Health innovation policy for the people

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ABSTRACT

The US government has long played a central role in innovation, both through the patent system and by directly supporting research and development. In articulating innovation priorities and defining how to achieve them, policymakers have relied heavily on the expertise of scientists and market players. This has expanded the technical workforce, increased the numbers of scientific publications and patents, and produced macroeconomic growth. The benefits for the population are less clear: there is growing social and economic inequality and the needs of marginalized groups are invariably ignored.

This paper identifies four harms of this approach, specifically for health equity. It does not consider concerns of accessibility or affordability, defining these as health care, rather than innovation, problems. It limits the range of innovators, and also distorts innovation incentives. Finally, it tolerates harmful, and even biased, innovation.

The paper concludes with recommendations for addressing these negative consequences: sponsoring much more interdisciplinary research, engaging marginalized communities as experts, and exploring non-market avenues for health innovation.
We tend to think of innovation, especially in the United States, as a largely industrial affair. But the federal government has long played a central role, through what scholars call “push” policies to stimulate activity (Sarewitz, 1996). The government should set the right conditions for research and development to flourish, the logic goes, which will in turn produce markets, economic growth, and societal benefit. This effort began early, when the country’s founders articulated intellectual property protections in the Constitution and Congress passed the first patent law in 1790. In addition, the US government has directly funded scientific and technological development for well over a century, through both its own laboratories and investments in university and industrial research, both basic and mission-driven.

In this approach, policymakers may prioritize innovation in particular areas, such as “the war on cancer” or the development of COVID-19 vaccines, but scientific and market expertise are crucial to shaping how these public priorities are interpreted and met. This makes some sense. After all, both scientists and market players (whether companies or universities) have deep knowledge about the state of technical fields and the feasibility of particular initiatives. Furthermore, market players understand the economic landscape, and the US government has always seen the marketplace as a crucial mechanism for making new technologies available to the population. But has this approach to innovation generated sufficient public benefit?

Some argue that it has. Despite questions about whether they are an appropriate way to measure innovative activity, patents are increasing: in 1900 the US Patent and Trademark Office (PTO) issued approximately 25,000 patents per year, in 1980 it was about 62,000 per year, and in 2020 PTO issued 352,066 patents (Jaffe and Lerner, 2004; USPTO, 2021a). Others highlight an increase in both the highly skilled workforce and the gross domestic product (Jorgenson, Ho, and Stiroh, 2008; NASEM, 2017a). When looking specifically at the health sector, government investments have stimulated significant private sector development (Cockburn and Henderson, 2000), which in turn has created new knowledge, tools, and important inventions: one review showed that between 1970 and 2009, government resources had directly contributed to the discovery of 153 drugs and vaccines (Stevens et al., 2011).

And yet, if the last year and a half has taught us anything, it’s that our health innovation policies are not benefiting all of us, and that low-income individuals, historically disadvantaged people of color, and otherwise marginalized communities are often paying a large price (Parthasarathy, 2020). In fact, differential access to crucial health technologies may even be exacerbating social and economic inequalities.

The life expectancy for the wealthiest 1% of Americans is far higher than for the poorest 1%: 10.1 years more for women and 14.6 for men (Chetty, 2016; Dickman, Himmelstein, and Woolhandler, 2017). The lower the income,
the higher the prevalence of chronic conditions such as stroke and arthritis (Woolf et al. 2015). Health inequalities are particularly pronounced between racial categories, and were replicated through the COVID-19 pandemic (NASEM, 2017b); Black people, for example, were much more likely to contract and die from the disease than their white counterparts (Abedi, 2020).

Although there are multiple structural causes for these inequalities (Yearby, 2018), innovation policies are an important part of the picture and yet are rarely discussed in this context. Potentially life-saving drugs, devices, and vaccines tend to reach the most privileged first, and some never “trickle down.” Racial bias is built into technologies—including those crucial to managing COVID-19 such as the pulse oximeter—and yet there seems to be little incentive among scientists, physicians, government, or private sector players to identify and address these problems. And overall, there seems to be much less innovation related to issues of concern to marginalized communities.

This article examines the equity implications of the US approach to health innovation policy, and offers suggestions for how it might be improved. I argue that while our current approach, driven by scientists’ and market priorities, may have expanded the country’s innovation infrastructure and produced macroeconomic growth, it has not benefitted, and often has even harmed, less privileged populations.

The paper begins by briefly describing the history of the US innovation system and its relation to health and biomedicine. I then discuss four types of problems created by this system and offer suggestions for how we can reimagine health innovation policies that are equitable and just. While “innovation policy” could be interpreted quite broadly, here I focus on research funding and the patent system.

**Background: Defining the public interest in US innovation policy**

Innovation has always been central to America’s identity. The country’s founders argued that if they could foster innovation and entrepreneurship through intellectual property, then the country would benefit in terms of access to new technologies and economic growth. In fact, the intellectual property system was deemed so important to the fledgling country that it was envisioned in Article I of the Constitution, which gave Congress the power to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” In the process, the founders assumed that the inventors’ and public interests were synonymous: all citizens were prospective inventors, and if their needs were met then the country would prosper (Parthasarathy 2017a).

This philosophy was then embedded in the structure of the patent system that Congress ultimately developed. Unlike its European counterparts, the United States created a system that encouraged broad participation: patent application fees were low, and new inventions were displayed across the country in order to engage the citizenry in innovation (Biagioli, 2011). Furthermore, while European governments had bestowed patent “privileges” upon favored entrepreneurs, US leaders framed patents as legal “rights” to commercialize an invention for a limited period of time (Walterschied, 1995). And, the US system framed itself as objective, relying on scientific and technical knowledge in addition to the law to adjudicate patent claims.

With this foundation, American technological development grew throughout the 19th century, particularly through the agricultural and railroad industries (Usselman, 2002). At the same time,
the scientific enterprise was developing in scope and complexity, largely on the basis of funding from philanthropic individuals and foundations, and state governments (Kay, 1996). Meanwhile, the federal government began to invest in scientific work to inform its decisions, from meteorology to public health (Harden, 1986). By the early 20th century, it was becoming clear that federal funding of science could also facilitate technological development. Perhaps the clearest case was the creation of the Office of Scientific Research and Development (OSRD) during World War II, which funded scientists in both university and federal laboratories to conduct research and development for military purposes including the atomic bomb (known as the Manhattan Project) (Groves, 1962).

In response, President Franklin D. Roosevelt invited OSRD director Vannevar Bush to recommend how the government could aid research activities “by public and private organizations” during peacetime, in order to “stimulate new enterprises, provide jobs for our returning service-men and other workers, and make possible great strides for the improvement of our national well-being” (Bush, 1945). In response, Bush published Science—the Endless Frontier in 1945, which articulated a strategy for US research policy and, crucially for the purpose of this paper, an ideology of the government’s role in innovation that is still largely in place today. In the report, Bush rejected OSRD’s mission-driven approach and instead argued that basic research, driven purely by scientific curiosity and funded on the basis of scientific peer review, would produce greater societal benefit. He noted:

“The Government is peculiarly fitted to perform certain functions, such as the coordination and support of broad programs on problems of great national importance. But we must proceed with caution in carrying over the methods which work in wartime to the very different conditions of peace. We must remove the rigid controls which we have had to impose, and recover freedom of inquiry and that healthy competitive scientific spirit so necessary for expansion of the frontiers of scientific knowledge.” (Bush, 1945)

Bush also saw the marketplace as the best way to distribute the fruits of federally funded research in the public interest. Although the National Institutes of Health (NIH) and other agencies already sponsored scientific research that informed government decision-making, Bush argued that basic research could help industry develop new technologies. To accomplish this, the government needed to sponsor university research but also facilitate the translation of the results to industry. Patents would provide both knowledge and incentives for businesses to develop the fruits of this innovation that would ultimately benefit society. Strong and reliable patent protections, he argued, would “stimulate new invention and…make it possible for new industries to be built around new devices or new processes. These industries generate new jobs and new products, all of which contribute to the welfare and strength of the country.” Embedded in this vision was the assumption that technologies based on government-sponsored research and developed by industry would be both beneficial and accessible.

Government leaders followed Bush’s advice as they dramatically increased federal funding for scientific research over the next decades, including expanding the NIH and establishing the National Science Foundation in 1950. Then and today, the scientific community guides these agencies’ research priorities and determines the types of research projects that should receive government support. This occurs through peer review, in which highly esteemed subject matter experts—both inside universities and employed by the scientific agencies—evaluate proposed projects based on the researcher’s background
The Bush approach concentrated federal funding in the hands of a few scientists at a handful of elite research universities, which has magnified geographic, socioeconomic, and racial inequalities.

and qualifications, the research plan, and the potential contribution to the state of scientific knowledge. Theoretically, projects deemed the most important and feasible are funded. An innovation system shaped by the most meritorious scientists, the logic goes, will generate more knowledge about the world, build a skilled workforce, and generate more innovation (Sarewitz 1996).

Research funding guided by scientists’ priorities seems like it would be ideal. After all, scientists have enormous technical expertise and a nuanced understanding of the research landscape, including gaps and opportunities. But, even when Bush published his report, there were concerns that this approach would not necessarily reflect public priorities and would only increase funding in regions where there was already a lot of research activity (Kleinman, 1995). As described in further detail below, the next decades would validate these concerns. The Bush approach concentrated federal funding in the hands of a few scientists at a handful of elite research universities, which has magnified geographic, socioeconomic, and racial inequalities (Sheltzer and Smith, 2014; Katz and Matter, 2019). It also leaves definitions of intellectual merit up to a demographically narrow set of scientists, whose interests and concerns may not represent the broader community or the greatest areas of societal need.

The US government also heeded Bush’s recommendations by focusing on patenting and commercialization as the central pathway for “translating” scientific research into public benefit. Although there had been some controversy over the scope of patentable subject matter and the social, economic, and health impacts of patent-based monopolies, policymakers still treated the market as the dominant mechanism for distributing potentially useful innovation (May and Sell, 2005; Parthasarathy, 2017a). And they trusted market players to have a nuanced understanding of consumers and the marketplace and therefore be likely to know which investments are likely to be needed to produce successful outcomes. So they encouraged companies to build on the scientific knowledge developed at universities to create new technologies.

But the pharmaceutical and other industries were hesitant: who would own the knowledge produced at universities with the help of federal funding? What rights would the government have in the intellectual property? And most important, would companies always have to worry that competitors were simultaneously building on the same academic knowledge, which might limit the value of their investments?

After decades of discussion, Congress finally passed the Bayh–Dole Act in 1980, which created a standard policy clarifying that universities could hold patents on the fruits of federally funded research conducted by their employees. The private sector supported this policy because it would clarify and enhance its monopoly power: universities could patent inventions at early stages and then license them to companies, who would use additional patents, trade secrets, and proprietary tacit knowledge to strengthen their market position. Meanwhile, this transformed universities into market players, concerned with extracting economic value from scientific research at a time of declining funding from
other sources (Popp-Berman, 2012). Scores of research-oriented universities created programs to help faculty, staff, and students patent their findings and license them to companies (Winickoff, 2013). Simultaneously, government funding agencies created offices focused on industrial technology transfer and translational research.

Despite this market-oriented framing, Congress did acknowledge that there might be cases where patents might contravene the public interest. Specifically, they anticipated that companies might charge exorbitant prices for their technologies, putting these fruits of taxpayer funding out of reach for many people. So, the Bayh-Dole Act established a “march-in” right that allowed the government to step in if the patent holder did not adequately commercialize the product (Treasure, Avorn, and Kesselheim, 2015). However, as discussed later, in practice it has never exercised this right. Industrial activity is privileged over equity in technology.

The Bayh-Dole Act, coupled with a 1980 Supreme Court decision that allowed patents on “anything under the sun made by man” including life forms, accelerated patenting related to health and at early stages of biomedical research including on genes, pieces of DNA, other biological materials, and methods of manipulating organisms at the molecular level (Boyle, 1996). Meanwhile, entrepreneurs recognized the value of monopolies for their business strategies, and thus sought to claim as much intellectual property as they could by simultaneously applying for multiple patents related to an invention, pursuing patents on incremental changes to an invention (known in the pharmaceutical industry as “evergreening”), and maintaining proprietary data generated by the patented technology to prevent follow-on innovation by others.

Although it took 200 years to issue the first 5 million US patents, it took only 17 years to issue the next 5 million, and now the USPTO issues almost 1 million patents every 2 years (USPTOa, 2021). It is hard to imagine that innovation has increased at the same rate, and observers argue that this is a sign of a broken patent system (Jaffe and Lerner, 2004). Indeed, scientists and some private actors have become concerned that patents can even stifle innovation (Heller and Eisenberg, 1998), but policymakers and the PTO have largely not acknowledged this.

In the meantime, the US approach to innovation has spread around the world. But there has often been discomfort over the assumption that the inventor’s interest is the public interest. European countries have long carved out exceptions to patentability based on public policy, morality, and public health, and over the last 30 years Southern countries and civil society groups have joined them (Correa, 2017; Halliburton, 2017). In response, US policymakers and specifically the US Patent and Trademark Office have largely insisted that patents are not related to these social concerns and only benefit society by stimulating innovation. But we have begun to see cracks in that position in the United States, most recently when the Biden administration announced it would support a global waiver on patents related to COVID-19 technology (Sorkin et al., 2017). The United States aligned itself with India and South Africa, who had made the proposal at the World Trade Organization (WTO), because it accepted that patents were impeding the increase of COVID-19 vaccine supply to meet demand in Africa, Asia, and Latin America. Waiving these patents, the Biden administration acknowledged, was a necessary step to vaccine access and could help stimulate the development of manufacturing capacity in low-income countries. However, at the time of this writing the proposed waiver remained extremely controversial and had not passed at the WTO.
The unfortunate consequences of US health innovation policy

By developing an approach based on scientific and market priorities, US policymakers have influenced not just the distribution of health innovation but its very development: the emphasis is on mechanistic investigation, generalizable conclusions, and scalable commodities. This section outlines four types of consequences vis-à-vis equity. First, this approach distinguishes between innovation and care, leaving questions of access, availability, and distribution to other parts of the government and society. As a result, crucial innovation is often inaccessible for those who need it most. Second, it focuses on a narrow range of research, leaving much crucial innovation undone. Third, by reinforcing a narrow definition of innovation in terms of scalable, patentable commodities, it distracts researchers away from interventions that would benefit vulnerable communities and produce more equitable health outcomes. And finally, it creates innovation incentives that are actually harmful for marginalized communities.

Distinguishing innovation and health care

Perhaps the most visible drawback of the US’s market-driven approach is that the resulting diagnostics, treatments, and devices are often inaccessible to the most vulnerable. In many cases, they are extraordinarily expensive, making them unaffordable. In others, while technologies may be relatively affordable, they are not distributed equitably. Some may argue that this is the fault of our decentralized, privatized health care system. But characterizing this as a health care rather than an innovation problem is political, driven by a definition of innovation as primarily producing scientific and economic output. And it has real costs for communities.

Patent policies and practices, for example, facilitate private sector efforts to build and maintain monopolies over particular inventions, and then charge extremely high prices for access. One analysis showed that on average, for each of the top 12 grossing drugs in the United States, 125 patent applications were filed (71 were granted), and these companies attempted 38 years of patent protection (almost double the life of a single patent) (i-Mak, 2018). These companies have taken advantage of the US’s commitment to strong patent protections in order to establish much longer patent monopolies and keep prices high. Consider the case of hepatitis C, which affects approximately 5 million people nationwide (20% develop severe complications that require medication, hospitalization, and liver transplant). In recent years, the US Food and Drug Administration (FDA) has approved a handful of new drugs to treat the disease (Trooskin, Reynolds, and Kostman, 2015). The new treatments are quite effective, but because they are patented and there are very few options available, the companies can charge astronomical prices: from $84,000 to $95,000 for a 12-week regimen. This ultimately limits their use (Henry, 2018).

The story of asthma, a disease that disproportionately affects Black children, is similar (Alexander and Currie, 2017). In recent years, the cost of albuterol inhalers, which help to control the disease, have also increased considerably due to patent-based monopolies. Albuterol has been available as a generic tablet for use in inhalers for decades, but in the 2010s the tablet was altered slightly after federal regulators required the redesign of inhalers so that they did not emit environmentally dangerous chlorofluorocarbons. The inhaler and tablets were re-patented. Likely as a result, the market price for albuterol tablets increased over 4,000% and triggered a decline in use, presumably due to insurer questions and limits and uninsured patients simply unable to afford it (Kenner, 2018; Rosenthal, 2013).
We might be tempted to see these primarily as problems of the patent system. But research funding agencies also shoulder responsibility for high drug prices because they imagine the unfettered marketplace as the primary means for distributing innovation and refuse to assert their authority to influence it. As noted above, the government has never asserted the “march-in” right included in the 1980 Bayh-Dole Act. This has real consequences. For example, the NIH and Department of Defense (DOD) provided grant funding for the development of Xtandi, a prostate cancer drug developed by researchers at the University of California, Los Angeles (UCLA) (Watanabe, 2016). UCLA patented the compounds and sold them to the Japanese firm Astellas Pharma, which now markets the drug for over $129,000 per year per patient in the United States (a much higher price than in other high-income countries).

In January 2016, a coalition of civil society groups asked the NIH and DOD to exercise its march-in rights, with the support of multiple US senators and members of Congress (Love, 2016; Love and Ress, 2016). DOD responded in August of that year, arguing that while the drug was costly it was widely available, and therefore that public health and safety needs were being met (Lopez-Duke, 2016). It did not grant the march-in request, nor did it respond to the coalition’s argument that the exorbitant price of the drug limited access and ultimately harmed public health.

High prices aren’t the only issue. Even when prices are reasonable, markets still distribute innovation inequitably and the situation is even worse when supplies are scarce. At the beginning of the COVID-19 pandemic, both public and private sector laboratories across the United States rapidly developed diagnostic testing to identify who needed to isolate themselves to limit disease spread. But even as supply increased, tests were still scarce among marginalized communities despite their disproportionate risk of contracting and dying from the disease (McMinn et al., 2020). Again, some might argue that these sorts of problems are not the fault of innovation policy but rather the market or health care system. But the NIH itself acknowledged that vulnerable and historically underserved communities were not able to access COVID-19 diagnostics, and created a research funding program (RADx-UP) to address this issue. This suggests that the agency itself recognized some responsibility (NIH, 2021a). Unfortunately, programs such as these are reactive and ad hoc, and often focus on health care pricing and access rather than the design of the technology itself. Policymakers and scientists could make systematic efforts to consider these concerns at the roots, when early stage research is funded and patent rights are awarded.

Put simply, innovation and health care need to be relinked in our public policies. There is no a priori reason why innovation and health care should be considered separately, as demonstrated by the other approaches found around the world.

Undone innovation

A policy approach guided by scientists’ and market priorities has also meant that much important health innovation—particularly what would benefit less privileged communities—is simply left undone. This starts with the structure of government research funding, including who has the power to make decisions and the types of decisions they make.

As discussed above, Vannevar Bush argued that allocating grants on the basis of merit would increase the likelihood of high-quality science and ultimately technologies and economic growth. Implementation of this approach, however, skewed benefits. Most federal funding goes to
a handful of universities in a few states (Feller, 2001); Harvard University, for example, receives more research funding than all historically black colleges and universities combined (Weller et al., 2020). In addition, women, historically marginalized communities of color, and disabled people receive less funding than their white male counterparts despite recent targeted initiatives to better balance support (Ginther, Kahn, and Scharf, 2016; Pohlhaus et al., 2011). These inequities are sometimes framed as the price we must pay for “excellence” (Hicks and Katz, 2011). However, “peer” review scores are poor indicators of productivity, much less successful grant outcomes (Fang, Bowen, and Casadevall, 2016).

This demographic homogeneity has a real impact on innovation, by shaping the research questions reviewers define as important and methods seen as appropriate. Scientists’ experiences, worldviews, assumptions, and values shape their definitions of merit and excellence (Gieryn, 1999). The NIH, for example, is much less likely to award R01 grants (large sums that are crucial to a successful research career in health science) to Black investigators than their white counterparts with similar educational backgrounds and training, countries of origin, previous research awards, and employer characteristics (Ginther et al., 2011). When researchers looked at this disparity more deeply, they discovered that an investigator’s choice of research topic made a significant difference in whether an application was funded (Hoppe et al., 2019). Black scientists tended to investigate less-funded topics: their proposals often included topic words such as socioeconomic, health care, disparity, lifestyle, psychosocial, adolescent, and risk, which focused on structural concerns and were less likely to lead to commercializable products. Meanwhile, the proposals that were most likely to be funded included words like osteoarthritis, cartilage, pri-on, corneal, skin, iron, and neuron (Hoppe et al., 2019). This study also showed that the proposals least likely to be funded overall were associated with women and reproductive issues (using the topic words ovary, fertility, and reproductive). In addition, others have calculated that the NIH spends 500 times more on genetics research as on structural racism and its impacts on health (Krieger, 2005). The consequences of these funding choices, by the country’s main funder of early-stage biomedical and health research, are significant. It highlights an emphasis on mechanistic research, which is more likely to interest the private sector because it can be more easily patented and commercialized, rather than on innovation at the community level, or in public policy or infrastructure. This approach doesn’t just limit our understanding of health inequalities, it perpetuates the false understanding that the solution to health problems lies in individualized, commodified technologies and that once they are developed they can and will be distributed equitably.

At the same time, pharmaceutical companies are famously reluctant to invest in diseases that affect marginalized communities, particularly if they are perceived as being on the economic margins. Pharmaceutical companies are famously reluctant to invest in diseases that affect marginalized communities, particularly if they are perceived as being on the economic margins (Moon, Bermudez, and ‘t Hoen, 2012). It is not simply an issue of economic power but also social and political privilege: there is currently little research into male contraception, for example, with industry citing uncertainties about market interest. This places the burden of birth control on the less powerful 50% of the
Ultimately, the demographic homogeneity of the research funding apparatus and the interests that shape it, coupled with its focus on the marketplace as the primary mechanism for achieving societal benefit, has led innovative activity away from the needs of the most marginalized communities. The concerns and problems of the privileged become the most crucial.

**Distorting innovation**

As noted above, in following scientific and market priorities the policy infrastructure tends to define health innovation in terms of development and dissemination of scalable, commodifiable technologies. Government investments are devoted to treating health problems once they emerge rather than addressing their root causes, which might lie in the built infrastructure or environmental pollution. In other words, by shaping themselves to meet market needs, research funding agencies and the patent system enable what some call “pharmaceuticalization,” in which social conditions are turned into individualized, biologically based conditions that the private sector can fix through technology (Abraham, 2010). Scholars who study this phenomenon have demonstrated how the pharmaceutical industry frames conditions such as insomnia as needing biochemical intervention, rather than requiring lifestyle changes or as indicators of problems with the social organization of work (Servitje, 2020). Pharmaceuticalization also connotes the creation of new diseases—such as shyness or premenstrual dysphoric disorder—that require a commodified cure (Greenslit, 2005; Lane, 2007). But the argument here can be taken one step further. Our policy institutions—by investing in research and interventions at the molecular level, viewing the marketplace as the primary route for technology to achieve the public good, and encouraging expansive patent rights—enable the development of commodified solutions that tend to be more accessible to already privileged groups rather than policy or infrastructural change that might be helpful at a community or population level and for the long term.

Let’s consider again the example of asthma. Its cause is unclear and there is no cure, but many of its triggers are external and specifically environmental, including air pollution, chemical fumes, and dust. It is also strongly associated with poverty (Kravitz-Wirtz et al., 2018). More and more people are being diagnosed with the disease, but its prevalence is increasing much more rapidly among historically disadvantaged communities of color. These communities are also likely to experience worse disease outcomes, including hospitalization and death. In response, governments have increased research funding, but this work has focused primarily on genetic and biological mechanisms rather than on how to transform environmental and socioeconomic conditions necessary to prevent and mitigate disease (Whitmash, 2008). This approach fits with both the dominant concerns and approaches of scientists in this field as well as the private sector.

Similarly, while patient advocates convinced Congress to increase research funding for breast cancer by 800% in the 1990s (Casamayou, 2001), studies related to prevention (broadly defined, from individual to environmental to societal causes) which are likely to produce less lucrative and likely infrastructural solutions, receive less than 10% (IBCERCC, 2013). Instead, most federally funded cancer research feeds into pharmaceutical interventions designed to extend the lives of disease sufferers. This is certainly a worthy cause, but it limits and distorts both our understanding of and solutions for the disease. Advocates fought for years to convince...
Congress to increase funds focused on breast cancer and environmental research (Casamayou, 2001; McCormick, 2009), but the NIH worried that legislation that mandated specific kinds of research would amount to political interference in “peer-review scientific integrity” (Richter, 2019). It did not acknowledge that the current approach, shaped by scientific and market priorities, had its own biases and limitations. Eventually, Congress passed a bill that merely funded an assessment, to be conducted by a new Interagency Breast Cancer and Environment Research Coordinating Committee (IBCER-CC). In 2015, the IBCERCC published the report based on this assessment, but it seems to have had no significant impact on government funding or attention to environmental causation of breast cancer (Richter, 2019). In fact, just the opposite: in 2019, the NIH ended one of its few initiatives in this area, the Breast Cancer and the Environment Research Program.

This focus on devices and pharmaceutical solutions has real consequences for equity. As suggested in the previous sections, these technological interventions are often more accessible to and tailored for more privileged communities. By contrast, public health, infrastructural, environmental, and policy innovation could be more widely used.

**Harmful innovation**

Finally, in its deferral to the marketplace and focus on regulating only a narrow range of physical risks, the US approach to health innovation helps to stabilize harmful and even biased technologies. For example, the FDA reviews pharmaceuticals and many medical devices, but focuses narrowly on questions of risk and benefit. It does not consider questions of racial or other forms of equity (Obasogie, 2012), nor, in many cases, even clinical utility (Parthasarathy, 2007). And in some cases of health-related innovation, such as some forms of genetic testing, it plays almost no role at all. As a result, the patent system may be the only government entity that assesses a technology. But the PTO generally only considers whether a technology is an invention according to the law and scientific prior art.

For example, in the 1990s, after participating in years of international collaboration to find hereditary genes linked to breast and ovarian cancer, US biotechnology company Myriad Genetics announced that it had identified two genes linked to these cancers, BRCA1 and BRCA2, and then applied for US and European patents and began offering tests (Parthasarathy, 2007). Citing these pending patent rights, Myriad then systematically shut down all other providers in the United States and tried to do the same in Europe. It offered its own “gold standard” test to US consumers, which sequenced the DNA of both genes for approximately $2,500 and provided customers with information about whether they had mutations that might cause disease. But European scientists and public health officials challenged the company’s proprietary position and continued to conduct research and offer BRCA testing through their health systems. Soon afterwards, French researchers announced that they had found a major flaw in Myriad’s approach: it missed large deletions and rearrangements in the genes that increase susceptibility to disease (Myriad Genetics had halted similar research in the United States). In other words, Myriad’s monopoly had led many women to make serious decisions about their health (e.g., to have a mastectomy or not) based on a faulty test. Meanwhile, the FDA had not reviewed Myriad’s test, because it was classified as a “homebrew” and therefore outside of its jurisdiction (US Congress, 1996). For years afterward, Myriad refused to acknowledge any problems with its test even as it maintained a patent-based testing monopoly across the United States, putting women’s lives at risk.
The history of the pulse oximeter reveals a similar problem. Oximeters measure the amount of oxygen in the blood by calculating how much light is absorbed by human tissue, and have been crucial technologies in managing the COVID-19 pandemic as they help both health care providers and infected people assess the seriousness of the case. However, skin tone affects light absorption.

When Hewlett-Packard developed the original oximeter in the 1970s, it took care to ensure its accuracy among varying skin tones by testing it among people of color and allowing it to be calibrated according to each individual (Moran-Thomas, 2021). But Hewlett-Packard eventually stepped away from this area of technology, and a small biotech company developed and patented a new version of the pulse oximeter that is now ubiquitous in COVID care and beyond. The new company did not test its device in a range of patients, and used its patent rights to not only prevent others from developing devices but also reject requests for information about their accuracy. It was only amidst the 2020 COVID-19 pandemic, when an anthropologist called attention to the problem, and a group of physicians conducted a study, that it became clear that the device systematically produced inaccurate blood oxygen readings for Black people (Moran-Thomas, 2020; Sjoding et al., 2020). The devices reported that Black people had higher blood oxygen than they actually did, which means that they might erroneously delay needed trips to the hospital for supplemental oxygen. There have been no studies of the device’s accuracy among other communities of color. The company has not responded to this issue, and while this device is regulated by the FDA, its potential racial bias is considered outside the agency’s scope.

We tend to assume that regulators such as the FDA protect us from harmful innovation. But the FDA’s scope is limited, and tends to focus on direct physical harms rather than even the harms wrought by inequitable design. In these cases, the inequities embedded in our innovation policies loom much larger.

**Innovation policy for equity**

The preceding sections demonstrate how our health innovation policies, which have been historically guided by scientific and market priorities and separated from questions of health care, reflect and even reinforce inequalities. Some observers argue that policymakers should respond by better using the tools already at their disposal, such as increasing research funding in particular areas or limiting the scope and power of patent
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rights. In fact, the NIH recently announced the UNITE initiative “to address structural racism and promote equitable representation and inclusion at NIH and throughout the larger biomedical research enterprise” (NIH, 2021b; McFarling, 2021). Others have offered more transformational suggestions such as nationalizing the pharmaceutical industry (Quigley, 2020). Below, I suggest that in order to achieve greater equity in health innovation, we must fundamentally change how we think about both innovation and innovators, and then restructure our approaches to research funding and intellectual property with equity centrally in mind. In the process, we must engage a much broader array of experts and publics and consider nonmarket approaches to innovation.

US institutions and policies tend to define and foster health innovation in terms of technologies that can be easily commercialized, including pharmaceuticals and medical devices. But this approach excludes genres of innovation that are likely to be particularly effective in promoting equity and inclusivity, such as low-tech interventions and new approaches to public policy, built infrastructure, urban and suburban planning, and pollution prevention and remediation practices that are more broadly accessible. With this should come a more inclusive understanding of who can legitimately participate in creating health innovation. The current system favors biomedical scientists and engineers, as well as industry representatives, as the primary innovators, with occasional participation from patient advocacy and other interest groups. But a more inclusive approach to potential innovators would include social scientists and other experts in health equity, as well as members of marginalized communities themselves. Innovation, after all, is not simply a technically sophisticated and market-oriented practice; for example, people who are “knowledge rich” but “resource poor” often innovate in the face of adversity. Harnessing these forms of innovation, in addition to novel interventions from social scientists and other experts in health equity, will help the United States not only achieve more democratically legitimate innovation processes but also increase the likelihood of more affordable interventions and ultimately, equitable outcomes. It would also reframe health innovation in community and social terms rather than primarily problems faced by individuals.

Interdisciplinary health innovation

To ensure equitable solutions, the NIH and other funding agencies must spend a substantial amount of its funds on truly interdisciplinary research that brings together life science, engineering, sociological, public health, economic, and other expertise. This approach would ensure that social context is taken seriously in both understanding disease causation and developing solutions to improve health outcomes (Pickersgill and Smith, 2021). Consider, for example, efforts to prevent heart disease and stroke, diseases which disproportionately plague the Black community. Researchers have been working on a variety of solutions designed to address this health disparity, including a mobile health app designed to encourage physical activity and nutrition. A properly marketed and distributed app seems like it would be a very useful intervention, because it is commodifiable and easily scaled. Quality can be controlled and it could reach a tremendous number of people.

However, one effort to develop such a technology, which employed experts in racial justice and the social studies of technology and involved interviews with the community, revealed the technology’s limitations (Merid, Whitfield, and Skolarus, 2020). Accustomed to being disrespected and even harmed by biomedical institutions, community members were skeptical of the new technology. And they revealed a serious
barrier to exercise: the lack of safe and accessible outdoor environments in many urban areas. One app, in other words, could not fit all. And the limitations were revealed early only because of the inclusion of diverse perspectives in the innovation process. This revelation could, with the addition of insights from experts in urban planning and environmental health, lead to more tailored technologies or projects focused on developing innovative infrastructural solutions that would ultimately improve health.

Truly interdisciplinary research could stimulate other innovation as well. Let’s return to the asthma case. Most US research funding has focused on understanding biological mechanisms and treating the condition at the molecular level. To the extent that social and environmental conditions have been considered, they have invariably reinforced stereotypes about problematic living conditions for low-income people, particularly those living in urban areas. Pharmaceutical treatment, designed as a simple solution and based on experimentation in a random sampling of the population, is seen as the primary solution. It works because there is a huge market for the product, because the product is scalable, and because it does not appear to require attention to location. Those for whom pharmaceutical solutions are inadequate are seen as occasional outliers and there is little dedicated attention to their plight. But some argue that asthma is actually a very different condition according to the context, dependent upon local environmental and infrastructural conditions (Whitmarsh, 2008). Preliminary evidence, for example, suggests that during the COVID-19 pandemic, when children were largely staying at home, cases of asthma in pediatric intensive care units plummeted (Zhang, 2021). While researchers have not pinpointed a cause, possibilities include local air pollution and school conditions, and suggest that at the very least the pharmaceutical solution is partial and other solutions might be cheaper and more effective depending on context. Investigating these factors and assessing solutions would require interdisciplinary investigation.

Simply increasing funding for interdisciplinary research, however, is insufficient. The NIH and other health innovation funding agencies must employ social scientists and other experts on health equity on their full-time staff for each funding program. They must also ensure these types of experts are consulted throughout the peer review process, and ensure that they have established metrics to assess health equity outcomes (similar to metrics focused on scientific productivity), in order to ensure that these proposals are reviewed appropriately (discussed further below).

Explicitly engaging marginalized communities as experts

Institutions involved in health innovation policy must also center the knowledge and perspectives of marginalized communities at every step of innovation. As noted throughout this paper, US innovation policies privilege scientists’ and market priorities in part because they are assumed to be objective, logical, and neutral. But this paper has shown how these policies actually reflect particular values that ultimately produce inequitable outcomes. Values are endemic to both technologies and policymaking, but innovation and innovation policy can better address and ameliorate inequality if the most marginalized communities are included and respected as central decisionmakers.

At present, beyond electing the representatives who make laws and allocate research funding and occasional advocacy through stakeholder organizations, publics have little opportunity to influence innovation policy. Technologists and policymakers often argue that nontechnical
If policymakers, scientists, and engineers aim to improve the health of communities, they must begin by understanding the perspectives and priorities of the communities they seek to help.

Publics lack the requisite knowledge and skills to participate, but this is incorrect on at least two grounds. These publics are experts in their own needs, lives, and circumstances. If policymakers, scientists, and engineers aim to improve the health of communities, they must begin by understanding the perspectives and priorities of the communities they seek to help. In recent years there have been numerous efforts to engage citizens in discussions about highly technical issues, using deliberative democratic methods—these usually take steps to explicitly include the perspectives of historically marginalized communities (Barnhill-Dilling, Rivers, and Delborne, 2020; Kleinman et al., 2007; Tomblin et al., 2017). While the exact approach varies, studies show that community members are able to grasp technical details with the help of background materials and question-and-answer exchanges with experts, and offer useful insights to guide policymaking. In the process, participants report that they appreciate exercising their civic duty and feel more incorporated into the community.

Community engagement should start with priority setting. The NIH and PTO directors might convene advisory committees designed to understand public priorities, needs, and suggestions vis-à-vis health. These convenings, which should take dedicated steps to ensure the participation of marginalized communities, must give publics the opportunity to understand the policy and institutional landscapes and peer into the organizations and practices of these agencies. Advisory committees would then offer recommendations to both executive and legislative branch leaders about how to develop health innovation in the public interest that must be taken seriously.

As a model, policymakers might look to participatory budgeting, the practice of having citizens set government priorities and determine funding allocation, recentering their power over the state (de Sousa Santos, 1998). Developed in the early 2000s, the method has now traveled around the world (Baiocchi and Ganuzza, 2014). They could also draw on growing interest in the theory and practice of democratic public ownership (DPO), which suggests various ways that public enterprises and agencies can institute more democratic, participatory, and deliberative governance and management approaches, as well as community-benefiting and equity-based values and principles (Cumbers and Hanna, 2019; Kishimoto, Steinfort, and Petitjean, 2020; Hopman et al., 2021).

Innovation policy institutions can also engage communities using its existing advisory structures. The PTO, for example, convenes a Public Patent Advisory Committee on a quarterly basis to review “the policies, goals, performance, budget, and user fees of patent operations and advises the director on [PTO] matters.” (USPTO, 2021b). However, its membership consists entirely of participants from the worlds of patent law and the tech industry, which demonstrates a very narrow understanding of the “public.” A more representative committee, which included citizens and scholars engaged in health equity, would provide the agency with a deeper understanding of the needs of the citizenry and specifically the health impacts of the patent system.

Second, innovation policy institutions must engage communities directly in their day-to-day
decision-making. For research funding agencies, this means including citizens on grant review panels. This idea is not new. In the 1990s, women with breast cancer, frustrated by the lack of medical progress in preventing and treating the disease, successfully advocated not only for increased research funding but the inclusion of patient voices in grant decision-making. Only they, these women argued, understood the disease experience and had crucial expertise to evaluate the impacts of different interventions to address breast cancer. Their campaign was successful, and today they regularly participate in scientific “peer” review panels (Platner, Bennett, Millikan, and Barker, 2002). Their technical colleagues report that this inclusion is beneficial, and “serves as a reminder of the human dimensions of the disease.”

Engaging publics in PTO decision-making would look somewhat different. There, citizens might inform technical examiners about the health costs of broadly written patents, or even remind them of colloquial understandings of novelty and invention. The European Patent Office has engaged citizens in both town hall meetings and scenario-planning reports which have had similar impact (Parthasarathy, 2017a). Meanwhile, it is easier for members of the public to register their grievances about specific patents in European patent “opposition” proceedings. At present, the PTO severely limits civil society engagement in patent office activities.

Finally, research funding agencies in particular should authorize more grants that engage communities as partners and even primary investigators. Community-based research has two advantages: It privileges grassroots priorities and is geared towards solutions with community direct benefit and context in mind. As noted above, in the past the NIH has funded successful research centers focused on the environmental causes of breast cancer where scientists and women with breast cancer collaborated on research priorities and design. These partnerships had real impact (Osuch et al., 2012). Communities did crucial mapping work to identify the links between pollutants and breast cancer. They also convinced scientists to assess the impacts of low-level radiation exposure even though it required a different set of measurement tools. Ultimately, community-based participatory research doesn’t just increase community trust, it produces knowledge and innovation that is more clearly tied to implementation and societal benefit.

Evaluating equity impacts

Research funding agencies should also require prospective grantees to submit equity impact assessments. The National Science Foundation, for example, requires all applicants to submit information about how their projects will achieve “broader impacts” that will serve society, which is then evaluated during the grant review process (Woodson, Hoffman, and Boutilier, 2021). The NIH and others funding health and biomedical innovation could create a similar process focused on equity, which might ultimately be deployed to evaluate the full range of scientific projects across agencies.

All grant applicants would be required to provide information about how their research meets the following criteria:

- **Design equity.** This would examine the extent to which innovators critically examined the impacts of the proposed research and innovation for inequality, and the measures taken to ensure that the innovation—in the design itself—does not reinforce social or economic marginalization.

- **Distributional equity.** This metric would assess the extent to which research-
ers are considering the availability (including, but not limited to, cost) of the innovation. This could produce changes to the design itself, or to decisions about whether and how the technology is patented and licensed.

- **Procedural equity.** Applicants would be asked whether and how potentially affected communities were consulted in the research and innovation process. They would also report the extent to which publics, particularly those who have been historically voiceless in the development of science and technology, influenced development of the innovation.

- **Historical legacy.** Too frequently, innovation is developed without any attention to the lessons learned from similar previous interventions. This criterion is designed to help innovators understand and assess the implications of similar previous technologies for inequality. They might also examine whether and how marginalized communities have resisted these types of technologies in the past, in order to make more informed decisions about their current research and development.

Implementing these equity impact assessments would require researchers to bring both members of marginalized communities and experts in the equity dimensions of innovation into their projects as equal partners. Data to inform these assessments would likely be both qualitative and quantitative. They will require science funding agencies to ensure that grant reviewers have appropriate expertise so that they can assess proposals properly. And, these agencies would need dedicated staff who could facilitate these partnerships, reach out to the correct experts, and evaluate and build on these forms of research and facilitate both interdisciplinary and community partnerships. This may be challenging, but such assessments have transformative potential to create a health innovation system truly dedicated to public priorities.

**New avenues for health innovation**

The government must also develop similar capacity to foster and distribute health innovation beyond the market. At present, the government invests in multiple initiatives to bring health innovation to the marketplace, from small business loans to patents. The NIH alone has multiple offices devoted to commercialization and technology transfer. But this paper has articulated multiple limitations to this market-oriented approach. It individualizes problems and focuses on expensive technologies that are unaffordable for many, often ignoring the social, economic, and environmental problems that lie at the root of health problems. It privileges technologies that can be easily replicated and scaled, rather than those that need to be developed in partnership with local communities. And it distorts innovation and can create incentives for harmful technologies.

This could be addressed through the creation of a new office within the NIH or the Department of Health and Human Services (HHS) focused on health innovation for communities. This new office would have three main objectives. First, it would identify community organizations already engaged in effective health innovation and help to support this work. Community groups are already innovating to solve local health challenges, bringing deep understanding of local needs and context to their interventions. But they often have extremely limited resources, and limited connection to federal funding agencies. They may be reluctant to apply for federal funding for their projects because they don't think that these opportunities are meant for them, or they are
unsure how to apply or application requirements are too burdensome. The new office could address these barriers, and perhaps even tailor application processes for these potential grantees.

For inspiration, it could look to the National Innovation Foundation, established by the Indian government in 2001 to strengthen “grassroots technological innovations and outstanding traditional knowledge” (Parthasarathy, 2017b). The NIF understands that much innovation takes place among those who are “knowledge rich” but “resource poor,” and its first goal is to identify this work where it is taking place (Gupta, 2012). So it offers awards, grants, and loans to people who are developing technologies that might benefit their communities. It also takes special steps to find innovation at the grassroots, through yearly scouting pilgrimages through low-resource settings (National Innovation Foundation, 2021).

This work, proponents argue, doesn’t just make low-cost, low-tech interventions more widely available. It also empowers communities that have been traditionally marginalized in the innovation system to believe that they can contribute despite their financial limitations. NIF, for example, invested in a low-cost windmill. Two farmers from the Indian state of Assam, who have only a high school education, were unsatisfied by the technologies available to irrigate their fields for winter crops. Existing hand pumps required a great deal of time and labor (and had negative health impacts), while pumps powered by a diesel engine were costly and had negative environmental impacts. So, these farmers developed a small, inexpensive windmill made of tin sheets and supported with bamboo rods (Gupta, n.d.).

NIF also works with the innovator to disseminate their technology. In cases where commercialization seems appropriate, NIF helps to secure patents and negotiates, on the innovator’s behalf, with companies who have manufacturing and distribution capacity (National Innovation Foundation, 2021). Because of NIF’s focus on equity, licensing agreements invariably include direct benefit-sharing provisions with the local community. The inventors of the low-cost windmill, for example, used a portion of their earnings to donate their windmills to needy farmers.

Second, this office could facilitate partnerships between these community groups and academic researchers, to ensure investigations “from the cell to the street” (Corburn and Riley, 2016). Community groups would benefit by developing systematic methods for evaluating interventions and perhaps learning about other similar interventions, while academic researchers—even those working on projects at the molecular and biochemical level—would develop more nuanced understandings of community expertise and how proposed innovation works on the ground. Eventually, this could produce research questions more centrally concerned with health equity and real partnerships that privilege inequality as a central concern even upstream in the research and development process.
The Healthy Flint Research Coordinating Center (HFRCC) offers a useful example. In the wake of the recent Flint water crisis, in which residents of the Michigan city drank and bathed for months in water contaminated with lead and bacteria due to the negligence of scientific and policy leaders, researchers and funding poured in to study the effects and offer solutions. But Flint residents were wary: how could they ensure that researchers didn’t replicate the racism and mistreatment from previous generations of scientific investigations? And how could they make sure the community benefited from the research? In response, they created the HFRCC, which evaluates and must approve all research conducted in Flint (Key and Lewis, 2018). HFRCC often suggests changes to proposed studies that would align better with community concerns and context, and ensures that benefits flow directly back to the community. In return, HFRCC helps connect researchers with funding opportunities.

Finally, a new office would both explore and support additional nonmarket-based approaches to health innovation. As noted throughout this paper, the United States has focused on the marketplace as the central mechanism for distributing health innovation, which has not only led to inequitable access but created perverse incentives for the types of technologies produced. The office could fund research into more equitable (including, but not limited to, nonmarket) methods for developing, deploying, and distributing innovation, and then pilot these alternative approaches. This might include, for example, articulating clear standards for when the government might decide that an innovation is so important to public health that it should be developed through its national laboratories, rather than relying on the private sector.

In funding this work the new office must explicitly recognize that it might produce both scalable and nonscalable solutions. Too frequently, health research privileges the identification and implementation of scalable solutions, because it is focused on producing generalizable truths and helping the maximum number of people possible and because it often views the marketplace as the most efficient distribution mechanism. But in many cases—particularly for those who have been historically marginalized—maximum effectiveness is only possible when the innovation is made by and for the community. In fact, innovation developed for scalability and maximum uptake can actually harm these communities as described above. Community-based research and innovation is one approach to addressing this problem.

There are, however, potentially useful scalable interventions that are difficult to develop because the private sector does not see a financial benefit. The new NIH institute and other innovation policy institutions should address this gap, by fostering the development and dissemination of crucial health technologies and helping non-governmental partners do the same, and also evaluating these approaches to determine best practices. In some respects, the seeds for this were sown in the early days of the NIH, when its primary task was to fund and conduct research that would inform the CDC’s public health recommendations as well as other policies and practices across the government (Harden, 1986). But in this case, we are focused on both technological and other types of innovation that would serve public interest objectives.

The government could do this in a few ways. While the NIF helps many of its innovators commercialize their technologies, it also recognizes that in some cases interventions are socially important but not commodifiable. Or, the developers simply do not want to sell it on the open market. Under these circumstances, it simply helps to disseminate information about the technology and its benefits, and how to build
it, in multiple Indian languages. They may also help the inventor develop it on a small scale to help their community using the capacity of national laboratories. In some respects, we recently saw a version of this when the US government encouraged pharmaceutical companies to invest in COVID-19 vaccine development through grants and promises to purchase millions of doses.

Other governments have engaged in more ambitious versions of this approach to solve major public health and environmental problems. The Indian government, for example, developed a “grand challenges” program focused on multiple priorities including clean water (Grand Challenges India, 2021). Innovators who made progress towards these goals received prizes and promises of government procurement on a large scale. One could imagine other versions as well, in which once an innovator received a financial prize for their work, all intellectual property was released and the government committed to using its own (or securing additional) capacity in order to manufacture the new technology.

**Conclusion**

Much of US innovation policy is based on the assumption that if we simply foster the best research and development according to the priorities of scientists, engineers, and the marketplace, the benefits will simply trickle down. We now clearly see the consequences. While the most privileged among us may benefit, many do not. Some simply cannot access important technologies, including those that are crucial to maintaining their health. But this is only part of the problem. This prioritization leads much crucial innovation undone, focuses attention on commodifiable solutions rather than policy or infrastructural change that are likely to yield more egalitarian benefits, and actually creates incentives for harmful innovation.

This paper offers solutions to address these problems at their roots, through both research funding and intellectual property policies and infrastructure. Health and biomedical research funded by the government must explicitly consider equity at the outset, through community knowledge and social scientific expertise, even when the work seems basic and far removed from social impact. In addition, innovation policy institutions must facilitate the widespread distribution of non-commodifiable health innovation.

These changes could start with the new Advanced Research Projects Agency for Health (ARPA-H) proposed by the Biden administration, designed to produce breakthrough advances for common diseases. It is modeled on the famed Defense Advanced Research Projects Agency, which led to the internet among other innovations.

The Biden administration’s proposed $6.5 billion budget for ARPA-H is a large and laudable investment, but in order for it to further, and not harm, the administration’s strong equity objectives, it must foster innovation that is based in interdisciplinary and community insights and transferrable beyond the marketplace.
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HEALTH INNOVATION POLICY FOR THE PEOPLE


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About The Democracy Collaborative

The Democracy Collaborative is a research and development lab for the democratic economy. Making democracy the operating system of a new equitable and just economy that honors planetary boundaries requires the redesign of basic institutions and activities—companies, investments, economic development, land, employment, purchasing, banking, commons management, resource use, and so much more—so that the core purpose of the economy is to serve the common good. In its fundamental design, a democratic economy aims to meet the essential needs of all of us; balances human consumption with the regenerative capacity of the earth; repairs legacies of oppression, bias, and harm; and shares prosperity and power without regard to race, gender, national origin, or economic status.

Our mission is to demonstrate in theory and in practice the principles of a democratic economy, offering a vision of what that economy can be, designing models that demonstrate how it operates, and building in coalition with others the pathways to a new reality. By making the democratic economy conceivable, visible, and practical, we open minds, ignite hope, and inspire action.