THE HAMILTON PROJECT

POLICY PROPOSAL 2017-16 | DECEMBER 2017

Promoting Energy Innovation with Lessons from Drug Development

Anna Goldstein, Pierre Azoulay, Joshua Graff Zivin, and Vladimir Bulović

MISSION STATEMENT

The Hamilton Project seeks to advance America's promise of opportunity, prosperity, and growth.

We believe that today's increasingly competitive global economy demands public policy ideas commensurate with the challenges of the 21st Century. The Project's economic strategy reflects a judgment that long-term prosperity is best achieved by fostering economic growth and broad participation in that growth, by enhancing individual economic security, and by embracing a role for effective government in making needed public investments.

Our strategy calls for combining public investment, a secure social safety net, and fiscal discipline. In that framework, the Project puts forward innovative proposals from leading economic thinkers — based on credible evidence and experience, not ideology or doctrine — to introduce new and effective policy options into the national debate.

The Project is named after Alexander Hamilton, the nation's first Treasury Secretary, who laid the foundation for the modern American economy. Hamilton stood for sound fiscal policy, believed that broad-based opportunity for advancement would drive American economic growth, and recognized that "prudent aids and encouragements on the part of government" are necessary to enhance and guide market forces. The guiding principles of the Project remain consistent with these views.

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BROOKINGS

Abstract

Accelerating energy innovation is both a necessary part of climate change mitigation and a spur to economic growth, but there are a number of institutional challenges that make such innovation particularly difficult in energy technology. By comparison, the system for bringing new technologies to market in pharmaceuticals is more effective. We consider three aspects of the pharmaceutical innovation system that might be instructive for policy makers who want to advance energy innovation: (1) the availability of contract organizations to perform specialized research, (2) a centralized regulatory framework for staged trials, and (3) public financial support for research when costs are greater than potential private payoffs.

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Chapter 1. Introduction

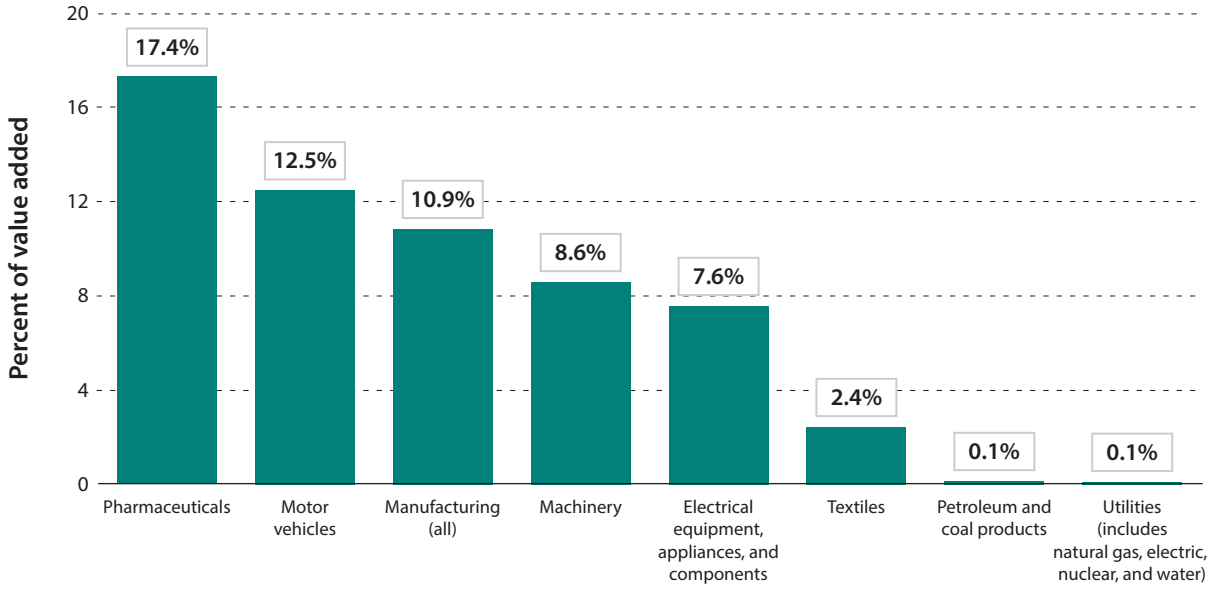
Energy is a part of almost every economic activity and an important share of the global economy. Improving the availability of reliable, inexpensive energy services can have wide-ranging benefits for businesses and consumers. As has become increasingly clear in recent decades, however, the use of fossil energy sources generates large costs that are spread across society in the forms of conventional air pollution and worsening climate change. The evidence of climate change is abundantly clear in the rising sea levels, rising surface temperatures, and the increasing incidence of natural disasters. As populations around the world gain access to electricity and transportation, global emissions of greenhouse gases (GHGs) and the risks inherent to climate change continue to increase. Although there are many sources of global GHG emissions, energy—comprising production and use of both electricity and fuel in homes, businesses, and vehicles—is the largest contributor to GHG emissions in the United States (U.S. Environmental Protection Agency [EPA] 2017, chap. 3).

Energy-related emissions increase with three factors: the size of the economy, the energy intensity of the economy, and the emission intensity of the energy supply (Intergovernmental Panel on Climate Change [IPCC] 2014, 368). As economies grow, bringing many benefits for human welfare, there is an urgent need to shrink the latter two factors by reducing both the energy required for economic activity and the emissions that are required to supply energy to the population. Both energy intensity and emissions intensity have in fact declined in the United States in recent years, in part thanks to a shift to cleaner energy sources (Council of Economic Advisers 2017). To continue this trend and push for transformation to a clean energy system, energy technology policy is critical.

Discussions of energy policy often focus on technology-pull strategies: using these strategies, government can incentivize the use of cleaner energy technologies, including the removal of fossil fuel subsidies and the creation of new policies to better align private and social costs, such as carbon fees and cap-and-

FIGURE 1.

Domestic R&D Intensity, by Industry



Source: Bureau of Economic Analysis 2013; National Science Foundation 2013; authors' calculations.
Note: R&D intensity is defined as domestic R&D expenditures divided by value added. Calculations are for 2013.

trade. By encouraging the use of cleaner energy technology, these strategies indirectly promote innovation and cost reduction. This indirect incentive, however, is only effective to the extent that companies are able to appropriate the returns on their investment by profiting from the outcomes of research and development (R&D). Because returns to R&D are notoriously difficult to appropriate, even with the protections offered by intellectual property rights, the incentive to invest in R&D on the basis of increased demand for a given technology is quite weak.

Technology-push strategies, on the other hand, directly encourage R&D and advance technological progress as a result. These strategies involve incentives that can include anything from expediting commercialization of a new technology to sponsoring research into the physical principles underlying the technology's operation. The majority of technology-push energy innovation efforts in the United States are coordinated by the U.S. Department of Energy (DOE) through its various programs to fund R&D and demonstration projects. These programs are important complements to technology-pull incentives: as existing technologies are more broadly implemented, state-of-the-art technology must continue to advance so that future emissions targets can be met (DOE 2017).

Despite progress toward a cleaner energy system, current U.S. policies—whether of the push or pull variety—appear insufficient to reduce emissions enough to avoid catastrophic climate change while sustaining economic growth. Private investment in energy innovation remains particularly low. As seen in figure 1, R&D intensity for fuel suppliers and utilities is negligible relative to other industries, especially compared to the high intensity of R&D in pharmaceuticals.

Chapter 2. The Challenge

In this paper we examine the similarities and differences in the challenges of energy and pharmaceutical innovation. There have been large public investments in both systems, and yet the system of drug discovery and development has been more successful in bringing new and improved products to market (Cockburn, Stern, and Zausner 2011). Where there are differences, we consider how observations of the pharmaceutical sector might be usefully applied to energy innovation. We identify three specific conditions for pharmaceutical innovation that are lacking in energy innovation that would accelerate the creation and deployment of improved energy technologies: (1) a robust system of contract research, (2) uniform technical standards for communicating reliability, and (3) better regulatory incentives for electric utilities.

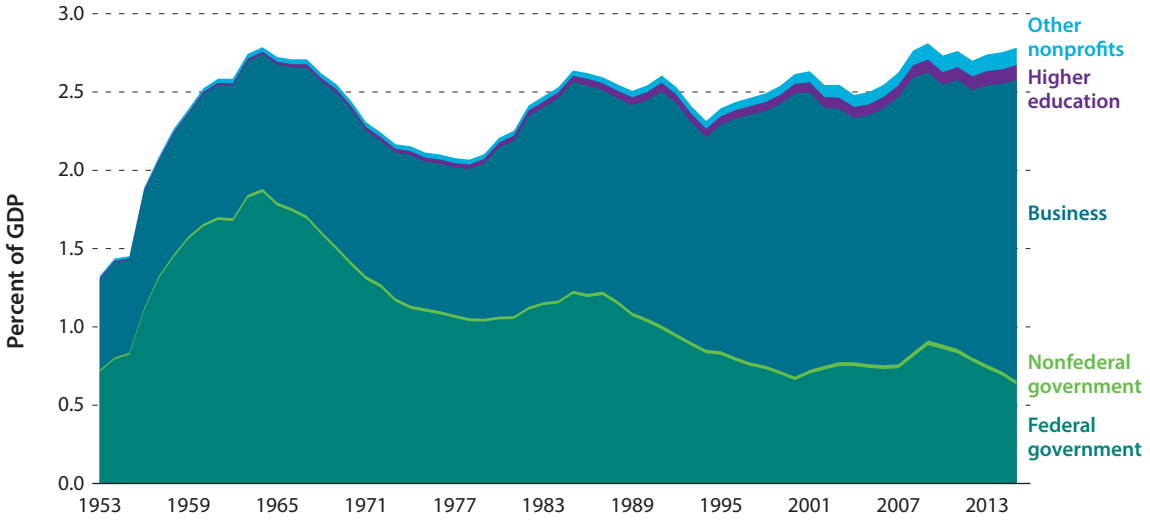
SIMILARITIES IN THE CHALLENGES OF ENERGY AND PHARMACEUTICAL INNOVATION

Before examining the different environments for innovation in energy and pharmaceuticals, we review some of the common elements between the two. First, both energy and pharmaceutical innovation are particularly relevant to public policy. Pharmaceuticals can extend and improve lives by curing and preventing disease. Energy technology, in particular heating, cooling, transportation, and lighting, are essential for health and comfort. There are also safety risks associated with consumer use of both drugs and energy—a poorly formulated drug can lead to fatalities, as can loss of electricity or heat, or a failure of transportation fuels.

Both energy and pharmaceuticals face challenges that are common to all types of technological innovation. There is a long-standing body of economic theory detailing the reasons private investment in research tends to be insufficient (Arrow 1962; Nelson 1959), one of which is that the benefits of R&D cannot be exclusively captured by any one firm and often spill over to other firms. Therefore, there is an important role for government- and university-sponsored research in creating the foundation of knowledge that can supply industries like energy and pharmaceuticals with new technologies (Azoulay

FIGURE 2.

U.S. Spending on R&D, 1953–2015, by Source



Source: National Science Foundation, 1953–2015.

et al. 2015; Li, Azoulay, and Sampat 2017). This role has likely become more important as firms have become less vertically integrated, making it even more difficult for them to appropriate the returns to R&D, and yet federal spending on R&D has declined significantly as a fraction of GDP since the 1960s (figure 2).

From the underlying scientific research to the final manufacturing and delivery, both energy and pharmaceutical innovation pathways can be costly and prolonged.[1] In energy, the lag between public research funding and the issue of a resulting patent can be 20 years or more (Popp 2016). In pharmaceuticals, after a research investment has led to the creation of a valuable new molecular entity, 8 to 16 years are typically required until a product is released to the market (QuintilesIMS Institute 2017). Both energy and pharmaceutical technologies can be said to have a long gestation during which the specifications for optimum safety and performance must be tested and retested, involving expensive demonstrations or pilot plants. These undertakings require large investments from those who wish to ultimately commercialize the innovations. The so-called fail fast venture capital model—involving many initial projects, most of which are likely to fail—is not profitable when the cost of experimentation is high (Nanda and Rhodes-Kropf 2016).

DIFFERENCES IN THE CHALLENGES OF ENERGY AND PHARMACEUTICAL INNOVATION

One crucial difference between energy and pharmaceutical innovation is that energy-related emissions generate environmental costs that affect society at large, and not just energy producers and consumers. As long as carbon emissions are underpriced, there will not be a level playing field for clean electricity and fuels, which must compete directly on price with polluting energy sources. As a result, there is no market incentive to innovate for the sake of reducing emissions. Low-carbon energy supply technologies that have achieved market success have generally done so as a result of public incentives (e.g., Energiewende in Germany, state-level renewable portfolio standards in the United States, and investment and production tax credits for renewable energy sources).

Furthermore, for power generation in particular there are insufficient incentives to innovate even for the sake of more efficient energy usage. In most states a utility company's spending is regulated by a public utility commission. The utility earns a regulated rate of return on its capital assets, with reimbursement for operating costs. In contrast to pharmaceutical companies, which are sometimes rewarded with market power for investing in a more effective drug, a utility that invests in a more efficient use of fuel would merely reduce its operating cost reimbursement. This aspect of regulatory policy has its origins in the early days of the electric grid, when it was too expensive for utilities to compete with each other while covering the cost of transmission infrastructure for an entire region (Brooks 2015).

Another important difference between pharmaceuticals and energy innovation is in the scope of activities that fall within each category. Pharmaceuticals are relatively well-defined: they are chemical or biological products with patients as their end users, usually delivered via a pharmacy or a hospital. Energy, on the other hand, spans more than a dozen subsectors across industry, buildings, transport, and power generation (International Renewable Energy Agency [IRENA] 2017). The label "energy technology" can refer to the many technologies involved in either energy supply or energy consumption, including everything from oil drilling equipment and solar photovoltaics to automobiles and home appliances.

The diversity of technologies in energy markets leads to a complex regulatory landscape for energy markets, including both federal- and state-level oversight; on the other hand, the U.S. Food and Drug Administration (FDA) is responsible for centrally regulating the safety and efficacy of all drugs marketed in the United States. This centralization is possible in part because the effectiveness of a drug can be measured in a uniform way: How likely is it for the drug to have the intended effect on patients? In contrast, consider the numerous types of devices that consume electricity, which is itself only one type of energy use. This immense variety of energy technologies inhibits the development of simple metrics for safety and effectiveness that can apply broadly across the sector. This is a disadvantage for energy innovation, because such inhibition increases transaction costs for potential customers and reduces confidence for investors (Tassey 2017).

In summary, under current U.S. regulatory policy, suppliers of electricity and fuel have limited incentives to increase efficiency or to switch to cleaner technology. In addition, there is no single standards body to provide technology validation at different stages of innovation, as the FDA does for the more uniform pharmaceutical market (see box 2). The combination of these factors leads to greater uncertainty and lower demand in the market for new energy technologies, compared to the vibrant market for ideas in pharmaceuticals.

Chapter 3. The Proposal

Efforts to commercialize new technologies encounter difficulties both in launching new firms and in scaling up production. We describe some institutions and practices that support innovation in pharmaceuticals and are lacking in the energy sector.

A ROBUST SYSTEM OF CONTRACT RESEARCH

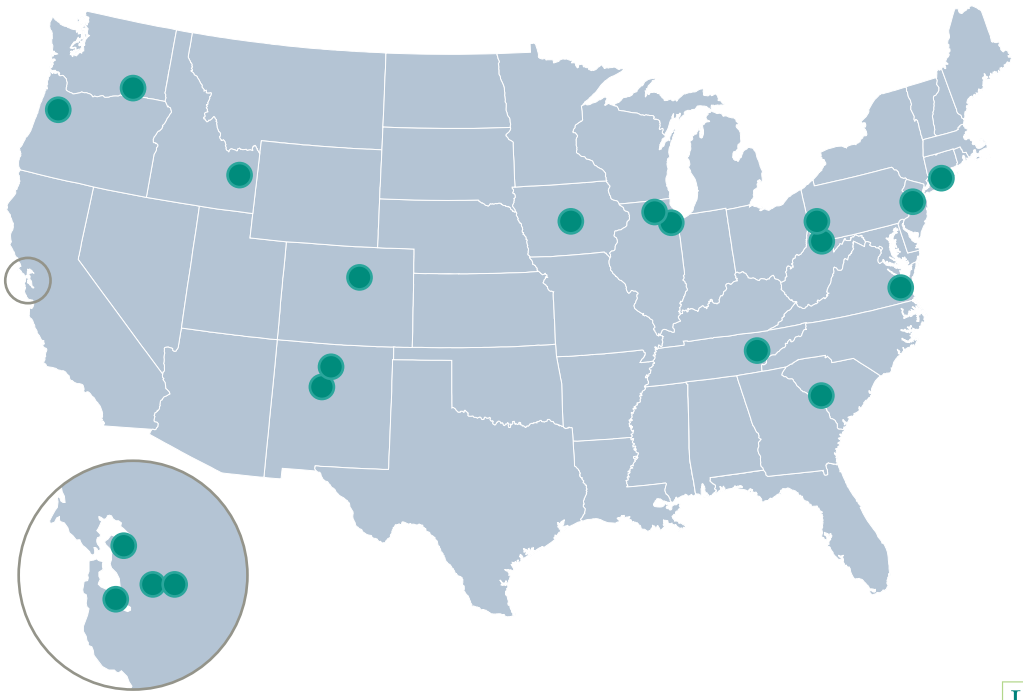
The early stages of the innovation pipeline entail proving that a new idea has promise, which allows a company to attract initial investment to continue developing the idea. In general, this phase of technology R&D is neither fast nor cheap. A new design for an energy storage device might require the creation of a working device prototype, followed by many rounds of testing and improvement. In the case of drug development, companies might need to optimize the synthesis of a new molecule, perform quality assurance, and conduct animal research before ever being approved to conduct human clinical trials.

Getting a drug from the concept stage to FDA approval is prohibitively expensive for a financially constrained start-up. Contract research organizations (CROs) facilitate this process by providing a standard set of services with a standard array of lab equipment and supplies. In addition to outsourcing their preclinical research, companies also frequently hire CROs to conduct clinical trials (Azoulay 2004; Harris Williams & Co. 2014). The global contract research industry has grown significantly in both size and scope over the past several decades, with some companies even offering contract manufacturing services (Scott Morton and Kyle 2011). The industry today is worth many billions of dollars; in the United States alone, there were more than 3,000 CROs active at the end of 2011, with more than 150,000 employees (Getz et al. 2012).

There are some firms that offer R&D contract services to companies developing energy technology, but the diversity of technological paradigms in energy research means that each

FIGURE 3.

Department of Energy National Laboratories



Source: DOE 2015.

Note: There are currently no National Labs in Alaska or Hawaii.

company's needs are likely to be different. The instrumentation required for most energy research or product development is often highly specialized and expensive. Each contract research facility might meet the needs of only a small segment of companies, whereas there are enough companies active in drug development with similar needs to provide economies of scale and a viable business model for a CRO.

The availability of contract research in energy technology is therefore much lower than in pharmaceuticals, in large part due to fundamental differences in the economics of the sectors. There is nevertheless room for improvement in energy innovation by importing this valuable practice from the pharmaceutical industry. We propose that regional actors—governments, universities, national labs, and companies—work to foster the creation of a robust set of research service providers to supplement existing user facilities. These services would be matched to regional strengths, taking into consideration the local business environment and the local scientific expertise. Nationwide, these efforts would combine to form a diverse research service industry that operates across the varied subsectors of energy technology.

One way to improve the availability of contract research for energy technology companies would be to work within the infrastructure of the DOE National Laboratories. Given the wide geographic coverage of the National Lab system (figure 3), it can provide a robust starting point for our proposed network of research service providers. The National Labs are authorized to provide research services to companies under a cooperative research and development agreement (CRADA), in which a company and National Lab jointly agree to contribute resources toward a mutually beneficial research project (Federal Technology Transfer Act of 1986; Stevenson-Wydler Technology Innovation Act of 1980); an example is described in box 1. Another option for energy companies to work with National Labs is through technology-specific testing and user facilities, such as the five Nanoscale Science Research Centers. Research support from a user facility is much less interactive than with a National Lab CRADA; staff members provide technical assistance rather than direct engagement with the research project.

In order to enhance the impact of these National Lab efforts, we propose that practices be implemented to stimulate a more entrepreneurial culture among National Lab researchers. Individual scientists and engineers with an interest in working with start-ups should be encouraged to do so. Part of this encouragement should come in the form of staff performance evaluation, which would take into account the high failure rate of start-ups and reward researchers for engaging with start-ups devoted to energy technology innovation. An example of a program that encourages this mindset is the DOE's Lab-Embedded Entrepreneurship Program, which was pioneered at Lawrence Berkeley National Lab in their Cyclotron Road program. Cyclotron Road admits entrepreneurs for a competitive two-year program during which they receive a living stipend and gain access to Lab resources to incubate their technology idea (Singer and Bonvillian 2017). The Lab-Embedded Entrepreneurship Program has grown to include two similar programs at Argonne National Lab and Oak Ridge National Lab and should be expanded further to serve additional regions of the United States.

UNIFORM TECHNICAL STANDARDS FOR COMMUNICATING RELIABILITY

As a new technology progresses toward a marketable product, companies must prove that the technology can be produced economically. In order to appeal to investors, they must also demonstrate that the product will meet the performance targets required by the market. For drugs, clinical research is needed to demonstrate safety and efficacy of the product; investors can use the three stages of FDA-approved clinical

BOX 1.

Cooperative R&D in the National Laboratories

Partnership with the National Laboratories was key to the founding of start-up Ampulse in 2007. Ampulse aimed to commercialize a lower-cost silicon deposition method for photovoltaic solar power generation; in so doing, it relied on intellectual property from Oak Ridge National Lab and silicon growth expertise at National Renewable Energy Lab (Perry 2010). Ampulse received private seed financing and signed CRADAs with both labs; the project also received direct financial support from the DOE.

Unfortunately, the project came up against barriers both technical and nontechnical. As is often the case when dealing with scientific uncertainty, the research took longer than anticipated. Furthermore, there was a mismatch of incentives and motivations between the company and the team at the National Lab. Some of the difficulty in executing a successful collaboration comes from lack of experience. Scientists and engineers at the National Labs are accustomed to significant academic freedom in choosing and directing their own projects. When they do engage in partnership with firms, it tends to be by licensing their IP to large companies that can afford to pay up front and continue development and commercialization efforts internally. A greater degree of participation is required for National Lab researchers to work with cash-constrained start-up companies, who need to take advantage of the National Lab's expertise and resources rather than complete the R&D in-house.

BOX 2.

Regulated Stages of Innovation at the FDA

The power of the FDA to approve or reject drugs for marketing in the United States illustrates the importance of regulatory standards in facilitating an industry's growth. Since 1938, when a drug used to treat strep throat was sold as a suspension in the poisonous solvent diethylene glycol, the FDA has been charged with reviewing the safety of new drugs (Junod 2008). The process of FDA review has evolved, and now includes formal requirements for controlled testing to prove that the drug is not just safe, but also effective for specific uses.[2]

The three phases of FDA clinical trials serve as uniform benchmarks for a new drug's performance, allowing an investor to quickly assess the degree to which a drug has been proven. Each stage offers investors an increasing level of confidence in the value of a new drug. Phase 1 of clinical trials is the first and smallest study conducted on humans, providing initial information on side effects and dosage levels. Phase 2 is a controlled study designed to measure effectiveness in a group of treated patients, ideally compared to a placebo group. If the drug shows signs of effectiveness in Phase 2, it advances to a larger Phase 3 trial to establish the appropriate labeling information, including risks and benefits.

trials as a benchmark for progress toward marketability, as explained in box 2. Energy products, on the other hand, have no such benchmarking system to allow investors to quickly assess the level of risk.

The closest analog in energy technology to the multiphase process for drugs is the technology readiness level (TRL), first defined by the National Aeronautics and Space Administration (NASA) in the 1990s for the purpose of assessing the maturity of space flight technology (NASA 2010). The TRL scale was adapted for use by the U.S. Department of Defense and later by the DOE, which has issued voluntary guidance on how programs can use TRLs to assess the readiness of a new technology (DOE 2011). The nine levels of readiness range from immature to fully mature: Basic Technology Research, Research to Prove Feasibility, Technology Development, Technology Demonstration, System Commissioning, and finally System Operations. Table 1 gives more detailed information for each TRL.

Although the TRL scale provides a common language for describing technology maturity, similar to the FDA phases for drugs, the scale's voluntary nature is an important difference. There is no certification associated with a company claiming that its technology is at a given stage of readiness, because there is no governing body serving the FDA's role of gatekeeper. As such, the TRL system does not substantially reduce the need for costly investigation by potential investors.

There are significant risks associated with energy technologies that can deter investors, beyond the uncertainty of

TABLE 1.

Technology Readiness Levels

Technology Readiness Level	Definition	Maturity
TRL 1	Basic principles observed and reported	Basic Technology Research
TRL 2	Technology concept and/or application formulated	
TRL 3	Analytical and experimental critical function and/or characteristic proof of concept	Research to Prove Feasibility
TRL 4	Component and/or system validation in laboratory environment	Technology Development
TRL 5	Laboratory scale, similar system validation in relevant environment	
TRL 6	Engineering/pilot-scale, similar (prototypical) system validation in relevant environment	Technology Demonstration
TRL 7	Full-scale, similar (prototypical) system demonstrated in relevant environment	System Commissioning
TRL 8	Actual system completed and qualified through test and demonstration	
TRL 9	Actual system operated over the full range of expected conditions	System Operations

Source: DOE 2011.

manufacturing cost. Some technologies carry safety concerns that require testing and quality control before release; examples are cars, batteries, building insulation, and nuclear reactors. Other concerns relate to the reliability of a product's performance, such as the lifetime of a solar panel, or the longevity of a battery's stated capacity over many cycles. Establishment of clear technical standards is of great importance in these cases, where consistency and reliability are required before widespread adoption of a new technology; an example of useful standards in solar inverters is discussed in box 3.

Technical standards should be governed in some way, though this process does not need to take place within the federal government. A credible third party can play a similar role in certifying a given technology's readiness or reliability. In general, developing a quality infrastructure to govern device manufacture, installation, and maintenance in a growing industry proceeds in several stages (IRENA 2015). First, industry associations organize around premarket technologies and begin planning their future approach; as the market grows, practices are developed to train practitioners, test equipment, and set standards. A maturing industry needs an organizational structure in place to offer accreditation for laboratories, inspection procedures, and training facilities.

Policy makers and energy industry professionals within each subsector should work to create an environment where uncertainty is minimized through certification by trusted standards bodies. As much as possible, standards should be uniform, rather than segmented and overlapping, to minimize costs for compliance. Standards should be regularly evaluated to ensure that they do not prevent adoption of significant technology improvements. Even when standards are led by industry associations, they should receive public support and funding, especially in their infancy. Government can play a valuable convening and facilitating role in standards development.

BETTER REGULATORY INCENTIVES FOR ELECTRIC UTILITIES

Although many pharmaceutical products can be made profitable if they are proven safe and effective, this is not universally true. Vaccines against neglected tropical diseases, for example, address a patient population that is largely poor and unable to pay for vaccination. Similarly, until the 1980s developing drugs to treat rare diseases—defined as those afflicting fewer than 200,000 individuals in the United States—was generally not profitable. Drugs for rare diseases, also known as orphan drugs, have such small markets that a company typically cannot expect to recover the cost of discovery and development from sales alone. With an estimated 25 to 30 million Americans having a rare disease, policy makers saw a clear public need to encourage orphan drug development (National Institutes of Health [NIH] 2010). Box 4 discusses how public investment became part of the solution.

The story of federal support for orphan drug development illustrates how public programs can shape an industry by reducing the cost of innovating and increasing the potential rewards for successful innovations. This lesson could be particularly helpful for electricity generation, where the lack of incentives for innovation is somewhat analogous to the situation in rare disease treatment before the Orphan Drug Act. As with the enzyme needed to treat Gaucher disease, which was known but too expensive to commercialize in the absence of incentives, there are currently some technologies—such as distributed energy resources (DER) and digital home sensing—that are available to improve energy efficiency but are not being fully implemented.

Utilities have struggled to adapt and incorporate innovative technology into their business strategy. To accelerate the evolution of the electric grid, utilities need direct incentives to participate in the innovation process. It is instructive to consider some isolated examples of programs to account for

BOX 3.

An Example of Best Practices: Standards for Solar Power Inverters

Clear technical standards have already been implemented for certain subcategories of energy technology: for example, power inverters used to connect solar panels to the grid. Since 2003, a set of requirements for solar inverters has been published by the member organization Institute of Electrical and Electronics Engineers (IEEE) (Basso 2014); these requirements are further supplemented by requirements from the company Underwriters Laboratories (UL). The IEEE and UL standards have been adopted by state public utility commissions and electric utility companies in determining the specifications required for new inverters to connect to the grid. This allows manufacturers to be confident that their product can be integrated safely and predictably into an electrical grid.

Regulation for power inverters provides a good illustration of standard-setting within an existing product market. Such regulation, which can accelerate market adoption of incremental innovations, is a complement to policies that explicitly promote adoption of clean energy technology. Regulation is likely to be especially important for the diffusion of energy efficiency improvements, such as integrating new lighting technology or insulation materials in existing buildings (Weiss and Bonvillian 2009). Unfortunately, the standards set for technology adoption in buildings will not translate to other technical areas; standards must be established for each type of energy technology.

BOX 4.

The Orphan Drug Act and Genzyme

To address rare diseases, Congress passed the Orphan Drug Act (ODA) in 1983. This legislation enabled companies to profit from orphan drug sales, thanks to tax credits for the cost of clinical research and direct financial assistance for developing the drugs; the fund for these grants is currently $30 million annually (FDA 1997). Companies also get "a seven-year period of exclusive marketing given to the first sponsor of an orphan-designated product who obtains market approval from the [FDA] for the same indication" (FDA 2016).

The ODA proved extremely important for the field of rare disease treatments, as is demonstrated by the history of the biotechnology firm Genzyme and its work with Gaucher disease. Because Gaucher is so rare—afflicting only a few thousand patients in the United States (Deegan and Cox 2012)—Genzyme was able to take advantage of the ODA to help commercialize a treatment for the disease. The new treatment was approved in 1991 as the first-ever enzyme replacement therapy. Genzyme particularly benefited from the seven-year exclusive marketing period following FDA approval; the intellectual property for the method of enzyme production was held by researchers at the NIH, so Genzyme did not have patent protection (Office of Technology Assessment 1992).

Genzyme is not the only company that has capitalized on federal assistance to thrive as an orphan drug maker. According to the FDA, "The ODA has resulted in the development of more than 250 orphan drugs, which now are available to treat a potential patient population of more than 13 million Americans. In contrast, the decade before 1983 saw fewer than 10 such products developed without government assistance" (FDA 2016). Worldwide orphan drug sales are now more than $100 billion (Tribble and Lupkin 2017a). Careful study of clinical trials and the stock of available drugs before and after the ODA shows there was an increase in R&D investment, measured both as trials for new treatments and completed development of existing drugs (Yin 2008, 2009). The ODA, along with sizable direct government investments in R&D through the NIH, served as a major driver of growth in the biopharmaceutical industry (Lazonick and Tulum 2011).

It is important to note that exclusivity has led to concern over high prices for drugs approved under the ODA. Critics argue that many pharmaceutical firms exploit the ODA in ways that do not reflect legislative intent, such as repurposing mass-market drugs with orphan designations (Daniel et al., 2016; Tribble and Lupkin, 2017b). We are not proposing that additional exclusivity rights and associated monopoly power be implemented for the energy sector. Rather, we believe that the story of the Orphan Drug Act generally illustrates the potential impact of public incentives for innovation.

pilot projects when calculating a utility's permitted rate of return (MIT Energy Initiative 2016, 172). Among U.S. states, New York is at the forefront of reforming electricity regulation to ease the incorporation of DERs. Part of New York's effort includes demonstration projects for new technologies and new business models being tested throughout the state (New York State 2017). An example of these projects is described in box 5.

Electric utility reform represents an opportunity for state policy action that accelerates deployment of cleaner, more efficient energy technologies. Other states should follow New York's lead and create mechanisms to reimburse utilities for testing new technologies. States should also provide a clear path for these technologies to become part of the utility's standard assets once effectiveness is proven. Programs should be tailored to the needs of each state; options include guaranteed cost recovery for innovative projects or a competitive project selection process. If done correctly, any costs that are shared with electricity consumers will be repaid in the long run by lower operating costs when new technologies are successfully deployed.

BOX 5.

Coordination between Utilities and Private Partners

The utility National Grid is undertaking a potentially valuable demonstration project with Buffalo Niagara Medical Campus (BNMC) as the customer and Opus One as a private partner. The goal of the project is for Opus One to build a software platform that will coordinate the existing DER installations at BNMC with the local National Grid substation. The platform will allow DER to respond to electricity demand across the campus with real-time price signals. Through this project the utility will advance its understanding about how to incorporate DER into its business model, while also rewarding the owners of DER for the value of distributed generation.

The learning process under way in the BNMC demonstration could ultimately encourage installations of new DER, including natural gas generators, solar photovoltaics, and energy storage. It could also encourage further early-stage investments in R&D related to electricity, similar to the creation of new drugs that occurred in the wake of the ODA. Regardless of the fate of each particular idea being demonstrated, early signs are that coordination between utilities and private partners is advantageous for energy innovation.

Chapter 4. Questions and Concerns

1. Given the importance of technical standards, why hasn't third-party certification already emerged?

The lack of uniformity among different energy technologies makes it difficult for disparate industry groups to coordinate on performance standards. This problem is particularly acute for nascent technologies that might not be developed enough to have an industry association to facilitate the process. Our proposal recognizes that state and federal policy makers could be instrumental in establishing and legitimizing standards bodies for developing technologies.

2. What is the best candidate for an institution that would provide third-party certification?

The optimal third-party certification institution would depend on the subsector. Member organizations or industry associations are promising actors that can help to draft standards and establish certification practices. For technologies that relate to electricity generation, transmission, or distribution, public utility commissions and electric utility companies could support and enforce standards by incorporating them as requirements for connecting to the electrical grid.

3. If collaboration between National Labs researchers and entrepreneurs were enhanced, would National Labs resources be strained, impeding progress in existing projects?

The incentives for National Labs researchers to participate in entrepreneurial projects would be designed such that they do not crowd out the most valuable existing projects. Additional National Labs funding might be necessary, however, to accommodate the increase in entrepreneurial collaboration. With fees set appropriately for private-sector participants, an influx of energy innovation partners would help the National Labs to expand their impact.

4. Not all previous efforts to promote innovation in the energy sector have been successful. How would your proposal maximize the effectiveness of federal investments?

It is impossible to precisely predict which technological approaches will bear fruit; some efforts will naturally turn out to be more successful than others. Federal innovation policy should establish the conditions and incentives that are most likely to facilitate the development of successful technologies. Our proposal would address some shortcomings in energy R&D policy, helping entrepreneurs and innovators get the support they need during the most challenging phases of technology development.

Chapter 5. Conclusion

Informed by the experience of pharmaceutical innovation, we propose that a number of institutions be established and that existing institutions be strengthened to promote energy innovation. A robust system of contract research, uniform technical standards for communicating reliability, and better regulatory incentives for electric utilities will accelerate the creation and deployment of improved energy technologies. Importantly, improvements to the incentives and environment for technology deployment are complementary to investments in R&D. Both approaches will enhance the expected profitability of energy innovation and encourage investment in the transition to a clean energy system.

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Anna Goldstein is a Postdoctoral Researcher at Stanford University and Carnegie Institution for Science. She is also a Research Associate at Harvard Kennedy School's Belfer Center, having recently completed a Fellowship there in Science, Technology and Public Policy.

The focus of her research is energy innovation policy, particularly the organization and management of research and development (R&D) to accelerate creation and diffusion of clean energy technologies. She evaluates past energy innovation efforts in order to inform the design of future initiatives.

Goldstein received her Ph.D. in 2014 in Chemistry with an emphasis in Nanoscale Science and Engineering from the University of California, Berkeley, where she investigated nanomaterials for use in energy applications, such as artificial photosynthesis and electrochemical energy storage.

Pierre Azoulay is the International Programs Professor of Management and a Professor of Technological Innovation, Entrepreneurship, and Strategic Management at the MIT Sloan School of Management.

Azoulay teaches courses on strategy and technology strategy at MIT Sloan. Previously, he was an associate professor of management at Columbia University's Graduate School of Business. His research centers on how organizational design and social networks influence the productivity of research and development in the healthcare sector. Currently, Azoulay is studying the impact of superstar researchers on the research productivity of their colleagues in the academic life sciences. He also is interested in the topic of academic entrepreneurship, having recently concluded a major study of the antecedents and consequences of academic patenting. In the past, he has investigated the outsourcing strategies of pharmaceutical firms, in particular the role played by contract research organizations in the clinical trials process. He is a faculty Research Fellow at the National Bureau of Economic Research.

Azoulay holds a Diplôme D'études Supérieures de Gestion from the Institut National des Télécommunications, an MA in telecommunications from Michigan State University, and a Ph.D. in management from the MIT Sloan School of Management.

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Vladimir Bulović

MIT School of Engineering

Joshua Graff Zivin holds dual faculty positions at the School of Global Policy & Strategy and UC San Diego's Department of Economics, exemplifying his multidisciplinary research. His research interests are broad and include the areas of environmental, health, development and innovation economics. Policy relevance serves as a guiding force behind all of this work.

Much of his current work is focused on three distinct areas of research: the relationship between the environment, health and human capital, the economics of innovation with a particular eye toward the role of institutions, social networks and financial incentives, and the design of health interventions and their economic impacts.

Graff Zivin is a research associate at the National Bureau of Economic Research. He currently serves as co-director of UC San Diego's Global Health Institute and research director for International Environmental and Health Studies at the the UC San Diego Institute on Global Conflict and Cooperation.

After receiving his Ph.D. from UC Berkeley, he was an associate professor at the Mailman School of Public Health and the School of International and Public Affairs at Columbia University, where he served as director of their Ph.D. program in sustainable development.

Vladimir Bulović holds the Fariborz Maseeh Chair in Emerging Technology and is the MIT School of Engineering's Associate Dean for Innovation. He co-directs the MIT Innovation Initiative as well as the Eni-MIT Solar Frontiers Center. He leads the Organic and Nanostructured Electronics Laboratory (ONE Lab), which he developed as a unique open nanotechnology facility. Vladimir previously directed the MIT Microsystems Technology Laboratories (MTL). His research interests include studies of physical properties of organic and inorganic nanostructured films and structures and their applications in novel optoelectronic devices.

A practicing entrepreneur, Vladimir is a cofounder of QD Vision, Inc., which is manufacturing quantum dot optoelectronic components. He also co-founded Kateeva, Inc., which is focused on development of printed organic electronics, and Ubiquitous Energy, Inc., which is developing nanostructured solar technologies. These start-ups presently employ over 200 researchers in the U.S. and a similar number of employees abroad.

Vladimir received his Ph.D. from Princeton University. He is a recipient of the U.S. Presidential Early Career Award for Scientist and Engineers, the National Science Foundation Career Award, the Ruth and Joel Spira Award, the Eta Kappa Nu Honor Society Award, and the Bose Award for Distinguished Teaching. Vladimir was named to the Technology Review TR100 List, and in 2012 he shared the SEMI Award for North America in recognition of his contribution to commercialization of quantum dot technology.

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Endnotes

1. An exception to these long development cycles can be found in a certain type of energy innovation—those that are based on computing and communications technology. Innovations in software can be developed and distributed much more quickly compared to hardware. One example is a smart home system that reduces fuel consumption for heating and cooling by sensing whether anyone is home, as well as allowing remote control of home temperatures. Improvements to this product could be rapidly developed and released to homes over the internet, without production of any physical goods.
2. Since 1963, following a global crisis of birth defects in babies born to women who had taken the drug thalidomide during pregnancy (Carpenter 2014, chap. 4), the requirements for clinical trials have been defined in the Code of Federal Regulations (Section 312.21 of title 21).

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Highlights

The innovation system that develops and deploys new pharmaceuticals holds important lessons for energy R&D. Anna Goldstein, Pierre Azoulay, Joshua Graff Zivin, and Vladimir Bulović consider three aspects of the pharmaceutical innovation system that might be instructive for policy makers who want to advance energy innovation: (1) the availability of contract research organizations to perform specialized research, (2) a centralized regulatory framework for staged trials, and (3) public funding for research when costs are greater than potential private payoffs.

The Proposal

Establish a robust system of contract research. The authors propose that regional actors collaborate to establish contract research services well-suited to each region's local strengths. As part of this strategy, they propose working within the infrastructure of the US National Laboratories.

Implement uniform technical standards. The authors propose that policy makers and energy industry professionals within each subsector work to establish trusted standards bodies that would use certification to minimize investor uncertainty. These standards bodies would receive public support and funding.

Create better regulatory incentives for electric utilities. The authors propose that states create mechanisms to reimburse utilities for testing new technologies. States should also provide a clear path for these technologies to become part of the utility's standard assets once effectiveness has been proven.

Benefits

Accelerating energy innovation is both a necessary part of climate change mitigation and a spur to economic growth. The authors' proposed policies would enhance the expected profitability of energy innovation and encourage investment in the transition to a clean energy system. Improving the availability of reliable, inexpensive energy services can have wide-ranging benefits for society, including both businesses and consumers.

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