Innovation in a Rules-Bound World: How Regulatory Improvement Can Spur Growth

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Introduction

Economists and policymakers are always lauding innovation. In its purest form, innovation is like a free lunch: it boosts growth and incomes, creates good jobs, and opens up new possibilities for social reform and social mobility.

Today, innovation is needed more than ever. Productivity growth has been slowing in recent years. The 10-year growth rate of nonfarm business labor productivity is only 1.3 percent in 2015, compared to 3 percent as recently as 2005. A full one percentage point of that 1.7 percentage point decline, or more than half, is due to a slowdown in the growth rate of multifactor productivity, an indicator of innovation. In other words, the economic evidence suggests that this is an era of relatively weak innovation, outside of information technology.

Innovation, especially disruptive innovation, embodies unpredictability, change, and the creation of new products and markets. By contrast, regulators thrive on rules and predictability.

Indeed, encouraging innovation is more essential than ever before. Fortunately, industries such as health care, education, finance, and tech are attempting to adopt new technologies that offer the chance of faster growth and higher wages, desperately needed to overcome years of stagnation.

But regulators, both in Washington, and at the state and local level, struggle with a rapid pace of innovation. Innovation, especially disruptive innovation, embodies unpredictability, change, and the creation of new products and markets. By contrast, regulators thrive on rules and predictability. They maintain a process of identifying an existing market failure and then issuing regulations that aims to make consumers and society better off by correcting that failure. The regulation process is far more straightforward when markets change slowly and predictably.

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Additionally, innovation creates all sorts of ways for things to go wrong that regulators can be blamed for. Financial innovation, wrongly used, was one of the factors underlying the last financial crisis, and potentially the next one. Individual privacy is seriously threatened by the ubiquity of computing, and the threats will only get worse as our appliances, homes, and cars are linked to the Internet. Unmanned drones can interfere with commercial air-flight. And technological advances are giving companies more and more ways to evade regulators, as the recent example of Volkswagen shows. Its diesel cars and trucks use software to help them run better—but that same software enabled the giant German automaker to beat the pollution emissions test of regulators for years.

Faced with these potential dangers, it is tempting and even easy for regulators to adopt stricter rules to protect against potential dangers, even at the cost of slowing or even suppressing innovation and growth. Indeed, by some measures, federal regulation has intensified in recent years. The number of full-time employees at consumer protection and safety agencies, including the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA), has risen by 30 percent from 2000 to 2015. Similarly, the number of full-time employees at financial regulatory agencies, including the Securities and Exchange Commission (SEC), rose by 24 percent over the same stretch.[1] Meanwhile employment in the private sector only rose by 5 percent.

However, when the regulators adopt stricter rules to preemptively avert any potential dangers, the costs of these regulations can tend towards outweighing the benefits. Innovation-driven productivity losses come at a great economic cost that must be taken into consideration as well.

Innovation in a Rules-Bound World

To advance this conversation, on March 2, 2015, the Progressive Policy Institute hosted a conference titled "Innovation in a Rules-Bound World: How Regulatory Improvement Can Spur Growth" (the full agenda can be found in the appendix to this paper). The goal of this conference, which featured high-level regulators, elected officials, academics, and policy experts, was to help regulators find a middle ground between overly-aggressive crackdowns on new technologies and helpless passivity in the face of innovation.

This middle ground has been variously called regulatory humility (by FTC Commissioner Maureen Ohlhausen, a conference participant), permissionless innovation (by Adam Thierer, senior fellow at the Mercatus Institute and a conference participant), and light-touch regulation. The desired outcome is to find a way of keeping regulators alert for consumer-harming behavior without blocking innovation.

This paper builds on the results of the conference, in order to outline a new form of 21st century regulation that actually improves oversight of new technologies without imposing unnecessary barriers to innovation. In health care, for example,

genomics offers the possibility of tailoring cancer or other therapies to the precise needs of the patient. Yet as conference panelists point out, the necessary data is locked up by outmoded rules. Conference participant Michael Mandel, chief economic strategist of the Progressive Policy Institute (PPI) notes that, in part because of these regulatory hurdles, the United States has spent roughly $1 trillion on biosciences R&D over the past decade without getting great returns.

An alternative can be found in Japan, where the government has recently enacted legislation allowing new products in regenerative medicine to get conditional approval if they meet a standard of safety and probable efficacy. That gets products to market much faster and more cheaply, while using analysis of electronic health records to track efficacy and potential side effects in real patients.

Another example is auto emissions testing. Volkswagen was able to get away with its deception because regulators mandate that auto pollution from vehicles be measured under controlled conditions in test facilities. But the technology exists to do "on-road remote sensing" of auto emissions, using optical sensors to measure the pollution produced by individual cars, linked to their license plates. Such a methodology would test auto emissions under real-world conditions, eliminating the ability to cheat on tests and providing the information to better control pollution in the future.

The key to a 21st Century regulatory approach is data. As products and markets become more complex, regulators have to enthusiastically embrace the tools of big data in order to keep up. By harnessing technology to better track real-world outcomes, social goals can be achieved faster and at a lower cost.

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Unfortunately, some regulators have gone backwards in recent years, trying to cope with complex modern systems with antiquated tools. For example, the Federal Communications Commission (FCC) moved in February to bring broadband under Title II regulations, which date back to the 1930s. That decision is likely to slow innovation and investment.

Improving regulation could be an opportunity for liberals, moderates, and conservatives to find common ground. Social goals are easier to achieve in a growing economy. That's why improving our nation's outdated regulatory system is a core part of PPI's "Reinventing Government" project—a better-functioning government will better enable America's businesses to grow and consumers to prosper.

Keynotes: The Policy Framework

The policy framework for the conference was set by FTC Commissioner Maureen Ohlhausen and Senator Angus King. Commissioner Ohlhausen led off the conference by outlining her concept of "regulatory humility." She argued that in order to encourage innovation, regulators must approach consumer protection with humility and an open mind, rather than preemptively setting rules as if they could predict the future.

In her view, regulatory humility is about choosing to protect consumers in response to actual demonstrated harms, rather than creating rules to avoid potential harms that might or might not occur. This humility acknowledges that nobody is capable of foretelling what exciting innovations may arrive in the future or what the scope of their positive and/or negative effects will be, but also stresses the importance of guarding against the known illegal, fraudulent, or anticompetitive behavior of today.

Commissioner Ohlhausen noted that the alternate approach—prescriptively regulating in an attempt to avoid potential future harms—is not a good use of regulators' time and resources. Moreover, such a prescriptive approach can backfire by limiting the scope for future disruption and innovation. In that case, the regulator ends up harming consumers by trying to protect them. It goes against the mission of the regulatory agency.

By contrast, regulatory humility requires an awareness that each industry is different, that competitiveness may mean different things in different sectors, and that it may not be possible to fit companies within an industry into a predetermined box. It also requires a regulatory toolkit filled with nimble, transparent, and incremental rulemaking tools. It appreciates that the best regulations will allow for natural shifts in industry composition and dynamics.

Commissioner Ohlhausen gave two examples. First, she observed that Uber has emerged as a major new player in the ridesharing space, challenging the market share of long-dominant taxicab companies in just a few years. One of the big differences between Uber and taxicab companies is the use of data to set fares dynamically and to rate drivers and consumers. Such data-driven operations could conceivably raise privacy and competition issues. However, resisting the urge to over-regulate or to blindly favor incumbents has enabled consumers to embrace this new form of data-driven ridesharing. It's better to give Uber the benefit of the doubt and let consumers make the ultimate decision with their wallets. If Uber is found to violate consumer privacy laws, or harm consumers, then the FTC should step in and correct the market failure.[2]

An opposing example cited by Commissioner Ohlhausen was the FCC's approach to regulating broadband providers. Rather than waiting for actual harm, the FCC decided to apply the Title II regulations that were originally designed to regulate telephone companies like monopolies. This approach, noted Ohlhausen, could have somber implications for the future of the data-driven economy and the Internet of Things.

The second half of the policy framework was provided by Senator Angus King (I-Maine). The Senator explained that our current system has what he calls an "institutional imperative"—a natural inclination for agencies to constantly regulate at the risk of not being seen as productive or adding value. One example he outlined

is the Department of Education, which provides a small share of total education funding yet churns out countless regulations at all levels of education.

The Senator made a compelling case for why addressing regulatory accumulation is essential for economic growth, and why it could be best achieved through creating a Regulatory Improvement Commission (described later in this report). He shared several ideas on how to regulate responsibly going forward and how to address regulatory accumulation retrospectively. On the rule promulgation side, these included requiring stakeholder input upfront, imposing time limits for agency response to public comment, and requiring justification based on scientific data. If regulations on energy-efficient stoves, for example, make such advancements in technology too expensive, people will stick with their old inefficient stoves.

The Senator noted that the impetus for addressing our system's regulatory accumulation must come from Congress. That's because Congress can provide a broad-based strategy that spans agencies, instead of relying on each agency to look at their rules individually. A broad-based approach enables true evaluation of the interactions and conflicts of rules across agencies, without the pressures agencies face in self-review. Self-review within agencies tends not to be effective because agencies have little incentive to divert scarce budget resources away from promulgating new rules, given the institutional imperative.

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A Congressionally-authorized independent body to review rules could also provide a level of de facto agency monitoring and oversight. In addition to reviewing rules, it could act as an "umpire in the system" to counteract the institutional imperative, by reminding regulatory agencies that bad rules must be either improved or removed. The closest body we have currently to this is the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB), but that office is underfunded and understaffed. Nor does it holistically evaluate the interaction of individual regulations with the larger system of rules.

In this regard, the approach proposed by Senator King is to establish a Regulatory Improvement Commission (RIC), based on a PPI proposal.[3] The Senator first introduced the RIC as the *Regulatory Improvement Act of 2013*, co-sponsored by Senator Roy Blunt. Most recently, in March 2015, Senator King reintroduced the bill as the *Regulatory Improvement Act of 2015*, which now has both Democrat and Republican cosponsors.[4]

Commissioner Ohlhausen considered the impact of future regulations on innovation, while Senator King laid out the political and policy groundwork for dealing with the innovation drag imposed by the buildup of past regulations—what we have called regulatory accumulation.

It's worth noting that such negative impacts of regulation on innovation are not systematically studied as part of OIRA's annual review of the costs and benefits of federal regulation. In fact, the only substantive mention of innovation in the text of the 2014 report was a reference to studies that showed "there may be positive economic effects related to technological innovation in the years following increased environmental regulatory compliance costs."[5] It is unfortunate that OIRA chooses to focus on a single example of a potentially advantageous impact of regulation on innovation without citing equally compelling evidence for the negative effects of regulation.

Panel: The Political Framework

Next, Representatives Kyrsten Sinema (D-Ariz.) and Ted Yoho (R-Fla.) shared their perspective on current proposals for regulatory reform in this Congress. They both noted bipartisan support for establishing an independent commission to address the buildup of outdated, conflicting, and duplicative regulations over time.

For Democrats, regulatory improvement can reduce complexity and confusion in our current system. It makes it easier for consumers to see the benefits of the regulations designed to help them, and it makes the regulations work more effectively. For Republicans, reviewing existing rules is a commonsense way to help reduce regulatory obstacles for businesses to innovate and expand.

Reps. Sinema and Yoho gave several examples of how outdated or conflicting rules hurt businesses in their districts. For example, in Florida, farmers are forced to comply with onerous rules that make little sense, such as a ban on using wooden brooms around watermelons. Egg production and distribution are governed by a welter of rules as well.[6] In Arizona, conflicting language has made it so that one tankless water heater manufacturer could not get their product Energy Star certified despite it being more efficient than a model that was able to gain certification.

Regulatory accumulation also affects state and local governments, as federal rules conflict with or muddy their own rules. Multiple agencies can issue overlapping or duplicative rules without even realizing it and there is no process in place to resolve this. In Arizona, for example, one municipality struggles to issue bonds because of consultant requirements included in the Dodd-Frank Act that it cannot afford.

In many ways, addressing regulatory accumulation also addresses the larger question of how to ensure a well-functioning government. We need an approach to regulation that is responsive and adaptive to today's economic realities. Rep. Yoho vocalized this as avoiding putting yesterday's square pegs into today's round holes. He is concerned, for example, by the FCC's decision to enforce net neutrality by regulating ISP's within a framework laid out in the 1934 Communications Act.

Commentary

The discussion between Representatives Sinema and Yoho underscored the disappointing reality that few regulators are aware of all the rules that exist. At the very least, a 21st Century data-driven approach to regulation would serve to identify all the regulations affecting a particular industry in a straight-forward manner. Knowing the full extent of existing rules would enable regulators and legislators to make informed decisions regarding existing and future regulations.

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For example, Rep. Sinema noted that one tankless water heater manufacturer could not get their product certified as energy-efficient. When we explored this issue further, it turned out that the problem was more complicated—and more disturbing—than it seemed at first. Also known as instantaneous water heaters, tankless heaters save energy by heating water during consumption, as the water passes through the system, rather than heating and storing hot water in a large tank. This translates into large savings over time, since on average heating water comprises about 20 percent of a household's energy use.

Tankless water heaters can be powered by either gas or electricity. Gas tankless water heaters are eligible for the valued government Energy Star certification, while, oddly enough, electric ones are not. The Energy Star certification is typically featured prominently on packaging and sends a clear signal to consumers who are willing to pay a premium for energy efficiency.

Examining why electric tankless water heaters are ineligible for the certification leaves more questions than answers. That's because publicly available materials from Energy Star give seemingly conflicting information. For example, according to Energy Star criteria, gas tankless heaters must have an Energy Factor (EF) of greater than 0.9.[7] Yet a study by the Environmental Protection Agency (EPA), which administers Energy Star, found electric tankless water heaters have an EF in the range of 0.98 to 0.99. This is not only higher than the EF standards for electric tankless water heaters required by the Department of Energy (DOE),[8] but it is also higher than the EF of 0.9 required by gas tankless water heaters to earn the Energy Star certification.[9] In another twist, a page on the Energy Star website, no longer available as of November 2015, said that although electric tankless water heaters have an EF greater than required by the DOE, they were ineligible for designation because they had limited potential for further improvement.[10]

What's needed is a systematic, data-driven approach to inventorying regulations, on the federal, state and local levels. Initial attempts have been made to achieve this sort of systematic inventory,[11] but further investment would help identify the regulatory accumulation that is potentially impairing innovation.

Panel: Encouraging Entrepreneurship and Innovation

After the development of the policy and political frameworks for regulatory improvement, the conference turned to the need for a new model of regulation that encourages innovation and entrepreneurship. This conversation was motivated by

the steadily decreasing rate of new business formation over the last three decades.[12] Moreover, there appears to be a connection between the rate of business formation and the rate of innovation.

The panel of experts addressing the question of regulation, entrepreneurship, and innovation included Adam Thierer, of the Mercatus Center at George Mason University, Cary Coglianese, director of the Penn Program on Regulation at the University of Pennsylvania, and Michael Mandel of PPI.

Thierer started by stating that allowing "permissionless innovation" is a key component for fostering business formation. He defines permissionless innovation as "the general freedom to experiment with new technologies and business models." Thierer asserted that it was the atmosphere of permissionless innovation that facilitated the rapid development of the Internet and digital economy.[13] Without the ability to take risks, and sometimes fail, society would not be able to enjoy many of the innovations we benefit from today.

For example, consider the development of the digital economy in Europe compared to the United States. While the United States has seen enormous innovation and investment in telecommunications and broadband, in content distribution channels and the content providers that feed into them, Europe has notoriously lagged behind.[14]

Thierer credits the strength of the United States' digital economy to a historical light-touch approach in regulation, stemming from the separate treatment of the Internet in the Telecommunications Act of 1996. The light-touch approach resulted in enormous investment relative to Europe, faster broadband penetration and greater development of the data ecosystem. There was no preemptive regulation and no prescriptive rulemaking.

However, the regulatory climate has changed and Thierer is now questioning how current restrictive regulatory decisions on net neutrality and privacy will factor into the future vitality of the data ecosystem. If the Internet is regulated like a utility, will it stifle investment by the ISPs and result in reduced innovation across the entire ecosystem? Should the Obama administration's privacy "Bill of Rights" be mandatory or voluntary?

Previous PPI research has explained the various forms of regulatory accumulation in detail.[15] Ideally, the solution for regulatory accumulation is to not let it pile up in the first place. Thierer advocates for a light-touch or permissionless innovation approach to regulation, similar to Commissioner Ohlhausen's call for rulemakers to regulate with humility.

Thierer suggests using a "least common denominator" method where regulators impose the least amount of regulation necessary to protect consumers. The goal is

to provide the protection that consumers need, but in a way that doesn't automatically reward incumbents and doesn't impede innovation and entrepreneurship.

Cary Coglianese, on the other hand, advocates for a different approach. He suggests tackling regulatory accumulation in a targeted way, starting with the duplicative rules across regulatory agencies. Although each regulatory agency has a unique jurisdiction, in reality the rules promulgated within an agency's purview may overlap goods and services. For example, approximately 15 agencies regulate pizza. This includes agencies that no one would associate with pizza, like the EPA, which regulates grains in the crust.

Under the approach suggested by Coglianese, agencies would be required to coordinate and collaborate with each other. The key benefits of this method are that it is not costly or complicated; instead it is targeted and incremental. Nor does this approach overtly change the structure of current system. In fact, Coglianese argues that this is the most viable approach to regulatory reform, because it is implausible to expect agency consolidation or other major changes.

Moreover, there is a precedent for agency coordination both on the national and international level. For the United States, he cites the example of spilled milk being classified as a hazardous waste. As this is a burdensome regulation, the EPA was able to get an exemption from overseeing such spills. Internationally, there are existing memorandums of understanding between the United States and the EU for the harmonization of different standards on product quality.

Coglianese acknowledges one important shortcoming of this approach--that it may be challenging to implement. Agencies simply lack the needed incentive to collaborate and coordinate and fear being viewed as unnecessary or secondary in importance. However, Coglianese believes a Presidential Executive Order could overcome this limitation.

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Mandel's answer to the question of how to foster entrepreneurship and innovation is the formation of a Regulatory Improvement Commission. Such a Commission would review and then either improve or remove rules as submitted by the public, before sending the package of recommendations to Congress for an up or down vote. The structure of the Commission would ensure independence and public engagement in reviewing rules, while not creating a new bureaucracy since it would be dissolved upon completion and reauthorized on an as-needed basis. Most importantly, it would finally put a mechanism in place solely designed to relieve the burden of outdated, duplicative, and conflicting rules. As noted above, the RIC was incorporated in legislation introduced by Senator King. It is also part of another piece of regulatory reform legislation, a companion bill in the House, introduced by Representative Patrick Murphy (D-Fla.). The bill is circulating with bipartisan cosponsors in both chambers.

The panelists brought focus to the state-level governments as well, since they are also being forced to deal with outdated or conflicting rules as the traditional business model evolves in the shared economy. In some cases, such as with Uber and Airbnb, states are compelled to review and change decades-old regulation. The demand for sharing economy services will continue to surge as people become more connected, and thus the issue of regulatory ambiguity will increasingly arise. There is a clear imperative for state governments to address this in order to support consumers and businesses.

The federal government also has an opportunity to set the tone for how states approach these questions. Do we encourage states to regulate new industries as incumbents or reduce the overall burden of regulation and let consumers decide in the market? Which will encourage greater business formation and innovation? Adam Thierer pointed to the example of genomic coding start-up 23andMe, which has the potential to revolutionize preventive health care. Its operations have been severely limited by U.S. regulations governing data privacy, hindering the process of innovation and health care reform.[16]

Commentary

One place where regulation is lagging behind changes in the economy is employment. In recent years, states have put in more and more occupational licensing restrictions. These regulations build up over time and interact in ways we could not have foreseen or expected, limiting the ability to start businesses and to innovate. Moreover, with the rise of the sharing economy, the distinction between employees and self-employed is becoming blurred.

While ridesharing such as Uber and Lyft has been a commercial success, it is uncharted regulatory territory. One of the most pressing issues is how to treat the employment status of drivers. Ridesharing drivers choose their own hours, use their own car, and decide which customers they want to pick up. Sometimes these drivers were already going to a specific destination, but are picking people up on the way to make some extra cash. Many of the drivers have other full-time or part-time jobs that are their main source of income.

With such flexibility, ridesharing drivers do not fit any traditional employment category. Are they employees, independent contractors, or neither? Moreover, should drivers for each of these companies be treated equally, given the variations in business models? For example, Uber is more of a cab service, while Lyft is more like a carpool.

On one hand, these drivers are dependent on the technology supplied by the company to acquire work. And without these drivers, these ridesharing platforms could not function. This was the rationale of a recent ruling by the California Labor Commission, which ruled that an Uber driver was a traditional employee and thus should be compensated as such.[17]

Still, on the other hand, most ridesharing drivers do not consider themselves employees. They have no boss, no coworkers, and they set their own hours. A recent survey found that the majority of drivers on these ridesharing platforms consider themselves to be independent contractors.[18] This question will not be easily—or quickly—resolved.

Panel: Innovation in Health Care

Another area where a new regulatory approach is urgently needed is health care. Health care is one of the largest sectors and also the most regulated, with a myriad of rules covering everything from approval of new drugs and devices, patient privacy, payments for care, and quality of care.

For these reasons, the conference included a panel on regulatory reform in health care with Dr. Joseph Gulfo, Executive Director of the Rothman Institute of Innovation and Entrepreneurship at Fairleigh Dickinson University and former CEO of Mela Sciences, Robert Graboyes of the Mercatus Center at George Mason University, Dr. Toby Bloom of the NY Genome Center, and Gregory Daniel of the Brookings Institution. Michael Mandel of PPI moderated the discussion.

Health care is one of the largest sectors and also the most regulated, with a myriad of rules covering everything from approval of new drugs and devices, patient privacy, payments for care, and quality of care.

The panel began with a discussion of the current leadership and regulatory mindset at the FDA. Joseph Gulfo questioned their current approach to industry oversight, and challenged their status quo policies. This included examining the authenticity of touted improvements in FDA's drug approval process, which he argued was disingenuous because of its pre-approval criteria and narrow focus.

Gulfo advocated for the FDA to consider other metrics in their rulemaking, such as an "innovation impact index." If, in evaluation of potential rules, it doesn't result in a score above a certain threshold, the rule should not proceed. He also maintained that Congress should have the ability to overturn rules that harm innovation.

Robert Graboyes explained that although we live in a data-driven world, defined by technology and endless promise for societal improvements, health care rulemaking is still based in the 20th Century. Instead of encouraging innovation, health care regulation has become a relic of an old economic model that hinders innovation.

Policymakers must re-evaluate the goal of health care regulation, and how we can achieve that goal while enabling innovation. That may well mean shifting to an approach that focuses on outcomes over prescriptive rulemaking.

Few areas of health care have a more complex regulatory maze than bioscience. Toby Bloom highlighted how genomic research in particular has been dramatically affected by regulatory inconsistencies and confusion surrounding patient data privacy rules and the ability to collect DNA samples. This almost certainly impacts the relatively low return on investment to date from biomedical R&D.

The ability to collect and share health care data cannot be understated as a driver of the pace of innovation in health care. As Gregory Daniel explained, data sharing affects each part of health care design and delivery. On the front-end, we need better collection and availability of data inputs used for approval of medications and devices, including both clinical trials and real-world observations. And on the back-end of treatment, we need more comprehensive data on patient outcomes.

Without better data on outcomes, it is almost impossible to know if we are getting a good return on investment for R&D. Moreover, we are failing to adequately inform the regulatory process by limiting access to potentially valuable information. In this regard, Brookings, in partnership with the FDA and private health care insurers, is developing a massive database on medical devices designed for this purpose. This public-private partnership, called the "National Medical Device Postmarket Surveillance System," is a seven-year project that is just in the beginning stages.[19]

Commentary

Health care is an area where the interactions between innovation, data and rulemaking are pervasive. One example is the FDA's approach to pharmaceutical communications. Instead of encouraging pharmaceutical and medical device companies to harness the power of the Internet and social media, recent guidelines attempt to stifle ability to share valuable information.[20]

From a broader perspective, the private and public sectors have poured $1 trillion into biosciences research over the past decade. Yet the return on investment has been disappointing at best. There has been relatively little advancement in the design and delivery of health care, or in bringing down health care costs.[21]

One issue is whether regulatory obstacles may play a larger part on the limited returns to medical research than we realize. Panelist Toby Bloom raised the issue of regulations are making it difficult to use already existing data for genomics research. Genomics is the sequencing and analysis of DNA to determine causes and risk factors associated with disease, such as diabetes and Alzheimer's. Genomics research is data-intensive, often requiring hundreds of thousands of DNA samples from different individuals in order to conduct a single research study. For that reason, researchers try to use samples already collected for previous studies or as part of clinical practice.

Unfortunately, long-standing regulations have hindered researchers' ability to collect and share samples. The rules governing DNA sample collection are largely determined by a section in the Code of Federal Regulations known as "Protection of Human Research Subjects."[22] These rules apply to federally-funded research and nearly all genomic research is at least partially federally-funded and therefore held to these standards.

The rules require that a patient's sample must be part of a specific formal research study as approved by the governing Institutional Review Board (IRB) in order to be used. Moreover, the rules require each patient provide "informed consent." That is, unless the patient specifically consented to having their DNA used for that particular study, or that particular disease, the sample cannot be used, even if the patient gave consent to use it for a different study. Until recently, IRBs usually did not permit informed consents to allow for wide access to the data, under the reasoning that a patient couldn't be truly informed if they did not know in advance in which studies their data would be used.

The requirement of informed consent means that patient samples collected for other conditions are unable to be used for genomic research. Many of these are cancer patients whose genomes could shed light on genetic variants for other diseases. Given the number of samples that are collected as part of everyday hospitalizations, the untapped potential of these samples for research is tremendous. Yet because the patient was never asked for consent for future studies if their sample could be used—that data is unavailable.

Our current regulatory system is simply not equipped to deal with 21st Century dynamism. It is largely a relic of the last century, set up for the industrial age instead of the digital age.

And attempting to recapture patient consent is not viable, as many times patients are hard to track down, or could already be deceased. While deceased patients are not officially considered human subjects, genomic data is still often withheld, for up to 50 years, due to concerns about privacy of descendants. Yet the scope of that risk has not been assessed, nor have the benefits of making that data available been taken into account.

Genomic researchers are working within this limitation. They are moving forward, starting with new patient samples collected. At the New York Genome Center, the IRB approved a new study for the collection and sequencing of 1 billion willing people, healthy or sick, who volunteer to share their DNA. Amazon and Google are both working on a genomics data cloud to collect as many samples as possible.[23]

A new rule from the National Institutes of Health allows researchers to get a "broad consent" from patients to use their data across multiple future studies, which is helpful.[24] However, millions of existing samples remain unusable. Nor does it address the further limitations on data collection and sharing imposed by state laws.

In the case of genomic research, the answer may well be that improving—not removing—regulations could address the biggest barriers in genomic research. That gives regulators at Health and Human Services a unique opportunity to modify existing rules for genomic research, in a way that would provide a boost to research outcomes and finally generate higher returns on investment.

Post-conference Conclusions

Regulation provides a necessary foundation for economic growth and consumer well-being. Workers need protection from dangerous workplaces. Consumers need protection from unsafe products and services. And without environmental rules in place for uncontrolled pollution, our overall health and welfare would significantly deteriorate.

However, our current regulatory system is simply not equipped to deal with 21st Century dynamism. It is largely a relic of the last century, set up for the industrial age instead of the digital age. On the one hand, innovative industries struggle under antiquated rules. On the other hand, regulators need the ability to take advantage of technology in order to monitor outcomes more efficiently and with more flexibility.

The Volkswagen emissions scandal arose, in part, because regulators imposed a tight standard on nitrous oxide emissions from diesels, but simultaneously disallowed the systematic testing of vehicles under different driving conditions. That was due to resource constraints.

However, there were alternative and cheaper ways to collect better data using new technology that would have made this kind of cheating impossible—for example, using remote sensing equipment on roads that is capable of reading both the emissions of a vehicle as it passes as well as the make and model. As Farhad Manjoo wrote in the New York Times,

> … the lesson is that there isn't enough tech in vehicles. In fact, the faster we upgrade our roads and autos with better capabilities to detect and analyze what's going on in the transportation system, the better we'll be able to find hackers, cheaters and others looking to create havoc on the highways.[25]

As a result, the regulators at the EPA and the comparable agencies in Europe need to embrace technology in order to improve outcomes while reducing costs to both the agency and to the companies.

In health care, the same question looms—should regulators such as the FDA take advantage of the power of data to encourage innovation while improving outcomes for patients and lowering costs for health care providers? Will we open health care up to the disruptive innovation that's happening in other sectors, or impose increasingly restrictive rules? Ultimately, to encourage innovation in health care, regulators must face the reality of a data-driven world.

It is important to protect patient privacy, but not at the expense of enabling potentially life-saving research from pools of observational data. We must ensure truthful and non-misleading communication, but we should not be blind to the

reality that patients already go online for self-diagnosis and medication, getting information from unofficial sources.

And perhaps most importantly, the FDA's approval process for new drugs and medical devices must be modernized. Safety is essential, of course. But the way that the FDA applies the efficacy standard in approving new drugs and devices systematically screens out disruptive innovations. The requirement to prove before approval that an innovation is better than existing treatments is too strong—if it had been applied to the tech industry, it would have blocked both the early mobile phones (much worse sound than landlines) and the original personal computer (far less powerful than the existing mini-computers and mainframes).

Our solution to this is two-fold. First, once safety is assured and there are studies that indicate potential benefits, we propose to allow companies to tentatively introduce new drugs or treatments in limited populations and use the growing power of electronic health records to assess the actual benefits in real populations. Second, at the same time, we propose to allow companies to collect data on the economic efficacy of their product—that is, whether they boost medical productivity by reducing the number of worker-hours required to attain the same result.

Of course, the danger of giving more data tools to regulators is that they will be used to micro-manage the private sector. That's why the concepts of regulatory humility and permissionless innovation are so important.

Endnotes

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About the Author

Dr. Michael Mandel is chief economic strategist at the Progressive Policy Institute and a Senior Fellow at the Mack Institute for Innovation Management at the Wharton School at the University of Pennsylvania.

About the Progressive Policy Institute

The Progressive Policy Institute (PPI) is an independent research institution that seeks to define and promote a new progressive politics in the 21st century.

Appendix

CONFERENCE AGENDA

Innovation in a Rules-Bound World: How Regulatory Improvement Can Spur Growth
March 2, 2015
9:30 a.m.—2:30 p.m.
The Reserve Officer Association Building
One Constitution Avenue, NE - Washington

Opening Keynotes: The Policy Framework

Keynote: FTC Commissioner Maureen Ohlhausen
Keynote: Sen. Angus King (I-Maine)

Panel 1: The Political Framework

Panelists:
Rep. Kyrsten Sinema (D-Ariz.)
Rep. Ted Yoho (R-Fla.)
Moderator: Will Marshall, Progressive Policy Institute

Panel 2: Regulatory Accumulation and Entrepreneurship

Is the growing accumulation of regulations over time holding back business startups? And how can the regulatory system be improved to encourage entrepreneurship?

Panelists:
Michael Mandel, Progressive Policy Institute
Adam Thierer, Mercatus Center
Cary Coglianese, University of Pennsylvania

Panel 3: Encouraging Innovation in Health Care

Together the private and public sector spend roughly $100 billion per year on biosciences R&D. Yet despite enormous scientific progress in recent years, we've seen relatively few technological breakthroughs in biosciences run the regulatory gauntlet and make it to market. This panel will discuss whether regulatory processes at the FDA and CMS can be improved in a way that maintains the highest standards of safety while encouraging disruptive innovations that improve or maintain patient outcomes and reduce costs.

Panelists:
Joseph Gulfo, Former CEO, Mela Sciences
Robert Graboyes, Mercatus Center
Toby Bloom, New York Genome Center
Gregory Daniel, Brookings
Moderator: Michael Mandel, Progressive Policy Institute

*Reflecting actual order of speakers.