

Hacking the Regulatory State

BY MICHAEL MANDEL

TO LIFT LONG-TERM GROWTH LEVELS, POLICYMAKERS IN DEVELOPED countries must consider making systematic changes in the “operating code” of regulatory institutions in order to encourage innovation and disruptive innovation in particular. Advocating deregulation *per se* is rarely the right answer, because consumers and workers rightfully see regulation as essential protection against profit-focused businesses. Voters widely support social goals such as clean water and air, and even businesses would not want to see government abandon the market to the law of tooth and nail.

Yet even the most regulation-minded can see how the accumulation of well-intentioned rules can have a pervasive and negative effect on innovation. One useful analogy is that of a small child idly tossing pebbles in a stream. One or two or even ten pebbles won't make an obvious difference in the flow of the stream. Yet, accumulating gradually over the years, thousands of pebbles can make an effective dam. Or to put it into technology terms, asking a software developer to add one more feature or requirement to a program may seem like a small and innocuous request. Yet enough such ‘minor’ requests turns a simple task into a bloated, ungainly, and bug-ridden piece of code that may be virtually unusable.

In this essay I'll suggest two ways to hack the regulatory state in order to encourage innovation and long-term growth. One proposal, setting up a “Regulatory Improvement Commission,” was originally described in a 2011 report from the Progressive Policy Institute (Mandel, 2011). It has gained some traction since then, including being introduced as bipartisan legislation in both the Senate and House. My second suggestion is to broaden the approval criteria used by Food and Drug Administration (FDA) for new drugs and devices, as a way of encouraging disruptive innovations in biosciences.

Before describing these proposals, I note that hacking the regulatory state can be a bipartisan activity. The goal is not to make massive changes in the level of regulation, but rather to introduce fixes that make it work better.

1. The Regulatory Improvement Commission

The United States has a well-specified process for passing legislation and turning it into rules, complete with flow charts (see, for example, [this](#)). But if you ask about a similar flow chart for undoing or fixing regulations, you'll get a blank stare.

True, every president from Jimmy Carter to Barack Obama has tried to institutionalize the process of “retrospective review,” where executive agencies look back at their own past rules and identify which ones are out-of-date or need to be changed. (Barack Obama's executive order on retrospective review can be found [here](#)).

But retrospective review has always been ineffective, for a variety of reasons. I'll just name two here. First, rules are often the response to Congressional mandates, which executive agencies cannot evade. Second, the process of undoing an existing rule requires going through the same extensive process of taking public comments and cost-benefit studies that the original rule required. Paradoxically, cost-benefit studies on an existing rule are very expensive, because they require collecting actual data on the effect of the rule from companies.

That's why we need to hack the regulatory state, and set up a separate low-cost, non-bureaucratic back channel for undoing or fixing regulations. The Regulatory Improvement Commission (RIC) would be authorized by Congress for a fixed length of time, and consist of a panel appointed by the President and by Congressional leaders of both parties. The RIC would have a limited period of time to come up with a package of regulations to be eliminated or fixed, drawing on public suggestions. The package would then be sent to Congress for an up-or-down vote, and then onto the President for signing. (For details see Mandel and Carew, 2013).

Two important properties of the RIC are important to note here. First, the RIC does not purport to be objective and politics-free, like cost-benefit supposedly is. Rather, the RIC embraces the idea that regulations are a joint creation of the executive and legislative branches, with politics deeply embedded.

However, the RIC is specifically designed to be neutral in terms of the changes it can propose for rules. Regulations can be eliminated, changed, or even strengthened if that's what is needed to create a package that can pass Congress and be signed by the President.

Currently a version of the RIC has been introduced in the Senate and House, with bipartisan sponsorship in both cases (S.1390, Regulatory Improvement Act of 2013, and H.R.4646, Regulatory Improvement Act of 2014). It has the virtue of embodying regulatory reform that can be embraced by both Democrats and Republicans, and conceivably be enacted even in today's hostile political climate.

2. Approval Criteria at the FDA

The FDA is one of the fastest growing agencies in the federal government. In 2000, the FDA employed 12 workers for every 1,000 in the pharmaceutical, biotech, and medical equipment industries. Now the FDA employs 18 workers for every 1000 private-sector pharmaceutical, biotech, and medtech workers.

Not surprisingly, the intensity of FDA regulation has also increased by 40 percent since 2000, according to a recent paper from the Progressive Policy Institute (Carew, 2014). That's based on a new measure of regulatory intensity that applies a semantic analysis of written rules, looking for such restrictive words as "shall" and "must" (Al-Ubaydli and McLaughlin, 2014).

The same period has also been notable for an extraordinary amount of public and private spending on biosciences R&D. In 2012, for example, U.S. industry, government, and academic institutions spent roughly \$100 billion on biosciences-related research and development, second only to the roughly \$125 billion invested in computer and information sciences-related R&D. In recent years biosciences R&D has averaged somewhere between one-third and one-quarter of total civilian R&D.

This R&D spending has propelled tremendous scientific advances over this stretch. Yet so far, too few of these scientific advances have been translated into usable innovation. This problem is well-accepted. NIH set up a new **National Center for Advancing Translational Science** in fiscal year 2012, specifically to "develop innovations to reduce, remove or bypass costly and time-consuming bottlenecks in the translational research pipeline in an effort to speed the delivery of new drugs, diagnostics and medical devices to patients."

I will argue here that accelerating commercial innovation in biosciences requires "recoding" the criteria by which the FDA approves new drugs and devices. In particular, the sole focus on "safety and efficacy" has the effect of almost guaranteeing that potential disruptive innovations are not approved. What's more, the pharmaceutical and device companies have a deep understanding of the FDA's approval process, and therefore they do not pursue such disruptive innovations. Similarly, venture capitalists shy away from funding innovations that are not approvable.

Here I'm using the disruptive innovation in the classic Clayton Christensen sense — a product or service that starts out with somewhat worse performance than what's on the market right now, but much better economic or other characteristics. So when mobile phones originally were being widely sold, the quality of calls was lower than using

wired handsets. Similarly, the early personal computers were far less powerful than mainframes or minis.

The problem is that the FDA interprets the “safety and efficacy” standard as meaning at least as safe and clinically efficacious as anything on the market currently. That immediately rules out an innovation that is safe, much cheaper, but not as efficacious as best medical practice. So if the FDA had been in charge of the phone or computer markets at the time, early mobile phones and personal computers would have not been approved for sale because they provided inferior quality to existing products.

As a result, the FDA approval criteria systematically screen out disruptive innovations. What’s more, the pharmaceutical and device companies, and even the venture capitalist supporting start-ups, are all too aware of the FDA’s decision-making process, and are therefore unwilling to fund potential disruptive innovations.

What’s the solution? First, don’t weaken the safety requirement at all. The FDA is a key guardian against harmful products.

Second, separate the efficacy requirement into two parts — clinical efficacy, and economic efficacy. Allow innovating companies to present evidence that their potential new product reduces the amount of labor and other resources needed by the healthcare system, as compared to existing products or treatments. A new product needs to show both clinical efficacy and economic efficacy, but needs to be superior to existing products on just one of those measures.

Such a broadening of the FDA approval criteria won’t be easy to put into place, but could have enormous impacts on the incentives for research and development. If we want medical innovation *and* lower costs, we need to change the rules of the game.

References

Omar Al-Ubaydli and Patrick A. McLaughlin, “**RegData: A Numerical Database on Industry-Specific Regulations for All U.S. Industries and Federal Regulations, 1997–2012**,” George Mason University Mercatus Center Working Paper No. 12–20, August 2014.

Diana Carew, “**FDA Regulation in the Data-Driven Economy**,” Progressive Policy Institute, October 2014

Michael Mandel, “**How the FDA Impedes Innovation**,” Progressive Policy Institute, June 2011.

Michael Mandel, “**Reviving Jobs and Innovation: A Progressive Approach to Improving Regulation**” Progressive Policy Institute, February 2011.

Michael Mandel and Diana Carew, “**Regulatory Improvement Commission: A Politically Viable Approach to US Regulatory Reform**,” Progressive Policy Institute, May 2013

*The opinions expressed here are solely those of the author and do not necessarily reflect the views of the Cato Institute. This essay was prepared as part of a special Cato online forum on **reviving economic growth**.*

MICHAEL MANDEL

Michael Mandel is chief economic strategist at the Progressive Policy Institute.