifying topic area, methods, and investigators (Interview E). However, this is burdensome for these busy directors, and often results in pushback from both applicants (who can see their scores) and NIH staff (for whom this creates more work). Interviewees reported that there is growing recognition within NIH of overreliance on peer-review scores in guiding funding distributions, but not much direction on how to address this.

Disparities in NIH Funding

There are substantial disparities in funding rates for NIH grants based on applicant demographics, even when controlling for many cofounding factors (NIH Office of the Director, 2022). In 2011, economist Donna Ginther and colleagues (2011) published results demonstrating that the success rate of applications from Black investigators was half that for White investigators. This publication led the NIH Advisory Committee to the Director (specifically the Working Group on Diversity in the Biomedical Research Workforce) to begin an investigation, including public listening sessions: (1) on diversity and peer review, (2) with representatives of historically Black colleges and universities on expanding participation

[12] Unless otherwise noted in a funding announcement.

[13] That same year, the National Science Foundation (NSF) made "broader impacts" a formal criterion (National Science Foundation, 2014). NIH representatives have in recent years been in conversation with NSF regarding the benefits and drawbacks of the "broader impacts" criterion (Interview B).

in conducting biomedical research, and (3) including a broader public meeting to collect stakeholder perspectives (NIH Working Group on Diversity in the Biomedical Research Workforce, 2012).[14] The Working Group's report recommended efforts "across the pipeline" to address the funding gap, but in large part the 2012 report called on NIH to collect more detailed and appropriate data to allow for analysis of the factors underlying grant funding disparities.

A 2019 paper by NIH staff demonstrates that one of the main factors driving NIH's racial funding disparities is research topic area: Black investigators more often propose research on community and population level issues, which have lower funding rates than "mechanistic investigations" (e.g., molecular biology) (Hoppe et al., 2019). This suggested that peer reviewers may discount structural interventions compared with popular conceptions of "innovation" as including "micro," "nano," or digital. Katz and Matter (2020) found that independent investigator awards were apportioned in increasingly "unequal" ways from 1985–2015;[15] an additional NIH-led analysis confirmed that inequalities by career stage, gender, and race grew during the period when NIH's budget was doubled between 1998 and 2003 (Lauer and Roychowdhury, 2021). See Figure C-1 for an overview of the NIH peer-review process.

However, some NIH leaders (even in diversity administration) now argue that it is not topic choice, but rather the ICs of choice or assignment for Black investigators that primarily drives lower rates of funding, going as far as stating "peer review is not the problem" (Interview B).[16] These parties point to a reanalysis of the data from the 2019 paper published by a group of NIH staff,[17] which argued that "the lower rate of funding for ['African-American/Black preferred'] topics was primarily due to their assignment to ICs with lower award rates, not to peer-reviewer preferences" (Lauer et al., 2021, p. 1). While the 2019 paper did find these differences as well, they found that topic choice had a greater effect size, especially when using advanced natural language processing techniques for analysis, as the Office of Portfolio Analysis is capable of doing.

In spite of multiple factors of causality, it is clear that increasing funding to research at the community and population level (across ICs and especially at the ICs with lower funding rates) not only would benefit the most underserved populations through research outcomes, but also would do a great deal to address racial funding disparities. CSR has also investigated disparities in award rates based on demographic features including age/career stage, gender, and race and ethnicity; they found that anonymizing grants did not improve the scores of Black investigators but did diminish the bump in scores that well-known researchers appear to receive (Interview B).

Perspectives on the causes of funding disparities are thus mixed among NIH leadership, which may challenge the agency's ability to address these issues. However, NIH has made efforts to diversify peer-review boards and has recently implemented mandatory implicit bias training for peer reviewers. CSR's scientific review officers select and train members of peer-review panels, offer guidance in scoring and writing reviews, and oversee review meetings; these officers have a great deal of influence in bringing together perspectives and determining exactly what mix of expertise and demographics are crucial for a review panel.

[14] NIH has substantial experience with stakeholder engagement.

[15] The authors did not look at race and ethnicity, but rather resource concentration in "elite universities" and "elite investigators."

[16] While applicants can designate an IC of choice, often IC assignment is done internally at NIH.

[17] Only one author worked on both of the two papers: Michael Lauer, the current director of NIH's Office of Extramural Research.

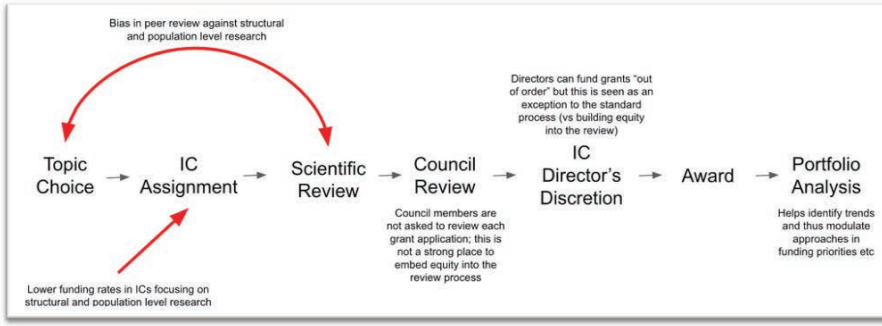

FIGURE C-1 National Institutes of Health (NIH) peer-review process with key equity moments.
NOTE: IC = NIH Institute/Center.

Portfolio Analysis

The expansion of the Office of the Director under Francis Collins helped support ICs through central initiatives with important equity implications; for example, the Office of Portfolio Analysis (OPA) was established in 2011 as part of the Division of Program Coordination, Planning, and Strategic Initiatives within the Office of the Director (NIH OPA, 2023). OPA focuses entirely on analyzing the distribution of NIH-funded research, based on variables including topic area (e.g., how much money funds projects on health disparities), and characteristics of the individuals and institutions receiving grants (e.g., gender, race, ethnicity, career stage, urban/rural, R1/R2/other). OPA is well funded and has grown from 5 to 30 employees in the last decade.

However, while OPA analyzes portfolio distribution, it does not determine the features of grants that NIH tags, or the classifications available for this, which is the responsibility of the Office of Research Reporting and Analysis within NIH's Office of Extramural Research (OER), in addition to the Research, Condition, and Disease Categorization (RCDC) system that was developed by OER's Electronic Research Administration. In 2006, Congress passed the NIH Reform Act, which required NIH to develop such a system (NIH RePORT, n.d.).[18] Notably, the RCDC system does not tag based on methods such as "ethnography" or even categories such as "ethics," which would allow the agency to evaluate and prioritize such forms of expertise, in order to generate more textured knowledge about the nature of inequity and justice.

RCDC categorization is conducted by automated text mining of project front matter (title, abstract, specific aims, investigator's stated public health relevance). Any one project may be tagged in multiple RCDC categories, and the entirety of the project budget will then be included in the total for each of those categories. However, 3 out of RCDC's 280+ categories are based on study "populations tracked by gender or ethnicity": Women's Health, Minority Health, and Health Disparities. NIH reports that the databases tracking these demographics "are complex and not yet compatible with the RCDC system" (NIH RePORT, n.d. "Frequently

[18] That provision followed on two reports by the National Academy of Sciences (in 1998 and 2003) recommending this type of system.

Asked Questions), but the agency has been trying to bring categorization of these grants into alignment with RCDC's standard process.

For example, prior to 2019, ICs assigned funding to the category of Women's Health based on the gender breakdown of each study's participants. Administrators were thus dividing or prorating project budgets when they tallied this category, as opposed to other categories that did not use prorating (i.e., the entire grant budget is attributed to any of the multiple topic categories the project falls under). In FY2019, internal subject matter experts across NIH agreed on a system to define women's health–related projects more concretely and apportion the project budgets to this category (not simply by number of participants). NIH subject matter experts now manually categorize projects to be tallied under Women's Health and Health Disparities, although there is automated support to identify relevant applications for this review. Reporting for the latter is prorated based on enrollment percentage of "minority subjects, as defined by the Office of Management and Budget or of other NIH-designated populations experiencing health disparities, including less privileged socio-economic status populations, underserved rural residents, and sexual and gender minorities" (NIH RePORT, 2022).

Using the data to analyze NIH's portfolio, OPA is able to draw attention to funding disparities.[19] However, there is little agreement on what the correct balance of funding for various topics and methods ought to be. This is one place that NIH may be able to increase equity and address the needs of a diverse population by altering the funding mix that it is targeting. However, interviewees noted that an important goal for the agency is staying out of the news headlines;[20] there have been past occasions when lawmakers have drawn attention to specific grants or programs as ridiculous, which is attention that most at NIH prefer to avoid. Beyond NIH's own authority in setting research priorities, Congress could also intervene to set goals, as it has done in the past (e.g., goals for AIDS research funding). Certainly Congress already sets priorities to a certain extent by determining funding levels for ICs.

NIH Benefits from a Large Base of Expertise

NIH has a large body of in-house expertise across domains, employing almost 6,000 researchers at the postdoctoral career level or higher, with funding of almost $5 billion for intramural research annually (NASEM, 2019). In addition to intramural research programs through the National Institute of Minority Health and Health Disparities, NIH's central bureaucracy has offices of Research on Women's Health (ORWH), Tribal Health Research (THRO), and Sexual & Gender Minority Research (SGMRO), all of which employ multiple PhD-level experts.[21]

This domain expertise, held by individuals in both research and administrative positions, allows NIH to draw on significant theoretical and practical resources to inform its approaches to equity. But while NIH's intramural programs have 79 principal investigators in the Behavioral and Social Sciences, the vast majority of this work is nonetheless rooted in biomedical and molecular analysis (e.g., biological markers of stress, brain circuits that control behavior), rather than qualitative work that delves into the deep experiences and knotty dynamics of injustice and power. The focus on biological analysis is also a trend in

[19] OPA was responsible for the 2019 topic choice paper (Hoppe et al., 2019).

[20] One equity leader noted, "Our job is to take money from Congress and send it out to the states through research awards. As long as we're not on the Washington Post, Congress is okay with what we're doing."

[21] ORWH was established in September 1990, and, in the NIH Revitalization Act of 1993, Congress mandated a significant role for the office. That same act mandated establishment of the Office of Behavioral and Social Sciences Research (see https://orwh.od.nih.gov/sites/orwh/files/docs/ORWH%20Leadership%20Role.pdf). THRO and SGMRO were established in 2015 and have not been given explicit guidance by congressional mandate.

NIH's extramural funding of Behavioral and Social Science, which is substantial: $7 billion in FY2021, up from $4.5 billion in 2017 (NIH RePORT, 2022).

NIH Focus on Workforce Diversity

NIH has a longstanding and robust infrastructure for equity, diversity, and inclusion amongst NIH staff, including the investigators in its intramural program. The NIH Office of Equity, Diversity, and Inclusion (OEDI) has a history of over 20 years. Currently, the office focuses on training NIH staff on equity, diversity, and inclusion (EDI) topics, identifying EDI trends and barriers, developing strategies to overcome these barriers (along with partners in ICs), workplace conflict resolution, and offering organizational culture consulting services for parties across NIH. OEDI has not only federally mandated SEPs (portfolios on Women, People with Disabilities, and Hispanic), but also other portfolios, including Black; Native American; Sexual and Gender Minority; Asian American, Native Hawaiian, and Pacific Islander. Each portfolio is headed by a director and full-time strategist (and a larger team, in some cases).

In 2014, NIH established an additional Office of Scientific Workforce Diversity within NIH's Office of the Director. Under cardiologist Hannah Valentine, the office

1. established the Distinguished Scholars Program;
2. created the NIH Equity Taskforce (which Dr. Valentine co-chaired with NIH's deputy director for intramural research), which led to the establishment of the NIH Equity Committee;
3. developed and implemented the first NIH Workplace Climate and Harassment Survey (a tool other institutions can also use to assess and improve in this area); and
4. developed the Faculty Institutional Recruitment for Sustainable Transformation (FIRST) program (to hire at least 120 faculty of color in clusters of 3–4, for a total of at least 10 at any one institution, with the goal of testing whether communal support increases retention).[22]

Since fall 2020, Marie Bernard has led this office, as well as the UNITE program—a cross-institute committee working to "identify and address structural racism within the NIH supported and the greater scientific community" (NIH UNITE, 2022). UNITE has since launched a Common Fund initiative for transformative health disparities research and supported a request for applications on structural racism and its impact on health.

Case Study: NHGRI and Polygenic Risk Scores

The National Human Genome Research Institute (NHGRI) is one of NIH's smaller ICs, with a budget less than one-tenth that of the National Cancer Institute (NCI).[23] However, NHGRI has been the primary hub of ethics research within NIH. NHGRI has long funded a

[22] See https://commonfund.nih.gov/first (accessed July 19, 2023). Sponsored by NIH's Common Fund, whose programs are mean to "dramatically affect biomedical research by achieving a set of high-impact goals within a defined time frame, limited to typically ten years maximum" and "also sponsors novel approaches testing new ways of supporting the entire biomedical research workforce" (NIH OSC, 2022).

[23] Appropriations for NHGRI in FY2022 were $639 million, as compared to NCI at $6.9 billion (https://officeofbudget.od.nih.gov/pdfs/FY22/Approp%20History%20by%20IC%20FY%202020%20-%20FY%202022.pdf; accessed July 19, 2023).

program in Ethical, Legal and Social Issues (ELSI) in genetics and genomics; since 1991, the institute has dedicated 5 percent of its annual budget to this program.[24]

The categories that NIH uses to tag grants and analyze across its portfolio make it difficult to ascertain what amounts of various ICs' budgets are dedicated to in-depth qualitative or humanistic research. However, NHGRI funds enough ethics and justice research on genomics for bioethicists to be concerned that this focus is taking away from attention to justice in other areas of health and biomedicine; some scholars have recently argued that this focus on "genetics, genomics, neuroethics, and the ethics of other emerging technologies disproportionately harms People of Color" because it does not allow for sufficient ethics and justice attention to the many other health issues of interest to underserved Americans (Fabi and Goldberg, 2022, p. 9).

Scholars in academic interpretive social science and the health humanities broadly consider NHGRI to be the NIH IC that primarily funds ethics in their research areas (Fabi and Goldberg, 2022). NHGRI has a close and long-standing relationship with the ELSI research community, a field that the institute itself largely created through its research funding (Dolan et al., 2022). This scholarly community and its relationship with NHGRI have been the basis for the institute's extensive work in stakeholder engagement (NHGRI is a leader in this), codesign of research agendas (especially with the underserved), and policy work. For example, NHGRI has extensive programs for engaging and supporting Native American researchers, and for addressing data sovereignty.

NHGRI has had to confront significant resistance to genomics research generated by such ethical violations as the wronging of the Havasupai tribe by genetics researchers in the 1990s and early 2000s (Garrison, 2013). The Human Genome Diversity Project was also a hugely controversial venture, proposed in the early 1990s to sample "isolated and indigenous populations" globally before they "vanished" (Reardon, 2001). Indigenous groups and activists accused the project planners of biopiracy and colonialism (especially related to talk of commercializing and patenting results from the proposed project), mentalities of extraction and lack of respect for Indigenous sovereignty, and treating Indigenous peoples as "living fossils" (Reardon, 2001). These controversies have led NHGRI to develop robust ethics programs, collaborations with tribal leadership, stakeholder engagement activities, and relationships with scholars of ethics and genetics.

These long-term relationships with communities of qualitative social science and humanities researchers are a central reason why NHGRI has become a leader in key areas of equity such as engaging members of underserved groups in setting research priorities, and in valuing forms of knowledge outside of mechanistic biological research. The institute also has robust collaborations with many civil society groups representing marginalized Americans, such as nonprofits, museums, and educational institutions, and is in close contact with these groups. For example, NGHRI's collaboration with the National Congress of American Indians (NCAI) and their joint workshops at NCAI meetings led the institute to support (financially and technically) NCAI in developing an online resource guide on genomics research for tribal leaders and citizens; this guide underlines the importance of

[24] In light of public discussions in the mid-1980s regarding the implications of sequencing the human genome, James Watson (director of the Human Genome Project [HGP]), announced in 1988 that a portion of the HGP budget would go toward addressing social issues in genetics. This promise grew into a 3 percent budget commitment by NHGRI (then still a "Center" and not an Institute), which it scaled up to 5 percent by 1991. In the 1993 NIH Revitalization Act, Congress required that "not less than five percent" of NHGRI's budget go to such research (Dolan et al., 2022).

Indigenous knowledge.[25] Health equity staff at NHGRI are well aware of the significance of such forms of knowledge, and treat traditional knowledge as an important source of value.[26] Such "epistemological humility" is also evident in NHGRI's acknowledgement that they are not experts in tribal health or engagement, and deference to NIH's Office of Tribal Health (Fricker, 2007).

NHGRI put in place a director on health disparities two full decades ago, and has recently established a new Office of Training, Diversity and Health Equity (TiDHE)—a title that nods at efforts not only to describe disparities, but to focus on proactive work toward addressing those disparities in pursuit of equity. The institute also has four external working groups made up of health activists and social science researchers who advise NGHRI and its council on topics including Community Engagement and Genomics as well as Genomics and Society.

In recent years, genomics researchers have begun to develop polygenic risk scores (PRS), which combine the impacts of multiple different genes in order to estimate the disease risk of any one individual based on multiple genes. However, biomedical research over the past several decades has disproportionately focused on people of European descent, in large part because they are often already engaged in medical systems, making such individuals easier to recruit for research. This oversampling of people of European ancestry means that findings from existing genetic data are less reliable in people descended from populations outside of Europe (Pope and Fullerton, 2016).

However, these population categories are often misused and misrepresented as racial categories, although such authoritative groups as the American Society for Human Genetics have continued to make official public statements emphasizing that race is a social category that does not reflect underlying biology. The conflation of race and ancestry contributes to racism in medicine by reinforcing the idea that races are inherently biologically distinct (Amutah et al., 2021; Lee et al., 2008).

NHGRI has recognized PRS as an emerging technology with significant equity implications. As such, the institute has worked within the broader NIH landscape to establish a Polygenic Risk Methods in Diverse Populations Consortium; in June 2021, NHGRI announced that it set aside $33 million for research "to improve the methods and application of polygenic risk scores (PRS) in diverse populations," in addition to $5 million toward this goal through the NCI (NHGRI, 2021, 2022a). In addition to shaping its budget thus in order to conduct research towards addressing equity in this emerging technology, NHGRI has also developed fact sheets on the limitations of PRS in non-European populations, meant to inform the public through the NHGRI website (NHGRI, 2022b).

Barriers and Challenges

In recent years, the racial funding gaps described above have lessened to some extent, which many at NIH account to the agency's efforts providing targeted mentorship and professional development opportunities for members of underserved groups. In interviews for this report, several NIH staff argued that a lack of clarity on definitions, including that of "equity,"

[25] It notes, for example, "A meaningful ethical framework needs to be maintained by all parties seeking to work with tribes and tribal organizations. This includes a mindfulness toward traditional harms of research, cultural knowledge that is both historic and current, and acknowledgement of the worldview of each participating partner in the research proposal" (https://www.ncai.org/policy-research-center/research-data/prc-publications/NCAI_genetics_research_resource_guide_FINAL_2012_PDF.pdf, p. 98 [accessed August 8, 2023]).

[26] In interviews, this staff was easily conversant on the topic and could quickly reference NHGRI's work on the topic. This differs significantly from staff working on health disparities interviewed from other ICs.

is a major roadblock in their equity efforts. Surprisingly, they did not argue that financial or other resources are currently a major impediment. Rather, they emphasized the massive resources being dedicated to equity work currently. However, as noted above, some did point to an overreliance on peer-review scores to drive funding distributions as a significant impediment to funding both a more diverse group of investigators and research that better addresses the needs of a diverse population. The lack of allotted time and budget for advisory councils to conduct thorough review of grant applications also limits NIH's ability to pursue a program focused on equity in innovation, as does the independence of each IC to pursue its own priorities, although the former is much more likely to be changed than the latter. As described above, lower funding rates in ICs for most community- and population-level research is a major impediment to equity in innovation at NIH.

FEDERAL TRADE COMMISSION

As opposed to NIH, the Federal Trade Commission (FTC) is a very small agency, with approximately 1,200 employees and a budget of $376.5 million appropriated for FY2022 (less than 1 percent of NIH's total budget, and less than 15 percent of NIH's administrative operating budget). FTC is a law enforcement agency, responsible for policing business practices that are anticompetitive, deceptive, or unfair to consumers, under the FTC Act of 1914. The agency is composed of two large segments: the Bureau of Consumer Protection and the Bureau of Competition, in addition to eight regional offices and several smaller support offices. In addition to pursuing enforcement actions (legal cases) against businesses, FTC also has a mission to protect consumers through education and to pursue policy in support of these goals.

A large percentage of FTC's staff are lawyers; therefore, American legal traditions, norms, and habitus exert significant power in the organization. And while Hispanic American men and women are underrepresented at FTC compared with the civilian labor force (as are White women), White men are overrepresented by this metric, as are Black men and women (FTC, 2017). FTC staff consistently report being extremely overburdened and lacking sufficient support to accomplish important tasks. And while the agency pursues education activities and frequently holds public workshops on significant issues in antitrust and consumer protection, it has been rather reserved in public communication about its activities on the whole.[27] The U.S. Chamber of Commerce (the world's largest business organization) recently launched a campaign promoting transparency at FTC, arguing that FTC is overreaching its authority and conducting investigations based on "secret votes" without bipartisan support. While this can be interpreted as a partisan attack, it is rooted in FTC's less transparent approach to governance when compared with many other agencies—an approach that is likely justified in light of the agency's mandate for policing businesses.

In addition to enforcement actions, FTC also frequently sends "warning letters" to indicate to businesses that FTC may pursue legal action if those companies continue practices identified therein. For example, in 2016 FTC sent warning letters to app developers using code from the software development kit company Silverpush, which was using audio beaconing technology to turn on consumers' mobile phone microphones to monitor their TV viewing patterns and use this information for advertising. Silverpush is based outside of the United States, but FTC's warning letters indicated that if the company followed these

[27] This is evident in the difficulty encountered in engaging FTC staff for this report. While this report is greatly indebted to the effort that several FTC staff made to support the project, it is clear that FTC exerts much more control over staff in speaking about their work than does NIH, in line with the private legal matters handled by FTC.

practices in the United States, the FTC might bring a case against them. Technology media usually reports on such letters, which then function as warnings also to the broader industry.

But while FTC has authority to police "unfair" business practices, these have been difficult to support legally (Interview G); they require a legal weighing to demonstrate that the practices are not reasonably avoidable by consumers and that the benefits of the practice are not outweighed by the drawbacks. In the Vizio TV case settled in 2017 for $2.2 million, the company was collecting pixels aftermarket from their smart TVs to see what customers were watching and at what time, and then selling that information to analytics and advertising companies. FTC argued that this was unfair business practice, as consumers do not expect such surveillance and it was not of any benefit to them. In July 2021, FTC rescinded a 2015 policy limiting its own enforcement ability under the FTC Act (Section 5), which Democratic commissioners argued "doubled down on the Commission's longstanding failure to investigate and pursue 'unfair methods of competition'" (Khan et al., 2021, p. 5). By rescinding the policy, these commissioners argued that FTC could better pursue its obligations to enforce the prohibition of unfair methods of competition, extending beyond the Clayton Antitrust Act of 1914 (PL 63-212) (Khan et al., 2021).

Innovation and Emerging Tech

When asked about "equity in innovation" (and even "equity in emerging technology"), many interviewees at FTC emphasized that agency's work is law enforcement, with no particular attention to innovation or technology. However, historian and legal scholar Chris Jay Hoofnagle has argued that FTC "has evolved into the most important regulator of information privacy—and thus innovation policy—in the world" (Hoofnagle, 2016, pp. i-iv). In recent years, FTC has held numerous workshops[28] and issued reports and guidance to the companies it regulates regarding the Internet of Things (IoT), big data, data brokers, data security, online marketing, debt collection, health care, and the sharing economy, among other "equity in innovation" topics. It has brought cases in these areas as well, regarding, for example, such devices as baby monitors and connected toys.

Commissioner Edith Ramirez, who led the agency from March 2013 to January 2017, made health care and technology two of her primary areas of focus at FTC; *Time* magazine called her "the woman keeping silicon valley in check" (Luckerson, 2014). Along with one of FTC's chief technologists under the Obama administration (Ashkan Soltani), Chairwoman Ramirez led the founding of FTC's Office of Technology Research and Investigation (OTech), which "supports all facets of the FTC's consumer protection mission, including issues related to privacy, data security, connected cars, smart homes, algorithmic transparency, emerging payment methods, fraud, big data, and the Internet of Things"[29]. OTech sits within the Bureau of Consumer Protection and has led FTC in increasing its tech expertise (e.g., establishing an annual PrivacyCon; establishing a fellowship program for graduate-level technologists).

[28] For example, the April 2021 FTC workshop on Bringing Dark Patterns to Light focused on internet design features that impair customer autonomy (e.g., by sneaking items into shopping carts or making it difficult to remove additional products/services); this panel specifically investigated "the especially pernicious effects of dark patterns on communities of color" (see https://www.ftc.gov/news-events/events/2021/04/bringing-dark-patterns-light-ftc-workshop; accessed July 19, 2023) Additional workshop topics have included privacy and other data risks with regards to drones, smart TVs, connected cars, Ed Tech, etc.

[29] See https://www.ftc.gov/about-ftc/bureaus-offices/bureau-consumer-protection/our-divisions/office-technology-research-investigation (accessed July 19, 2023).

FTC's Explicitly Political Structure

FTC is an explicitly bipartisan agency, led by five commissioners serving 7-year terms, who are nominated by the U.S. president and subject to Senate confirmation. No more than three of these commissioners can be from any one party at any time. The president also selects one of these commissioners to serve as chair. This explicitly political infrastructure contrasts markedly with NIH's efforts to be a neutral, apolitical scientific agency. The bipartisan structure has at times hampered equity efforts at FTC. For example, when FTC recently released a statement on algorithmic discrimination, one commissioner immediately released an additional statement claiming that this focus overreaches FTC's legal authority. Any new FTC policy requires approval by vote of the commissioners; "equity" has been a politically charged term, making policies in this area difficult to pass.

Public Engagement

Under Commissioner Lina Khan, FTC has made efforts to increase public involvement in the agency's work, by, for example, holding open commission meetings with periods for public comment. In enforcement actions, FTC's work on "vulnerable groups" has focused primarily on children and the elderly; FTC has seen these groups as particularly vulnerable to fraudulent advertising. However, FTC has in recent years paid increasing attention to racial equity—for example, through the Every Community Initiative (ECI). ECI was established in 2014 with a focus on identifying and addressing areas of fraud that particularly affect communities of color, and the disproportionate burden of fraud that falls on members of these groups (FTC, 2021). Two years later, FTC issued a congressionally mandated report, *Combating Fraud in African American & Latino Communities: The FTC's Comprehensive Strategic Plan*. In addition to racial equity, FTC has long pursued enforcement actions based on advertising in Spanish, and it has increasingly done so in other languages as well.

From ECI's early focus on fraud, the initiative has expanded to address a wide array of equity issues within FTC's mission. ECI has worked to develop a feedback loop of contact with marginalized communities, which ECI staff see as especially important because FTC has observed in its consumer reports data that people of color less often report issues to FTC, even though it is clear that fraud falls more heavily upon them. ECI collaborates closely with FTC's Legal Services division, and last year started an initiative to partner with legal aid organizations to expand outreach to lower-income communities to improve reporting on consumer protection issues, as well as to improve involvement in FTC's education efforts. ECI also works closely with FTC's Consumer and Business Education Department, which has developed long-term connections with libraries, ethnic media outlets, community and senior centers, teachers of English as a second language, and others, which allow FTC to be in closer contact with underserved communities and address issues of concern to these groups. FTC's regional offices play a large role in this work, as they are more closely integrated with work being done "on the ground" in different parts of the country.

FTC has also engaged the public through "tech challenges," such as its 2016–2017 Internet of Things Home Device Security Contest, which offered a $25,000 prize for the top proposal to help consumers address security vulnerabilities in IoT devices.[30] Additionally, FTC publishes Analyses to Aid Public Comment on its cases.

[30] The winning app focused on analyzing whether their devices security systems are out of date and whether their networks are secure: https://www.ftc.gov/news-events/news/press-releases/2017/07/ftc-announces-winner-its-internet-things-home-device-security-contest (accessed July 19, 2023).

Legal Authority and Antiracism

The bounds of FTC's legal authority with regards to equity have been a battle of late. FTC recently recruited a civil rights lawyer to advise the agency's chairwoman, examining legal theory in order to establish the limits of FTC's civil rights authority; the goal of this work has been thinking holistically about the intersections of civil rights and consumer protection, which have traditionally been treated quite separately from consumer protection and competition law. Some at FTC have tried to push the agency to see that equity and civil rights are important elements of both FTC's consumer protection and antitrust work.

In the summer of 2020, amid widespread protests regarding racial equity in the United States, FTC Commissioner Rebecca Slaughter argued in a tweet that FTC must become antiracist and that antitrust laws can play an important role in racial equity (and should be explicitly antiracist) (Feiner, 2020). Prior to this, legal theory on antitrust as an equity issue was extremely limited; however, in the last 2 years, legal theory on this topic has multiplied rapidly (Interview C). In spite of public backlash from some stakeholders, Chairwoman Lina Khan has made public statements supporting antiracism in antitrust as well.

FTC Technologists

Under the leadership of Chairwoman Khan, the agency has also vastly expanded its team of technologists and has centralized many of these technical experts in an Office of the Chief Technology Officer, where they can support legal experts across the agency. Over the last decade, FTC has typically hosted chief technologists for a period of 1 year each, most often on leave from academic positions. The role of FTC technologists has been the subject of great debate in recent years. When Republican Commissioner Joe Simons was appointed FTC Chairman in 2018, he began investigating whether to establish a Bureau of Technology within FTC (Miller, 2018). However, Simons was apparently at odds with the Trump administration, which attempted to pressure FTC into pursuing cases against Twitter and other social media companies for anticonservative bias (Nylen et al., 2020).

Commissioner Rohit Chopra, who has directed the Consumer Financial Protection Bureau since October 2021, argued vehemently in late 2020 that FTC had become reactive with respect to issues in technology, following media reports rather than identifying cases proactively through its own research. Writing in a dissenting opinion on the Zoom settlement that year, which he and Commissioner Slaughter argued did not hold the company sufficiently accountable for its privacy gaps and misleading language regarding security, Chopra argued that FTC should "make a concerted effort to increase the proportion of technologists and others with technical knowledge in our investigative teams" and that the commission "has deprived our litigators and enforcement attorneys of ... needed expertise" (Victor, 2020).

Technology experts, advocacy groups, and journalists have in recent years consistently argued that FTC lacks sufficient technical expertise to hold technology companies accountable for privacy issues, and some observers have drawn attention to the impacts of this gap on equity as well (Wood, 2019). Chairwoman Khan has long been critical of "big tech" and has prioritized FTC attention in this area. In addition to ongoing attention to monopoly power in social media, search engines, eCommerce, and similar areas (and how a lack of competition can allow for known racially discriminatory features in Google searches, for example), Chairwoman Khan has helped drive FTC's recent attention to algorithmic bias.

Case Study: Algorithmic Bias

Under Chairwoman Edith Ramirez, FTC examined issues of "Inclusion" and "Exclusion" in the arena of big data and issued a report on the topic in early 2016 (FTC, 2016). During Commissioner Ramirez's time at FTC, the agency brought several cases related to data concentration (e.g., a merger case regarding educational marketing data),[31] cases in which companies have used geolocation data for advertising beyond the control of consumers,[32] and numerous cases regarding insufficient security and privacy measures that endanger consumers and their data.[33] FTC's big data efforts during this period also focused on enforcing the Fair Credit Reporting Act (FCRA); FTC pursued more than 100 FCRA cases under Chairwoman Ramirez, emphasizing that when companies buy data about consumers from analytics companies or data brokers, and use that data to make eligibility determinations regarding housing, credit, employment, insurance, and the like, the company must notify consumers and give them an opportunity to correct inaccurate information.

With the new presidential administration and the departure of Chairwoman Ramirez in early 2017, some of FTC's big data efforts slowed. However, in May of 2018, two new commissioners joined FTC, and continued to push on big data issues, including internet privacy: Commissioner Rebecca Slaughter and Commissioner Rohit Chopra. That year FTC brought a case against real estate software company RealPage, arguing that the company did not take proper steps to ensure the veracity of data it provided to landlords and property managers,[34] drawing attention to this significant element of algorithmic equity: the quality of data on which algorithms are based.

In April 2020, Bureau of Consumer Protection (BCP) director Andrew Smith published a blog post titled "Using Artificial Intelligence and Algorithms," warning that FTC could use FCRA to police the use of data and algorithms in making decisions about consumers. This guidance also emphasized that the Equal Credit Opportunity Act and the employment provision of the Civil Rights Act give FTC authority to enforce discrimination against "protected classes." One year later, in April 2021, a lawyer in the BCP wrote a blog post titled "Aiming for Truth, Fairness, and Equity in your Company's Use of AI" (Jillson, 2021). The post highlighted health AI as a prime site for algorithmic bias, since the data on which models are trained often reflect racial bias and then result in algorithms that perpetuate systemic racism. In a phrase that spread rapidly in the tech industry, the post cautioned companies to "hold yourself accountable—or be ready for the FTC to do it for you" (Jillson, 2021).

Throughout this period, FTC continued to hold public workshops on AI-related topics, such as voice cloning and dark patterns (see note under Innovation and Emeging Tech), as well as sessions on algorithmic bias, at PrivacyCon 2020 and 2021. Commissioner Slaughter also continued to write and speak extensively on algorithmic bias, promoting the importance of the topic to a wide array of audiences. Upon taking on the role of chairwoman in June 2021, Commissioner Khan brought in a legal advisor with extensive experience in algorithmic bias. In September of that year, FTC passed new investigation regulations regarding algorithmic and biometric bias, which allow staff to investigate allegations of such bias. While no enforcement

[31] Dun & Bradstreet Corp., Dkt. No. 9342 (filed May 7, 2010), https://www.ftc.gov/sites/default/files/documents/cases/2010/05/100507dunbradstreetcmpt.pdf (accessed July 19, 2023).

[32] See Press Release, FED. TRADE COMM'N, Mobile Advertising Network InMobi Settles FTC Charges It Tracked Hundreds of Millions of Consumers' Locations Without Permission (June 22, 2016), https://www.ftc.gov/newsevents/press-releases/2016/06/mobile-advertising-network-inmobi-settles-ftc-charges-it-tracked.

[33] For example, cases against Wyndham Worldwide (whose lax security allowed hackers to place memory-scraping malware on the company's servers, leading to financial information breaches) and TRENDnet (whose lack of security in home video security and baby monitors allowed hackers to post live feeds on the Internet).

[34] RealPage settled the case for $3 million.

actions on algorithmic bias are public at this time,[35] many observers have taken the new investigation regulations and the April 2021 blog post as an indication that FTC is likely bringing cases in this area currently or will do so in the near future.

In August of 2022 BCP released an Advance Notice of Proposed Rulemaking regarding Commercial Surveillance and Data Security (as well as a fact sheet on the topic), requesting public comments before October 21, 2022; in September FTC also held a virtual forum for public commentary. This notice used the term "algorithmic discrimination," asking for public comments on the following questions:

- How prevalent is algorithmic discrimination based on protected categories such as race, sex, and age? Is such discrimination more pronounced in some sectors than others? If so, which ones?
- How should the Commission evaluate or measure algorithmic discrimination? How does algorithmic discrimination affect consumers, directly and indirectly? To what extent, if at all, does algorithmic discrimination stifle innovation or competition?
- How should the Commission address such algorithmic discrimination? Should it consider new trade regulation rules that bar or somehow limit the deployment of any system that produces discrimination, irrespective of the data or processes on which those outcomes are based? If so, which standards should the Commission use to measure or evaluate disparate outcomes? How should the Commission analyze discrimination based on proxies for protected categories? How should the Commission analyze discrimination when more than one protected category is implicated (e.g., pregnant veteran or Black woman)?
- Should the Commission consider new rules on algorithmic discrimination in areas where Congress has already explicitly legislated, such as housing, employment, labor, and consumer finance? Or should the Commission consider such rules addressing all sectors?

However, the designation of "discrimination" has been difficult to support legally, and (as noted above) has raised criticism from some parties; although this recent report uses the term, FTC has considered other terminology such as "negative differential treatment" (Interview C).

FTC has thus addressed algorithmic bias through public education and engagement (e.g., public comment on rulemaking, and in open sessions), as well as through regulatory guidance. In June of this year, FTC issued another congressionally mandated report on AI; this one required FTC to investigate the use of AI in combatting predatory online behavior, such as child sexual exploitation and incitement of violence, as well as scams, fakes, and the like. However, FTC released a much broader report, drawing attention to its extensive AI work.

FTC's Equity Action Plan

As opposed to NIH, which does not have its own Equity Action Plan (EAP) because it falls under the EAP from HHS, FTC developed an independent EAP in accordance with the Biden administration's Executive Order 13985 of 2021 (FTC, 2022a). Few interviewees at FTC had heard about this EAP, even one administrator who was designated a team leader on one of the EAP goals. Members of the EAP team note that this kind of equity work is totally new at

[35] This statement depends on definitions. FTC's June 2022 report to Congress highlights two recent facial recognition tech cases as relevant: one against Facebook and another against Everalbum, both holding that these companies deceived consumers about the company's use of facial recognition technology.

FTC, and requires major shifts in mindsets, toward seeing equity as a significant contributor to all of FTC's work, rather than an added requirement on top of an already overburdened workforce. In addition to attempts to navigate explicit resistance to equity work, staff also have to navigate an extremely limited budget for equity work. Furthermore, the agency does not have experience in this arena, and is "building the airplane while flying" (Interview K).

One of the primary goals of the EAP is for the BCP to develop a toolkit for "evaluating the impact of deceptive or unfair practices in the use of emerging technologies (e.g., algorithmic bias and the gig economy) on underserved communities" (FTC 2022a, p. 4). The agency plans to measure this according to the following rubric:

Short term (2-4 years out):
1. Have we implemented the new toolkit and directed resources toward this effort?
2. Have the efforts resulted in law enforcement actions?
3. Are market actors responding to our efforts?

Long-term (5-8 years out):
1. Use of the toolkit is embedded in staff's work.
2. Robust law enforcement, community outreach, and new policies or initiatives (e.g., rulemakings, market studies, or other initiatives) that address relative harms to different market participants, including underserved communities.
3. Market actors affirmatively avoiding disparate harm to market participants, including underserved communities.

However, FTC has not established many metrics beyond these broad guidelines; it is still in the process of working this out. Beyond identifying equity issues in emerging technology, FTC plans to address these issues both through enforcement actions and by ensuring that members of marginalized groups receive appropriate shares of any compensation from FTC's suits and settlements.

On the antitrust side, the EAP laid out how FTC's Bureau of Competition (BC) will "revise its case selection and evaluation process by (1) systematically collecting information regarding the impact of proposed mergers and alleged anticompetitive conduct on communities that are already at a disadvantage in the American economy, particularly low-income communities, rural communities, and communities of color; and (2) including restrictive covenants and effects on workers, particularly low-wage workers, in BC's merger analysis" (FTC, 2022a, p. 6). In the past, FTC has not selected antitrust cases by explicitly analyzing the impacts of competitive practices on specific demographics or on workers, beyond the categories of children and the elderly.

FTC has not established metrics for this goal for the BC. However, staff involved in developing the EAP stressed that FTC is becoming a leader on this equity issue among antitrust and consumer protection agencies globally; only the antitrust organizations of Canada, South Africa, and the United Kingdom have even started developing policies relating to equity. Building on this work, FTC's strategic plan for 2022–2026 (released in August 2022) lists top ranking goals of "supporting equity for historically underserved communities through" both the agency's consumer protection and competition missions (FTC, 2022b).

Health Care

FTC has also pursued numerous cases and policy action in pharmaceutical antitrust and consumer protection;[36] although equity has not always been a primary driver in selecting these areas of focus, this work has significant equity implications, and (as described above) FTC is increasingly acknowledging equity as a factor in case selection. For example, FTC engaged their in-house civil rights expert in a recent case brought against DaVita Dialysis, recognizing that this case would significantly impact people of color in the United States. Likewise, recent policy work on pharmacy benefits managers' role in drug pricing has drawn some attention to impacts on low-income groups. However, these equity elements continue behind the scenes, outside of public visibility.

Limitations and Barriers

While FTC has advanced significantly in recent years on equity efforts, the terrain is still new for the organization, and many leaders in the organization oppose this very framing of work within FTC (as described above). Within FTC's own workforce, in spite of the federal mandate requiring agencies to have a federal women's program and Hispanic employment program, FTC runs neither of these SEPs (Interview F). Equal employment staff at FTC account this to insufficient budget. There are some obvious areas of racial inequity in consumer protection and antitrust where FTC has not taken action. For example, while racial inequities in credit reporting are well known, FTC has not pursued enforcement or policy in this area (Interview L; this contrasts with FTC's reference to the Equal Credit Opportunity Act as a basis for antidiscrimination authority). It is unclear whether this is because of political constraints, lack of budget, or other reasons. However, it is certain that FTC staff doing equity work are often taking on these responsibilities on top of a full set of additional job responsibilities; there are extremely limited financial and human resources for this work at FTC. Specific budget set-aside for equity work could go far in supporting FTC's "scrappy"[37] efforts in this area.

FTC has been working to address equity in innovation within the bounds of current laws and regulations. However, additional congressional mandates in this arena could help the agency address political roadblocks at the level of FTC's five commissioners (whose votes are required for policy action). While Congress asked FTC to make recommendations in its June 2022 report regarding laws that could advance the use of AI to address online harms, FTC instead argued that Congress should pass laws to ensure that AI tools do not cause additional harms. Similar equity-focused laws would likely be beneficial in other areas of emerging technology.

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[36] For example, the well-known Martin Shkreli "pharma bro" case, as well as numerous others in which FTC has required companies to divest from certain drug programs that would be anticompetitive.

[37] That is, creative and admirable work in the face of opposition and limited resources.

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Appendix D

Committee Member and Staff Biographies

COMMITTEE MEMBERS

Keith Wailoo, Ph.D. (*Co-Chair*), is Henry Putnam University Professor of History and Public Affairs at Princeton University. He is jointly appointed in the Department of History and the School of Public and International Affairs. Dr. Wailoo is former vice dean of the School of Public and International Affairs, former chair of history, and current president of the American Association for the History of Medicine (2020–2022). His research straddles history and health policy, touching on drugs and drug policy; on the politics of race and health; on the interplay of identity, ethnicity, gender, and medicine; and on controversies in genetics and society. In 2021, Dr. Wailoo received the Dan David Prize for his "influential body of historical scholarship focused on race, science, and health equity; on the social implications of medical innovation; and on the politics of disease." His writings have advanced historical and public understanding on a range of topics: racial disparities in health care, the cultural politics of pain and opioids, how pandemics change societies, and the FDA's decision to ban menthol cigarettes. Before joining the Princeton faculty, Dr. Wailoo taught history and social medicine in the Medical School at the University of North Carolina at Chapel Hill, and at Rutgers University, where he was Martin Luther King Jr. professor of history and jointly affiliated with the history department and the Institute for Health, Health Care Policy, and Aging Research. He was elected to the National Academy of Medicine and the American Academy of Arts and Sciences, and is the recipient of numerous other academic honors. As of May 24, 2023, he was elected a member of the board of directors for the Greenwall Foundation. Dr. Wailoo holds a Ph.D. in the history and sociology of science from the University of Pennsylvania, and a bachelor's degree in chemical engineering from Yale University.

Keith R. Yamamoto, Ph.D. (*Co-Chair*), is vice chancellor for science policy and strategy, director of precision medicine, and professor of cellular and molecular pharmacology at the University of California, San Francisco. He is a leading researcher investigating transcriptional regulation by nuclear receptors, which mediate the actions of essential hormones and cellular

signals; he uses mechanistic and systems approaches to pursue these problems in pure molecules, cells, and whole organisms. Dr. Yamamoto has led or served on numerous national committees focused on public and scientific policy; public understanding and support of biological research; science education; and diversity, equity, and inclusion and antiracism. He chairs the Coalition for the Life Sciences, co-chairs the National Academies of Sciences, Engineering, and Medicine Roundtable on Aligning Incentives for Open Science, and is vice chair of the Advisory Council for the California Initiative to Advance Precision Medicine. Dr. Yamamoto sits on the board of directors of the Public Library of Science, the board of directors of Rapid Science, the governing board of the California Institute for Regenerative Medicine, the oversight committee of the California Institute for Regenerative Medicine, the board of counselors for the Radiation Effects Research Foundation, and the advisory board for Lawrence Berkeley National Laboratory. He has chaired or served on many committees that oversee training and the biomedical workforce, research funding, and the process of peer review and the policies that govern it at the National Institutes of Health. Dr. Yamamoto was elected to the National Academy of Sciences, the National Academy of Medicine, the American Academy of Arts and Sciences, and the American Academy of Microbiology, and is a fellow of the American Association for the Advancement of Science.

Amy Abernethy, M.D., is president of product development and chief medical officer at Verily, where she leads teams in the development and delivery of products that bridge the gap between clinical research and care. Before joining Verily, she was principal deputy commissioner of Food and Drugs of the U.S. Food and Drug Administration (FDA) and the agency's acting chief information officer. Prior to her role at the FDA, Dr. Abernethy was chief medical officer, chief scientific officer, and senior vice president of oncology of Flatiron Health. Before joining Flatiron, she was professor of medicine at Duke University School of Medicine and directed the Center for Learning Health Care in the Duke Clinical Research Institute and Duke Cancer Care Research Program in the Duke Cancer Institute. Dr. Abernethy is a hematologist/oncologist and palliative medicine physician who has authored more than 500 publications. She holds a B.A. in biochemistry from the University of Pennsylvania, an M.D. from Duke University School of Medicine, and a Ph.D. in evidence-based medicine and informatics from Flinders University in Australia.

David A. Asch, M.D., M.B.A., is senior vice dean for strategic initiatives at the Perelman School of Medicine and John Morgan professor at the Perelman School and the Wharton School at the University of Pennsylvania. He created, and from 2001 to 2012 directed, the Center for Health Equity Research and Promotion—the Department of Veterans Affairs' health services research center for understanding and eliminating racial disparities in health and health care. From 1998 to 2012, Dr. Asch was executive director of the Leonard Davis Institute of Health Economics. From 2012 to 2022 he was executive director of the Penn Medicine Center for Health Care Innovation. His research is in the area of behavioral economics and aims to understand and improve how physicians and patients make medical choices. Dr. Asch is an elected member of the National Academy of Medicine and has received awards for teaching, mentorship, scholarship, and innovation.

Olveen Carrasquillo, M.D., M.P.H., is professor of medicine and public health sciences and associate dean for clinical and translational research at the University of Miami's Miller School of Medicine. For 8 years, he was director of the Center of Excellence in Health Disparities Research at Columbia University. For 13 years, he served as chief of the Division of General Internal Medicine at the University of Miami, where he led a clinical, teaching, and research

enterprise of 51 full-time faculty. Dr. Carrasquillo now serves as codirector of the university's Clinical and Translational Science Institute, whose mission is to drive research translation into evidence-based clinical and community practices to improve the health of South Florida's diverse population. Since the COVID-19 pandemic began, he has helped lead the health system's institutional response to COVID-19 and has taken a lead role in community education, including numerous media appearances and presentations to community groups. He is also leading the National Institutes of Health–sponsored Florida Community-Engaged Research Alliance Against COVID-19 in Disproportionately Affected Communities (FL-CEAL). Dr. Carrasquillo is a national expert in minority health, health disparities, community-based participatory research, access-to-care, and community health worker interventions. He is also active in the Society of General Internal Medicine, Physicians for a National Health Program, National Hispanic Medical Association, and Latinos for Health Equity. Dr. Carrasquillo is a board member of the Miami-Dade Area Health Education Center and the South Florida Health Council. He obtained his M.D. from the New York University School of Medicine. He also completed a 3-year internal medicine residency at Columbia-Presbyterian Medical Center, Harvard's 2-year general medicine fellowship, and an M.P.H. from the Harvard School of Public Health.

Amitabh Chandra, Ph.D., is Ethel Zimmerman Wiener Professor of Public Policy and director of health policy research at the Harvard Kennedy School of Government, and the Henry and Allison McCance professor of business administration at Harvard Business School, where he directs the joint MS/MBA program in the life sciences. Dr. Chandra is a member of the Congressional Budget Office's Panel of Health Advisors and is a research associate at the National Bureau of Economic Research. His research focuses on innovation and pricing in the biopharmaceutical industry, value in health care, medical malpractice, and racial disparities in health care. His research has been supported by the National Institute on Aging, the National Institute of Child Health and Human Development, and the Robert Wood Johnson Foundation. His work has been published in the *American Economic Review*, the *Journal of Political Economy*, the *New England Journal of Medicine*, the *Journal of the American Medical Association*, and *Health Affairs*. He is chair editor of the *Review of Economics and Statistics*. Dr. Chandra is an elected member of the National Academy of Medicine and the National Academy of Social Insurance.

R. Alta Charo, J.D., is professor emerita of law and bioethics at the University of Wisconsin, and now works as an independent consultant to government and industry on medical and biotechnology ethics, policy, and governance related to human therapeutics, agriculture, species conservation, and national security. She was a member of President Clinton's National Bioethics Advisory Commission and worked as a legal and policy analyst for the former congressional Office of Technology Assessment, the U.S. Agency for International Development and the U.S. Food and Drug Administration. Ms. Charo has been elected to the American Association for the Advancement of Science (AAAS) and the American Academy of Arts and Sciences, as well as the National Academy of Medicine. She is a member of the AAAS committee on science, engineering, and public policy, and has now or recently had consulting contracts with BioMADE, DARPA, Colossal, Conception, eGenesis, Vertex, Johnson & Johnson, Gameto, and Warner Bros. Entertainment. She has also served as a member of the National Academies Committee on Science, Technology, and Law, and co-chaired the Committee on Guidelines for Embryonic Stem Cell Research, the Committee on Genome Editing Governance, and the Committee on Emerging Science and Technology Innovation.

Hana El-Samad, Ph.D., is founding principal investigator at Altos Labs and professor in the Department of Biochemistry & Biophysics and deputy-director of the Cell Design Institute at the University of California, San Francisco. She is a control and dynamical systems theorist whose work generated fundamental insights into the principles of precise and robust cellular responses through the use of feedback control. Her recent work pioneered real-time measurement of feedback in living cells, synthetic feedback technologies to program cellular function, and theoretical frameworks to quantify biological homeostasis. Dr. El-Samad is founding editor in chief of *GEN Biotechnology*, and a staunch advocate for the diversification of the STEM workforce. She is the recipient of many honors and awards, including a 2011 Donald P. Eckman Award, and is 2013 Paul G. Allen distinguished investigator, 2017 senior investigator of the Chan-Zuckerberg Biohub, and 2020 fellow of the American Institute for Medical and Biological Engineering.

Michele Bratcher Goodwin, J.D., LLM, SJD, is Linda D. & Timothy J. O'Neill Professor of Constitutional Law and Global Health Policy at Georgetown Law School. She was previously Chancellor's professor at the University of California, Irvine, and senior lecturer at Harvard Medical School. Previously, she served as Everett Fraser professor at the University of Minnesota, with faculty appointments in the schools of law, medicine, and public health. She directed the first American Bar Association (ABA)–accredited health law program in the nation and founded the first law center focused on race and bioethics. Her primary areas of research span constitutional law, bioethics, and health law policy. Ms. Goodwin is the author of six books and more than 100 articles, book reviews, and commentaries. She is the recipient of the 2020–2021 Distinguished Faculty Award, the highest honor bestowed in the University of California system. In 2022, she received the distinguished Margaret Brent Award from the ABA. Ms. Goodwin was a Gilder Lehrman postdoctoral fellow at Yale University and earned her SJD and LLM (as well as B.A.) from the University of Wisconsin. She earned her J.D. from Boston College.

Anthony Ryan Hatch, Ph.D., is professor of science in society at Wesleyan University, where he is affiliated faculty in the Department of African American Studies, the College of the Environment, and the Department of Sociology. He is the author of *Silent Cells: The Secret Drugging of Captive America* (Minnesota, 2019) and *Blood Sugar: Racial Pharmacology and Food Justice in Black America* (Minnesota, 2016). He teaches and lectures widely on health systems, medical technology, and social inequalities. He is a fellow in The Hastings Center, a member of the Health and Social Equity Collective at King's College, London, and the Sydney Center for Healthy Societies. Dr. Hatch also serves on the Wellcome Trust Medical Humanities Discovery Advisory Group and the Community Development Community Advisory Council of the Federal Reserve Bank of Boston. He is on the editorial boards of *Science, Technology & Human Values* and the *Social History of Alcohol and Drugs*. At Wesleyan, Dr. Hatch is the founding director of Black Box Labs, an undergraduate research and training laboratory that offers students training in qualitative research methods in science and technology studies and the opportunity to collaborate with faculty on social research. He earned an A.B. in philosophy from Dartmouth and M.A. and Ph.D. in sociology from the University of Maryland, College Park.

Jianying Hu, Ph.D., is IBM fellow; global science leader, AI for Healthcare, and director of HCLS Research at IBM Research; and adjunct professor at Icahn School of Medicine at Mount Sinai. Prior to joining IBM in 2003, she was with Bell Labs at Murray Hill, New Jersey. Dr. Hu has conducted and led extensive research in machine learning, data mining, statistical

pattern recognition, and signal processing, with applications to health care analytics and medical informatics, business analytics, and multimedia content analysis, with recent efforts focusing on advanced computational methods for deriving data-driven insights from real-world health care data. She has published more than 140 peer-reviewed scientific papers and holds 48 patents. Dr. Hu served as chair of the Knowledge Discovery and Data Mining Working Group of the American Medical Informatics Association (AMIA) from 2014 to 2016, and on the Computational Science Advisory Board of The Michael J. Fox Foundation from 2017 to 2018. She has served as associate editor for many journals, and currently serves on the Journals and Publications Committee of AMIA, editorial board of *JAMIA Open*, and the External Advisory Board of Vanderbilt University Department of Biomedical Informatics. Dr. Hu is a fellow of the American College of Medical Informatics, International Academy of Health Sciences Informatics, IEEE, and the International Association of Pattern Recognition. She received the Asian American Engineer of the Year Award in 2013.

Lisa I. Iezzoni, M.D., M.Sc., is professor of medicine at Harvard Medical School, based at the Health Policy Research Center, Mongan Institute, Massachusetts General Hospital, and a 2022–2023 fellow of the Harvard Radcliffe Institute. After spending 16 years as codirector of research in the Division of General Medicine and Primary Care at Boston's Beth Israel Deaconess Medical Center, she joined the then Institute for Health Policy at Massachusetts General Hospital as associate director in 2006 and served as its director from 2009 to 2018. Her early research focused on risk-adjustment methods for predicting cost and clinical outcomes of care; since 1998, she has studied the lived experiences, health, and health care services of persons with disabilities. She served on the National Committee on Vital and Health Statistics and the Secretary's Advisory Committee on Health Promotion and Disease Prevention Objectives for 2020. She has served on the editorial boards of the *Annals of Internal Medicine*, the *Journal of General Internal Medicine*, *Health Affairs*, *Medical Care*, *Health Services Research*, and the *Disability and Health Journal*, among others. Dr. Iezzoni is a member of the National Academy of Medicine. She has an M.D. from Harvard Medical School and an M.Sc. from the Harvard School of Public Health.

Alex John London, Ph.D., is Clara L. West Professor of Ethics and Philosophy and director of the Center for Ethics and Policy at Carnegie Mellon University. An elected fellow of the Hastings Center, Dr. London's work focuses on ethical and policy issues surrounding the development and deployment of novel technologies in medicine, biotechnology, and artificial intelligence; on methodological issues in theoretical and practical ethics; and on cross-national issues of justice and fairness. His book, *For the Common Good: Philosophical Foundations of Research Ethics*, is available as an open-access title from Oxford University Press (2021). He was previously a member of the National Academy of Medicine Committee on Clinical Trials During the 2014–2015 Ebola outbreak, and was a member of the World Health Organization Expert Group on Ethics and Governance of AI, whose report *Ethics and Governance of Artificial Intelligence for Health* was published in 2001. He previously served on the U.S. Health and Human Services Advisory Committee on Blood and Tissue Safety and Availability, and he is currently a member of the U.S. National Science Advisory Board for Biosecurity. He also serves on the board of directors for the International Association of Bioethics. He has authored more than 100 papers or book chapters. He is coeditor of *Ethical Issues in Modern Medicine*, one of the most widely used textbooks in medical ethics.

Debra Mathews, Ph.D., is associate director for research and programs for the Johns Hopkins Berman Institute of Bioethics and an associate professor in the Department of Genetic

Medicine, Johns Hopkins School of Medicine. She is also ethics and governance lead for the Johns Hopkins Institute for Assured Autonomy. Her academic work focuses on ethics and policy issues raised by emerging technologies, with particular focus on genetics, stem cell science, neuroscience, synthetic biology, and artificial intelligence. In addition to her academic work, Dr. Mathews has spent time at the Genetics and Public Policy Center, the U.S. Department of Health and Human Services, the Presidential Commission for the Study of Bioethical Issues, and the National Academy of Medicine, working in various capacities on science policy. Dr. Mathews is an ad hoc member of the Working Group on Data Science and Emerging Technology of the National Institutes of Health NExTRAC and a member of the board of directors of the International Neuroethics Society. In 2020, she was elected as a fellow of the Hastings Center. Dr. Mathews earned her Ph.D. in genetics from Case Western Reserve University, as well as a concurrent master's in bioethics. She completed a postdoctoral fellowship in genetics at Johns Hopkins University and the Greenwall fellowship in bioethics and health policy at Johns Hopkins and Georgetown universities.

Shobita Parthasarathy, Ph.D., is professor of public policy and women's and gender studies, and director of the Science, Technology, and Public Policy Program at the University of Michigan. Her research focuses on the social, ethical, equity, historical, and policy dimensions of science and technology, in comparative and international perspective. She has published widely on genetics and biotechnology, intellectual property, innovation policy, and artificial intelligence. She is the author of numerous articles and two books: *Building Genetic Medicine: Breast Cancer, Technology, and the Comparative Politics of Health Care* (MIT Press, 2007) and *Patent Politics: Life Forms, Markets, and the Public Interest in the United States and Europe* (University of Chicago Press, 2017). The former influenced the 2013 U.S. Supreme Court case that determined that human genes were not patentable; the latter won the 2018 Robert K. Merton Award from the American Sociological Association. She writes frequently for public audiences and cohosts The Received Wisdom podcast. She has held fellowships from the American Council for Learned Societies, the Woodrow Wilson International Center for Scholars, and Max Planck Institute for Innovation and Competition. She holds a bachelor's degree in biology from University of Chicago, and master's and doctoral degrees in science and technology studies from Cornell University. She has held postdoctoral fellowships at Northwestern University; the University of California, Los Angeles; and University of Cambridge.

Timothy M. Persons, Ph.D., is a partner of PricewaterhouseCoopers LLP, leading its work in the development of innovative assurance solutions for the firm's clients in artificial intelligence/machine learning, data, algorithms, and other digital transformations to help them build and maintain trust with their customers and stakeholders. He was formerly chief scientist and managing director of the Science, Technology Assessment, and Analytics team of the U.S. Government Accountability Office (GAO). In addition to founding GAO's Innovation Lab and leading advanced data analytic activities at GAO, he directed GAO's science, technology, and engineering portfolio, including technology assessment, technical assistance, and engineering sciences in support of Congress and GAO. Prior to joining GAO, Dr. Persons served as technical director for the Intelligence Advanced Research Projects Activity, as well as technical lead for the Quantum Information Sciences and Biometrics research groups for the Information Assurance Directorate at the National Security Agency.

Arti Rai, J.D., is Elvin R. Latty Professor of Law and faculty director, The Center for Innovation Policy at Duke Law, and is an internationally recognized expert in intellectual property law, innovation policy, administrative law, and health law. Ms. Rai's extensive research on

these subjects has been funded (inter alia) by the National Institutes of Health, the National Science Foundation, Arnold Ventures, the Kauffman Foundation, the Greenwall Foundation, and the Woodrow Wilson Center. From March to December 2021, she served as senior advisor on innovation law and policy issues to the Department of Commerce's Office of General Counsel. She also regularly advises other federal and state agencies, as well as Congress, on these issues. Ms. Rai has served as a member of the National Advisory Council for Human Genome Research, as a public member of the Administrative Conference of the United States, and on numerous National Academies of Sciences, Engineering, and Medicine committees. She graduated from Harvard College and Harvard Law School.

Kaushik Sunder Rajan, Ph.D., is professor of anthropology, codirector of the Chicago Center for Contemporary Theory, and faculty board member of the Pozen Center for Human Rights at the University of Chicago. He works on the political economy of the life sciences and biomedicine. Dr. Rajan is the author of *Biocapital: The Constitution of Post-Genomic Life* (Duke, 2006) and *Pharmocracy: Value, Politics and Knowledge in Global Biomedicine* (Duke, 2017), and the editor of *Lively Capital: Biotechnologies, Ethics and Governance in Global Markets* (Duke, 2012). He has just completed a book on the politics of ethnography, titled *Multi-situated: Ethnography as Diasporic Praxis* (University of Chicago Press, forthcoming). Currently, Dr. Rajan is embarked on a research project that studies the intersections of health and law in South Africa.

Krystal Tsosie, Ph.D., M.P.H., is an Indigenous geneticist-bioethicist (Diné/Navajo Nation) and assistant professor in the School of Life Sciences at Arizona State University. She cofounded the first U.S. Indigenous–led biobank, a 501(c)(3) nonprofit research institution called the Native BioData Consortium. She also serves as the 2022–2023 global chair of ENRICH: Equity for Indigenous Research and Innovation, which focuses on enhancing Indigenous rights to develop, control, and govern Indigenous data and supports participation in STEM and in digitally enabled futures. Much of Dr. Tsosie's current research centers on ethical engagement with Indigenous communities in precision health. She also incorporates biostatistics, genetic epidemiology, public health, and computational approaches to cancer health disparities, particularly in women's health. At the laboratory bench, she developed and patented a combined targeted ultrasound imaging and chemotherapeutic drug delivery device for treating early metastases in cancer.

NAM FELLOWS

Gilbert S. Omenn Fellowship

Andrew A. Gonzalez, M.D., J.D., M.P.H., is assistant professor of surgery at the Indiana University School of Medicine. He is also associate director for data science and research scientist at the Center for Health Services Research of the Regenstrief Institute, Inc. Dr. Gonzalez is interested in novel uses of technology to improve patient outcomes. His current early career development project seeks to apply artificial intelligence (AI) and machine learning toward optimizing outcomes and value in peripheral arterial disease. Specifically, he is exploring three lines of research: (1) creation of a cloud-based platform to organize and analyze structured and unstructured data from the electronic health record, imaging systems, and wearables for clinical implementation and research data curation; (2) development of "doctor in the middle" paradigms for health care AI implementation; and (3) development of best practices for identifying and addressing bias in health care AI algorithms. His clinical

interests are limb optimization in the setting of chronic limb-threatening ischemia, advanced aortic interventions, and vascular trauma. Dr. Gonzalez earned his M.D., M.P.H., and B.S. from the University of Illinois at Chicago and his J.D. from the John Marshall Law School. He completed his residency at the University of Illinois and held a National Institutes of Health (T32) postdoctoral research fellowship in the Center for Healthcare Outcomes & Policy at the University of Michigan's Institute for Healthcare Policy & Innovation.

James C. Puffer, M.D./American Board of Family Medicine (ABFM) Fellowship

Steven Lin, M.D., is clinical associate professor and vice chief of technology innovation in the Division of Primary Care and Population Health at Stanford University School of Medicine. He is founder and executive director of the Stanford Healthcare AI Applied Research Team (HEA3RT). His research focus is at the intersection of health services innovation, digital health, and emerging technologies—specifically artificial intelligence and machine learning. Dr. Lin is the author of more than 350 scholarly works and conference presentations. He earned his M.D. from Stanford University and completed his training at Stanford's family medicine residency program at O'Connor Hospital.

Appendix E

Disclosure of Unavoidable Conflicts of Interest

The conflict-of-interest policy of the National Academies of Sciences, Engineering, and Medicine (https://www.nationalacademies.org/about/institutional-policies-and-procedures/conflict-of-interest-policies-and-procedures) prohibits the appointment of an individual to a committee like the one that authored this Consensus Study Report if the individual has a conflict of interest that is relevant to the task to be performed. An exception to this prohibition is permitted only if the National Academies determine that the conflict is unavoidable and the conflict is promptly and publicly disclosed.

When the committee that authored this report was established a determination of whether there was a conflict of interest was made for each committee member given the individual's circumstances and the task being undertaken by the committee. A determination that an individual has a conflict of interest is not an assessment of that individual's actual behavior or character or ability to act objectively despite the conflicting interest.

Dr. Amy Abernethy was determined to have a conflict of interest in relation to her service on the Committee on Creating a Framework for Emerging Science, Technology, and Innovation in Health and Medicine because she is president of product development and chief medical officer at Verily, a subsidiary of Alphabet, Inc. that focuses on the development of tools to use the increasing availability of health information and computing power to advance precision health. Dr. Abernethy also serves on the Board of EQRx, owns securities in 10x Genomics, Adaptive Bio, Beam Therapeutics, BeiGene, BridgeBio, Kura Oncology, and Organon, and holds an equity interest in Iterative Scopes.

Prof. R. Alta Charo was determined to have a conflict of interest in relation to her service on the Committee on Creating a Framework for Emerging Science, Technology, and Innovation in Health and Medicine because she is a consultant to several for-profit companies involved in the development of innovative products and services in the area of health and medicine, including Johnson & Johnson (on ethical trial design), Colossal Biosciences, and Gameto. She also serves on the ethics advisory boards of eGenesis and Vertex Pharmaceuticals.

Dr. Hana El-Samad was determined to have a conflict of interest in relation to her service on the Committee on Creating a Framework for Emerging Science, Technology, and

Innovation in Health and Medicine because she is a founding principal investigator of the biotechnology company Altos Labs and serves on the science advisory board of Sestina Bio.

Dr. Jianying Hu was determined to have a conflict of interest in relation to her service on the Committee on Creating a Framework for Emerging Science, Technology, and Innovation in Health and Medicine because she is an IBM fellow, director of Healthcare and Life Sciences Research, and global science leader of artificial intelligence for Healthcare at IBM Research.

In each case, the National Academies determined that the experience and expertise of the individual was needed for the committee to accomplish the task for which it was established. The National Academies could not find another available individual with the equivalent experience and expertise who did not have a conflict of interest. Therefore, the National Academies concluded that the conflict was unavoidable and publicly disclosed it on its website (www.nationalacademies.org).