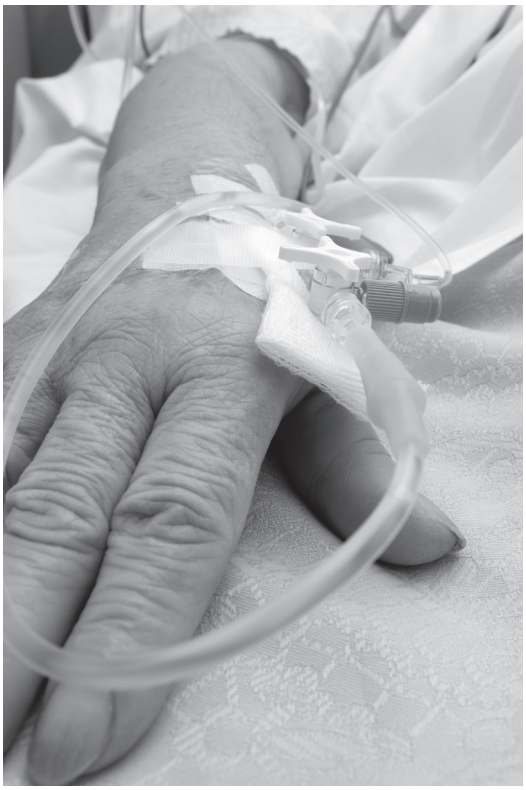
BRIEFLY NOTED

Is State 'Right to Try' Legislation Misguided Policy?

BY THOMAS A. HEMPHILL

Last May, Gov. John Hickenlooper (D) signed into law the "Right to Try Act" (Colorado House Bill 14-1281), making Colorado the first state to give terminally ill patients access to drugs that have not been approved for patient use by the U.S. Food and Drug Administration. A month later, Gov. Bobby Jindal (R) signed similar legislation in Louisiana. Another month later, Gov. Jay Nixon (D) signed a "Right to Try" bill in Missouri. In November, Arizona voters will consider a ballot initiative that would likewise give terminally ill patients access to non-FDA-approved investigational drugs. The Goldwater Institute, a libertarian-leaning nonprofit organization, has drafted model right-to-try legislation and purportedly has met with lawmakers in Florida, Massachusetts, Michigan, Oklahoma, Texas, and Utah who are interested in introducing such bills in their legislatures.



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Federal access / For compassionate, humanitarian reasons alone, who would not support granting access to potentially life-saving drugs to hundreds of thousands of terminally ill patients? On the face of it, virtually no one. Yet, at the federal level, efforts to pass similar legislation have met with little success. Rep. Diane Watson (D-Calif.) most recently introduced H.R. 4732 ("Compassionate Access Act of 2010") in the 111th Congress, only to see it flounder in the House Subcommittee on Health.

There are some existing federal regulatory options available for the terminally ill who want to try potentially life-saving, non-FDA-approved drugs. The FDA administratively allows expanded or "compassionate" use (on a case-by-case basis) of an investigational drug ("one not having been approved by the FDA as safe and effective") that has cleared Phase I trials (involving early human testing with small pools of test subjects, usually 20–80 volunteers). The drugs can only be used to treat a patient with a serious or immediately life-threatening disease or condition provided that the patient has no comparable or satisfactory alternative treatment option.

If the patient is to take advantage of this allowance, the drug manufacturer and the patient's doctor must make special arrangements to obtain the drug for the patient. As noted by the FDA, not all physicians are willing to manage the use of an investigational drug for patients in their care, nor are companies required to make their drug available through expanded access, or to manufacture a drug for "expanded use." Moreover, while some pharmaceutical companies provide the drug at no cost to the patient, others will charge costs associated with the drug's manufacture, and there can be additional expenses associated with administration and monitoring of the drug by health care professionals.

In the years 2010–2012, the FDA received between 950 and 1,200 annual requests through the expanded access programs to use non-approved drugs. The agency granted nearly all of those requests.

State action / For supporters of right-to-try, when their *federal* political lobbying strategy met resistance, they moved to a *state* political strategy. So what does the passage of state-level right-to-try legislation change for terminally ill patients? According to the Goldwater Institute (Policy Report no. 266, February 11, 2014):

> For patients suffering from terminal illnesses, the FDA is the arbiter of life and death. These patients, suffering from diseases ranging from ALS to Zellweger Syndrome, face little chance of recovery. ... [I]nvestigational medicines provide a glimmer of hope. The FDA, however, often stands between the patients and the treatments that may alleviate their symptoms or provide a cure. To access these treatments, patients must either go through a lengthy FDA exemption process or wait for the treatments to receive FDA approval, which can take a decade or more and cost hundreds of millions of dollars. Sadly, over a half a million cancer patients and thousands

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of patients with other terminal illnesses die each year as the bureaucratic wheels at the FDA slowly turn.

Ostensibly, the purpose of right-to-try legislation is to eliminate the bureaucratic federal process that hinders time-sensitive access to potentially life-saving drugs for terminally ill patients. Yet this administrative barrier is not necessarily removed by the passage of state legislation. Under the Interstate Commerce Clause of the U.S. Constitution, the FDA would be able to strongly (and convincingly) argue that state governments were in violation of this fundamental clause, thus striking down the state statute's authority. There is recent legal precedent for this argument. On August 7, 2007, in *Abigail Alliance v. von Eschenbach*, the U.S. Court of Appeals for the District of Columbia ruled in an 8–2 decision against the Abigail Alliance for Better Access to Developmental Drugs, reversing a 2006 Court of Appeals ruling and upholding a previous court decision that found no constitutional right to unapproved drugs by terminally ill patients. In early 2008, the U.S. Supreme Court declined to hear an appeal of the 2007 decision.

The Pharmaceutical Research and Manufacturers of America, the industry's trade group, has not been supportive of state efforts to usurp federal regulation of drug development protocols, arguing that the group has "serious concerns with any approach to provide patient access to investigational medicines that seeks to bypass the oversight of the [FDA] and clinical trial process, which is not in the best interests of patients and public health." Under the FDA's "expanded use" program, pharmaceutical companies have expressed concern that the agency would order additional testing of a drug candidate if unusual side effects are observed outside of trials. There is also industry concern about patients suing companies when such experimental drugs are proven unsafe. The variation in state laws may not adequately shield companies from tortuous action, even if companies require patients to waive their rights to sue. In spite of these regulatory concerns, some pharmaceutical companies have been willing to provide non-FDA-approved drugs outside of trials to patients under expanded access protocols.

Limits of state action / With state-level right-to-try legislation eliminating the need for the FDA approval process, will this encourage pharmaceutical companies to expand access to their experimental drugs? Not likely. When the "floodgates" open with no FDA "gatekeeper" available to manage patient requests, this will create an untenable ethical and operational dilemma for many research-based pharmaceutical and biotechnology companies.

State right-to-try legislation is a public policy attempt to help people who are desperately in need of help. Unfortunately, the legislation does not require that pharmaceutical manufacturers provide their investigational drugs to terminally ill patients, nor are physicians required to manage such an investigational drug protocol for their patients. Moreover, health care insurers (private or public) are not required to pay for the costs of such investigational drug applications for their terminally ill patients. While the FDA has not publicly addressed the issue of enactment of state right-to-try legislation, the recent wage of state actions could provide the stimulus for an FDA legal challenge at the federal level.

So, effectively, little has changed for terminally ill patients. What the state legislative efforts may accomplish is to reenergize this issue with the American public. Ultimately, the goal of "Right to Try" supporters is to secure the passage of similar legislation at the federal level and influence the pharmaceutical industry, the FDA, physicians, and health care insurers to cooperatively develop a workable, timely solution for their terminally ill family members and friends. It is unclear whether the state efforts will achieve that goal, regardless of noble intentions. *R*

The Highs and Lows in OIRA's Report to Congress

BY SAM BATKINS AND IKE BRANNON

As part of a Friday evening "document dump" last May, the Obama administration's Office of Information and Regulatory Affairs (OIRA) released its annual report on the "Benefits and Costs of Federal Regulation."

It confirmed that Fiscal Year 2012 was the costliest year ever for federal regulation, which can be credited in part to finalized major rules on vehicle fuel efficiency and coal-fired power plant emissions. In contrast, FY 2013, which is the main subject of the 2014 report, imposed the lightest burden of any year during the Obama administration and was one of the least active years of the past decade. The 2014 report estimates roughly $2.3 billion (in 2001 dollars) in annualized costs from regulation in 2013. But it derives that estimate by examining just seven rules that were finalized that year. If the report had examined all of that year's rules, the cost figure would be around $7.2 billion, or roughly three times the "official" figure.

Politics and regulation / Figure 1 shows the estimated cost of federal regulation for each fiscal year from 2002 to 2013, including the remarkable drop from 2012 to 2013. Why did that drop occur? Politics

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may have been at play. According to media reports, political influences likely delayed several notable regulations in 2013, including a rule to reduce the sulfur content in gasoline (part of the "Tier 3" vehicle emissions standards). The first quarter of FY 2013 occurred during the election season in 2012, so there may have been an impetus to delay a few controversial rules. For example, had the administration finalized the Tier 3 standards during FY 2013, it alone would have imposed $1.5 billion in annual burdens, raising that year's total to $3.4 billion (in 2001 dollars).

Yet another caveat on the low cost for FY 2013: all of the White House figures are in 2001 dollars. For example, the $19.5 billion in annualized costs for 2012 is actually $25.7 billion in today's dollars. If we were to include the cost of all rules—and the economy would surely bear those burdens—the total federal imposition was $38.6 billion (in 2013 dollars). Thus, in addition to the $27 billion in new taxes for 2013, regulatory burdens added $38.6 billion in costs, for a total of $65 billion in government burdens on the economy. However, as with most talk of regulation in public rhetoric, the "fiscal cliff" tax deal that was hammered out in late 2012 consumed all of the political oxygen, leaving historic regulatory costs largely unreported.

The $2 billion figure for FY 2013 might appear low. It does not represent all regulatory costs and benefits for the fiscal year, and even the administration acknowledges this reality. The report on regulation merely examines all major rules that monetize both costs and benefits that exceed $100 million annually. For example, an expensive Dodd-Frank rule or a health care regulation that lacks benefit data will not be tallied in the annual figures. Among the notable rules omitted from the official results in the recent report:

- ACA standards for Medicaid, the Children's Health Insurance Program, and insurance exchanges: $1.3 billion in annualized costs
- Dodd Frank regulation on swaps between affiliated entities: $650 million
- Affirmative Action guidelines for federal contractors: $395 million

With just seven major rules with monetized costs and benefits, the 2014 report contains the fewest number of rules since the 2006 edition, which examined six. The previous low for the Obama administration was 12 rules from the 2011 report. Table 1 lists the seven rules that OIRA highlighted in the 2014 report (costs and benefits in 2001 dollars).

FIGURE 1
ANNUALIZED COSTS OF MAJOR FINAL RULES
Rules issued by fiscal year

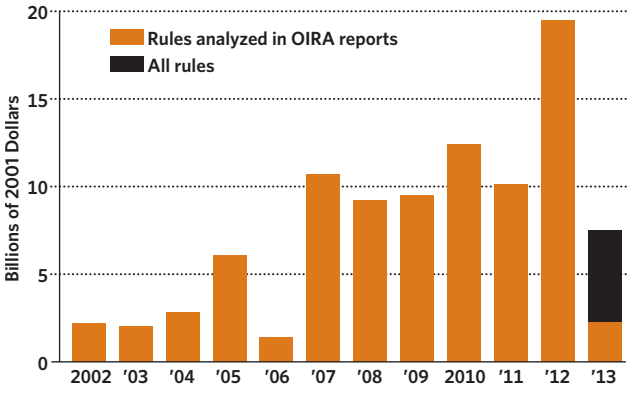

TABLE 1
COSTS AND BENEFITS OF FY 2013 FINAL MAJOR RULES
Rules examined in OIRA report

Regulation	Costs (in millions)	Benefits (in millions)
Boiler MACT	$1,336	$20,887
Air Standards for Combustion Engines	$400	$1,057
Standards for Particulate Matter (Soot)	$286	$6,702
Efficiency Standards for Transformers	$212	$1,049
Pilot Certification Requirements	$101	$19
Efficiency Standards for Microwaves	$46	$283
Gluten-Free Labeling of Foods	$5	$86

For comparison on scale, the U.S. Environmental Protection Agency's new regulation on existing power plants under Section 111(d) of the Clean Air Act could impose approximately $8.8 billion in costs annually. Regardless of the overall magnitude of costs, OIRA's tally is still a small fraction of total federal rulemaking, but the administration claims the report captures a "vast majority" of costs and benefits. For benefits, this may be true because few rules monetize benefits, but for costs the reported total will be just a slice of the total burden.

We examined every final rule published in FY 2013 and found $9.1 billion in annualized costs ($7.2 billion in 2001 dollars) and $40 billion in annualized benefits ($33.5 billion in 2001 dollars). Thus, OIRA underreports costs by more than 300 percent compared to a benefit figure approximately 10 percent of the actual total. Although OIRA will report benefits that are the majority of the published figure, the report's methodology will exclude billions of dollars in costs.

Future reports / In response to public comments, the OIRA report did undertake several reforms. Notably, the administration is now reporting figures "in both 2010 and 2001 dollars, in order to provide estimates that are closer to current year dollars." It made little sense for an agency to report costs and benefits in 2010 dollars, only to have OIRA convert to 2001 dollars and then to have the public adjust to current-year dollars to make sense of the data. For example, the $19.5 billion record cost figure from FY 2012 is now reported as $23.6 billion.

In addition, criticism from the Mercatus Center and the George Washington University Regulatory Studies Center about comparing the regulatory performance of different administrations prompted OIRA to assure

readers that future reports will no longer contain this politicized data. As OIRA concedes, "[C]omparisons of prospective analyses across time become more difficult as rulemakings are modified or remanded due to court rulings ... or simply don't have the impacts projected before the rule was issued." Critics charged that such comparisons reeked of politics.

Conclusion / The final figures in any year depend on the pace of new rulemakings. That pace has been very aggressive so far in 2014, but the administration may become averse to releasing controversial rules as this fall's election nears. Whatever the speed of new rulemaking, total burdens from the past two years have eclipsed $47 billion in today's dollars ($38.6 billion from FY 2012 and $9.1 billion from FY 2013). Recent totals might have been low, but that was likely an aberration based on a political calculus rather than a genuine attempt to reduce regulatory growth. R

Protectionism by Any Other Name

BY PIERRE LEMIEUX

Last June 3rd, the U.S. government threatened to impose "temporary" tariffs of 19–35 percent on Chinese solar panels and their component cells. Barely a month later, on July 14th, the World Trade Organization (WTO) issued a ruling in a dispute between the Chinese and U.S. governments that seemed to destroy the legal basis on which earlier U.S. solar panel tariffs had been imposed in 2012. The U.S. Department of Commerce then announced a new set of "temporary" tariffs on July 25th. Permanent tariffs may have been imposed by the time this article is published.

The legal procedures and political tussling over Chinese-made solar components will continue for a few years, and it is not clear what the outcome will be. In any event, the case provides a good illustration of protectionism and of some important points in political and economic analysis.

One of those points is that the cost of global warming, even in the worst case, is not infinite and so, in the view of the Obama administration, tradeoffs can be made. In this case, the tradeoff is between rising temperatures (assuming global warming is anthropogenic) and rough times for a few dozen solar manufacturers in America. In moving to forestall those rough times, the U.S. government effectively admits the existence of a tradeoff and chooses more global warming. The European Union did the same in 2013, even though it laboriously tried to spin the news so as to deny a tradeoff existed.

Refusing gifts / The official argument on behalf of the tariffs is that domestic producers of solar panels and components are harmed by unfair competition from Chinese competitors subsidized by their government. But why should those subsidies matter? Why would American consumers balk at having their consumption subsidized by foreign taxpayers while they love to have it subsidized by American taxpayers? Think of transportation, education, or even the whole field of science and technology. Some estimates put the proportion of applied research financed by various levels of American government at 40 percent. Renewable energies are subsidized. Solar development itself has been subsidized by American governments, although arguably less (or less directly) than the Chinese government subsidizes its manufacturers. In 2012, U.S. solar manufacturers Solyndra and Abound went bust, costing American taxpayers hundreds of millions of dollars in loan guarantees.

In short, Americans should be delighted that hapless Chinese taxpayers pay part of Americans' solar panel costs. And the Earth should be smiling, too.

Who will benefit from this latest round of tariff protection? Answer: American producers of solar panels and components. A tariff duty generally increases by its full amount not only the price of the imported good, but also the price of its domestically produced equivalent because domestic producers will take advantage of the higher price and produce more of the good at a higher marginal cost. And submarginal producers, who were incapable of earning a profit at the lower price, enter the industry (or do not leave it).

There are two cases when a domestic price may not rise by the full amount of a tariff: The first case is when the tariff is so high that it allows domestic producers to satisfy all domestic demand, thereby killing imports; the tariff is then called prohibitive. The second case is when the country where the tariff is imposed provides a significant part of world demand, in which case the domestic price will only rise by a certain proportion of the tariff, this proportion depending on the importance of domestic demand in world demand. By last July 25th, according to an executive in the panel installation industry, the previous round of tariffs had caused a price increase of 15–20 percent.

Americans should be delighted that hapless Chinese taxpayers pay part of Americans' solar panel costs. And the Earth should be smiling, too.

Special interests / The lobby pushing for the tariff is led by SolarWorld, the manufacturer who officially complained to the

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U.S. Department of Commerce. SolarWorld, a German company who owns a solar panel factory in Oregon, is the largest solar producer in America. IBISWorld, a market research firm, counts another three dozen firms in the industry and less than 3,500 employees. We thus have a standard case of small and concentrated special interests exploiting more important but diffuse interests, namely consumers and industrial users of solar panels.

It is a standard demonstration in the theory of international trade that a tariff nearly always costs consumers more than what producers and taxpayers gain. (Taxpayers indirectly gain the duties paid by importers of the tariffed goods.) And the "nearly always" becomes "always" if the welfare of all consumers and producers in the world is factored in—that is, if it is not assumed that the welfare of an American counts more than the welfare of a foreigner. A tariff results in a net domestic cost because it artificially pushes up the price of the protected good, reduces its consumption (and the consumer surplus), and incites domestic firms to produce something that would be less costly to import.

It is not clear if a tariff on solar panels and components generates more jobs among the protected manufacturers than are lost among solar panel installers. But that tradeoff does not matter; what is important is not employment, but consumer welfare. Lots of jobs could be created by banning technology—say, banning chainsaws. The ensuing "artificial" jobs would, however, be wasteful because Americans would work more to obtain less. If Chinese taxpayers send us gifts, the scarce resources that are released can be used to produce other desired goods and services. So the jobs argument is not valid.

Another argument is that Americans would lose in terms of supply security if Chinese competition were to destroy the American solar industry. What would happen, this argument asks, if the Chinese government later banned these exports to America? But this argument fails, too. First, solar panels and components are manufactured in countries other than China. According to IBISWorld's estimates, 88 percent of domestic demand for these products is satisfied by imports, of which more than half come from elsewhere than China. Other estimates put the Chinese share of solar panels at only one-third of American installations. Second, assuming that all domestic producers disappeared, a domestic solar sector could be recreated if and when future conditions warrant it. New industrial sectors are regularly created (and destroyed): greedy investors put up the billions in necessary investment when they think it will be profitable.

What's wrong with dumping? / In international trade law, enforced by such organizations as the WTO, exporting something at a price below production cost is called "dumping" and is forbidden. Exports of Chinese solar panels and components are a clear case of dumping if they are made possible by government subsidies, which seems likely. Note that a profit-maximizing firm without subsidies will not "dump" products, except to get rid of temporary surpluses or as a loss-leader type of promotion. So the fear of dumping is greatly exaggerated. It can only persist through government subsidies, and foreign taxpayers will not maintain their largesse forever.

Governments try to argue that protection against dumping is not protectionism. The European Commission declared (rather pathetically):

> Trade defence measures are not protectionist measures. Nor are they illegal. On the contrary: they are the legal response to save an industry that is suffering from massive dumping from a third country. Trade defence measures aim at restoring a level playing field. There is no such thing as a right to cheap but dumped imports.

The Commission would be more persuasive if it argued that there is no such thing as a general right to cheap and subsidized goods. But it would then be sawing the branch on which it stands because subsidizing is the essence of today's governments. It is a pretty uncontroversial statement that Americans and Europeans have no *right* to receive subsidized goods from Chinese taxpayers (that is, no right to force

Chinese taxpayers to pay for Americans' and Europeans' imported goods), but why should somebody have the right to *forbid* American and European consumers from accepting China's offer? The problem lies on the givers' side, not the recipients'.

It is too easy to disguise protectionism under the dumping label and the "equal playing field" excuse. Nowadays, most goods are subsidized by government one way or another, and trying to make distinctions between direct and indirect subsidies requires some talent in casuistry. Except for free trade—the freedom of buyers and sellers to say yes or no—there is no nonarbitrary definition of an equal playing field.

Unilateral free trade / The solar panel case provides a good illustration of the argument for unilateral free trade. If a state prohibits its residents from importing or forces its taxpayers to subsidize exports, individuals in another country gain nothing by imposing similar constraints upon themselves. If your neighbor dumps rocks in his harbor, you gain nothing by dumping rocks in yours. The best policy, for sure, is multilateral free trade. But if this cannot be achieved, unilateral freedom of importation is the second best. And because one country's imports are ultimately paid for by its exports, other countries will only be able to export if they allow imports in.

Imports are what is important. In his 1848 *Principles of Political Economy*, John Stuart Mill explained it well:

> [T]he only direct advantage of foreign commerce consists in the imports. ... The vulgar theory [of protectionism] disregards this benefit, and deems the advantage of commerce to reside in the exports: as if not what a country obtains, but what it parts with, by its foreign trade, was supposed to constitute the gain to it. ... This notion is intelligible, when we consider that the authors and leaders of opinion on mercantile questions have always hitherto been the selling class. It is in truth a surviving relic of the Mercantile Theory.

Let's break off from the mercantilism of the selling class. American consumers should relax and enjoy the unrequested generosity and mercantilist mistakes of the Chinese state. The federal government should not interfere with this enjoyment, whatever the producers' lobbyists say. Moreover, a possibility exists that Chinese mercantilism would push American producers to new levels of efficiency, while tariff barriers will (if history is any guide) make them complacent, lazy, and crying for more protection.

Of course, as long as the government is able to grant privileges such as tariffs, treasure hunters will continue to swarm over the pot of consumers' money. The real solution would be to devise institutional means to prevent Leviathan from interfering with free trade. R

The IRS's War on *Locum Tenens*

BY IKE BRANNON

The most life-changing innovation to come along since my family moved to our urban neighborhood in Washington, D.C., a decade ago has been the appearance of Uber, the app that allows someone to easily hail a ride using a smartphone. Besides making my car-less life much easier, it represents a tangible economic gain to society by allowing cars to be used much more productively.

A similar, though low-tech, practice in the medical profession known as *locum tenens* increases people's access to doctors and helps tamp down health care costs. However, the Internal Revenue Service may effectively end *locum tenens*, claiming (though offering no evidence) that the practice could help doctors to cheat on their taxes.

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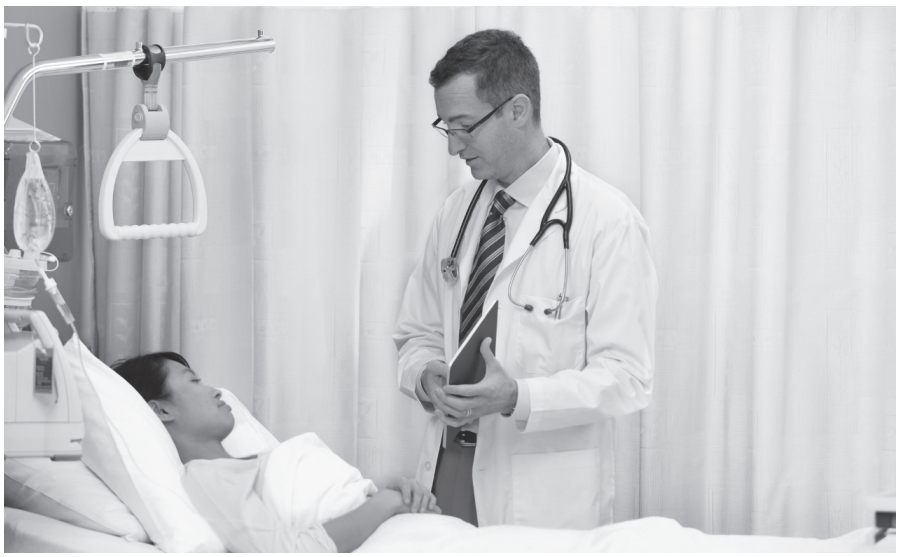
Temporary doctors / *Locum tenens* is a formal market for doctors employed on a temporary basis. While the vast majority of doctors employed by hospitals have a long-term contract, many medical offices find it necessary or convenient to also hire some doctors short-term, typically for a few weeks at a time. Hospitals use *locum tenens* to cover for doctors on vacation or to plug a hole between a resignation and a new hire. Sometimes it makes sense for hospitals experiencing a surge in demand to hire a series of doctors on short-term contracts



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rather than make a costly commitment to permanently add a new doctor to their staff. In rural, out-of-the-way markets, recruiting a full-time specialist can be quite difficult to pull off; bringing in someone for a week or two a month might be the only viable way to supply a necessary service.

On the supply side, it is easy to see why this model might be attractive for a semi-retired doctor. Rather than have a 40-hour-a-week job with regular on-call hours, a *locum tenens* could limit himself to working a week or two a month.

Tax evasion? / The problem is the IRS does not like how hospitals go about securing these doctors. Hospitals typically contact a *locum tenens* firm that has a stable of doctors on its roster and the company essentially acts as a middleman to place a doctor with a hospital. The hospital pays a fee to the *locum tenens* firm and treats the doctor as an independent contractor. The IRS claims that doctors acting as independent contractors may underreport the taxes they owe to the government, and wants to change the nature of the contract to make the doctors full-fledged employees of any hospital they work for.

However, the IRS has trouble explaining how this tax larceny might work. The hospitals still issue 1099s to their contractors. And hospitals are large information reporters, not small mom-and-pop firms that might bungle their accounting or be tempted to not report and abet tax fraud. Besides, what benefit would hospitals or *locum tenens* providers gain from misreporting? If hospitals cannot be trusted to issue 1099s, who can the government trust?

Nonetheless, the IRS wants to force hospitals to turn these short-term doctors into full-time employees for a short period of time. And the hospitals would incur a significant cost to do so. For starters, they must put the doctors on the hospital payroll, which may qualify the doctors for the hospitals' full panoply of employee benefits, including 401k, health insurance, and myriad and sundry other benefits that someone coming in for a handful of weeks likely would not use. Further, hospitals may have to include the doctors in the hospital's existing pay scale, instead of tailoring compensation to the preferences of the temporary fill-in. This convoluted stricture makes being a doctor on short-term employ much less attractive for many doctors seeking such positions. The transaction becomes much more burdensome and complicated, with the middleman *locum tenens* firm (and the benefit it supplies) essentially shoved aside.

If the government really thinks that tax evasion is a problem in this profession, there are easier ways to fix it besides eradicating an entire market.

Benefiting no one / If the government really thinks tax evasion is a problem in this profession, there are easier ways to fix it besides eradicating an entire market that developed organically. More audits or a closer scrutiny of hospitals that avail themselves of this practice would clearly be a more cost-effective way of dealing with this problem—if it really does exist.

But as it currently stands, demanding that doctors employed on a short-term basis no longer be independent contractors is a step away from a market solution that will result in fewer productive and engaged doctors bothering to seek out employment. That, in turn, will result in higher costs and less patient access to doctors.

Adopting a policy that harms public welfare in every aspect is a tough feat to pull off, but a government edict that effectively ends *locum tenens* earns that dubious distinction. It is the equivalent of the various states and municipalities that attempt to ban Uber from operating in their jurisdiction, something that is always ostensibly done "for the benefit of the consumer."

But those edicts are at least easy to comprehend, since banning Uber would help existing market participants. Ending *locum tenens* helps *no one*: not doctors, not patients, and definitely not the government, which would almost surely end up with less tax revenue as a result. *R*

Looking Back to Move Ahead

BY SOFIE E. MILLER

In July, the U.S. Department of Energy (DOE) announced that it is seeking public input on how to effectively review its existing regulations and reduce regulatory burdens, pursuant to Executive Order 13563. EO 13563, signed by President Obama in January 2011, instructs regulatory agencies to "consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned." This retrospective review is meant to ensure that regulations achieve their intended outcomes and to improve agencies' use of ex ante analysis by comparing projected outcomes with actual results. To that end, the DOE is seeking input on how best to promote periodic retrospective reviews of its rules and how to select the rules to review.

The DOE should take three steps to further its retrospective review efforts. First, it should incorporate plans for retrospective review into its economically significant or major rules. Second, it should allow enough time between releases of new energy efficiency standards to allow for a full review of each rule's effects before issuing updated rules. Third, it should use

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the Herfindahl-Hirschman Index (HHI) to measure whether its existing energy efficiency standards have had negative effects on competition in the regulated industries.

Retrospective review / As part of its ongoing Retrospective Review Comment Project, the George Washington University Regulatory Studies Center examines significant proposed regulations to assess whether agencies propose retrospective review as part of their regulations, and provides agencies with suggestions on how best to incorporate plans for retrospective review into their proposals. However, our research indicates that many agencies—including the DOE—are not currently complying with EO 13563 and OMB's direction to write and design rules "so as to facilitate retrospective analysis of their effects."

In his June 14, 2011 implementing memo on retrospective review, then-administrator of the Office of Information and Regulatory Affairs Cass Sunstein stated that "future regulations should be designed and written in ways that facilitate evaluation of their consequences and thus promote retrospective analyses and measurement of 'actual results.'" In its 2013 *Report to Congress on the Benefits and Costs of Federal Regulations*, the Office of Management and Budget states that such retrospective analysis can serve as an important corrective mechanism to the flaws of ex ante analyses. According to the report, the result of systematic retrospective review of regulations

> should be a greatly improved understanding of the accuracy of prospective analyses, as well as corrections to rules as a result of ex post evaluations.... [*I*]*mportantly, rules should be written and designed, in advance, so as to facilitate retrospective analysis of their effects.*

While each economically significant rule proposed by the DOE this year mentions EO 13563, none include a plan for retrospective review of its standards. The rules in question are all energy efficiency standards, and each has the potential to incur billions of dollars of costs and benefits. Because of the magnitude of these rules and the frequency with which the DOE updates the stringency of its energy efficiency standards, the DOE should write plans for retrospective review into the text of its rules, to facilitate transparency, public accountability, and measurement of the success of its rules.

Review of previous standards / The DOE should also review the efficacy of its existing energy efficiency standards before making a determination that further standards are necessary. This is particularly important because the DOE often promulgates updates to its standards before enough time has elapsed to adequately measure the effects of its previous rules.

The DOE tends to conduct detailed *ex ante* analyses of the costs and energy savings associated with its proposed rules, but these (necessarily) are heavily dependent on assumptions about future prices of energy and other goods, opportunity costs, and producer and consumer preferences and behavior. Retrospective review that compares predicted outcomes with actual outcomes is essential to test those assumptions and calibrate the DOE's models. This should be done before the DOE proposes new standards based on uncertain parameters.

For example, pursuant to the Energy Policy and Conservation Act (EPCA), the DOE regularly promulgates energy efficiency standards for residential and commercial appliances. The standards, which apply to microwave ovens, dishwashers, clothes dryers, air conditioners, and other home and commercial appliances that consume energy, affect a broad swath of the American public, businesses, and consumers alike. EPCA also requires the DOE to determine at intervals whether updates to its existing energy efficiency standards are "technically feasible and economically justified." However, on more than one occasion the DOE has determined that such updates are necessary very shortly after implementing its previous standards, without allowing time for a retrospective review of the standards' effectiveness. This does not allow the DOE to learn from implementation of past standards before implementing new rules.

The DOE should write plans for retrospective review into the text of its rules, to facilitate transparency and public accountability, and measure success.

Measuring anticompetitive effects /Pursuant to EPCA, the DOE is required to consider "the impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the imposition of the standard" before finalizing a new energy efficiency rule. This evaluation is conducted by the Antitrust Division within the Department of Justice (DOJ). While this prospective evaluation is finalized before the rule goes into effect, it is also important to measure anticompetitive effects after a standard is implemented to determine whether the standard is economically justified, as required by statute.

As part of reviewing its energy efficiency standards, the DOE should undertake to evaluate the effects of its standards on competition. The DOE should consider applying the HHI, which the DOJ uses to evaluate the anticompetitive effects of mergers, to measure concentration in regulated industries pre- and post-enforcement of the DOE's standards. The DOE should prioritize measurement of concentration within industries affected by standards that the DOJ has determined would have anticompetitive effects.

As it plans to retrospectively review each of its economically significant efficiency regulations, the DOE should commit to measuring any anticompetitive effects and to examining changes in the HHI upon implementation of its standards. Understanding the regulations' effects on market structure will be important to understanding whether the rules achieve their stated objectives and identifying the benefits and costs associated with implementation. This should inform the public about any unintended anticompetitive effects of the DOE's energy efficiency standards and improve the DOE's analysis of future standards.

Conclusion / By seeking input from the public on its retrospective review efforts, the DOE is taking a step in the right direction. Effectively implemented, retrospective review should improve regulatory outcomes and the DOE's ex ante analyses alike. Going forward, the DOE should incorporate plans for retrospective review into its major rules to facilitate transparency, public accountability, and measurement of the success of its rules.

Additionally, the DOE should review the efficacy of its existing energy efficiency standards before making a determination that further standards are necessary. After conducting the review, the DOE should incorporate any lessons learned or unintended consequences into its future standards, both to improve ex ante analysis and rulemaking outcomes. Finally, these retrospective reviews should include application of the HHI to measure any potentially anticompetitive effects, especially for energy efficiency standards that the DOJ has determined would have anticompetitive effects on the regulated industries. R

How to Slow a Diabetes Epidemic

BY PAUL H. RUBIN

When a drug is protected by patent, the manufacturer may spend a lot of money advertising and promoting the drug. Many authorities are opposed to this expenditure. For example, Marcia Angell, the former editor of the *New England Journal of Medicine*, wrote an entire book, *The Truth about the Drug Companies: How They Deceive Us and What to Do about It*, complaining about the behavior of major pharmaceutical companies, including their advertising and promotion expenditures.

However, when a drug is not covered by patent, there may also be harm to public welfare. Without a patent, the manufacturer will have little incentive to provide information to physicians or patients about the drug's benefits. As an example, consider the drug metformin, also called Glucophage, a major anti-diabetes medication.

Prevention / Metformin was invented in the 1920s, but not widely used until much later; it was only introduced in the United States in 1995. It is now the most widely prescribed anti-diabetic drug in the world. It is no longer covered by patent and generic versions are available at major drugstores for as little as $4 per month. Sometimes, it can even be had for free. Side effects for healthy individuals are minimal and there is some evidence that the drug reduces other health risks, including cancer.

The drug is commonly prescribed for treatment of Type 2 diabetes and is very effective. However, there is substantial evidence that it is also useful for *preventing* diabetes in people with somewhat elevated blood sugar (sometimes called "prediabetes"). The best evidence is that metformin alone can reduce diabetes risks by about one-third after three years of use. This effect persists for at least 10 years of use, although the magnitude is reduced over time. Major lifestyle changes, including significant weight loss, are more effective, but much more difficult and more expensive to achieve.

Why is the drug not used more broadly for prevention? The use of statins and aspirin, which help to prevent heart disease, indicates that significant numbers of people can be convinced to take a daily medication to prevent a future disease even in the absence of symptoms. But there are some important differences between the statin regimen for preventing heart disease and the metformin regimen for preventing diabetes. The most important difference is that during the period when statins were

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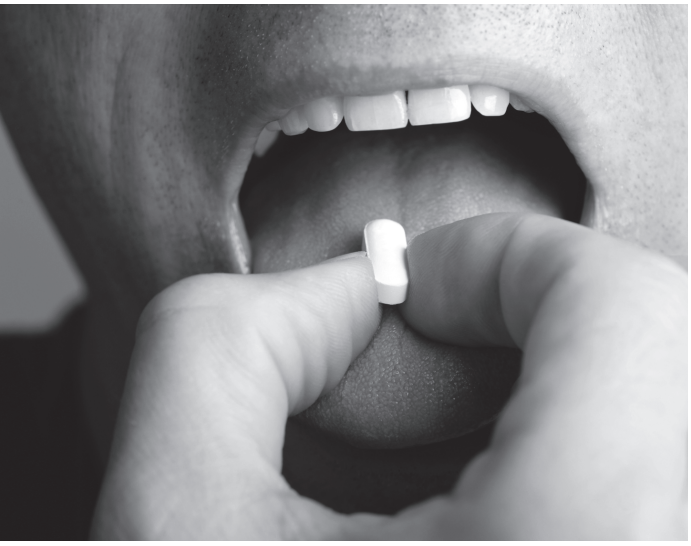

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becoming popular, they were protected by patents. This means that the drugs were much more expensive (although generally covered by insurance). It also means, however, that the pharmaceutical companies were willing to spend significant resources providing information about the drugs to physicians and patients through expenditures on promotion. Metformin is no longer covered by patent and is made by several generic producers, so there is relatively little money to be made from promoting it, so no one has much incentive to do so.

Because of the lack of promotion, many physicians may be unaware of the preventative uses of the drug. (Anecdotally, I have found this to be true. I have taken the drug for several years and whenever I see a new physician I must convince him or her that I am not a diabetic.) Moreover, many physicians are biased against drugs and prefer to recommend their patients simply follow a regimen of "diet and exercise," a proposal that is easy for doctors to prescribe but hard for patients to follow. Of course, diet and exercise is a sensible recommendation, especially since the same evidence that indicates metformin is useful also indicates that diet and exercise is more effective. However, if a physician observes that a patient is not getting any thinner and blood sugar remains elevated, metformin should be (but often is not) the alternative.

The U.S. Food and Drug Administration has approved metformin for diabetes treatment, but not prevention. Physicians are allowed to prescribe an approved medicine for any condition, so the lack of FDA approval does not mean the drug cannot be used for prevention. However, firms are not allowed to advertise or promote a medicine for an unapproved use. That lack of promotion means that physicians are significantly less likely to understand the benefits and prescribe the drug. Moreover, because the drug is not protected by patent, no one has the incentive to spend the resources needed to convince the FDA to approve the drug for prevention, even when—as in metformin's case—the evidence is solid.

Suggestions/ If you are a person with somewhat elevated blood sugar, ask your physician to prescribe metformin. If the doctor refuses, you may want to seek another physician. Use of this drug can increase length and quality of life, and is worth the bother of seeing another doctor.

If you are a doctor, consider prescribing metformin for your patients with elevated blood sugar, particularly if previous suggestions to lose weight and increase exercise have not worked. After the third or fourth unsuccessful admonition to lose weight, another approach is needed.

If they can find a way, FDA officials should seriously consider approving this drug as a diabetes preventative. Moreover, the drug is sufficiently beneficial and safe that it should be considered for over-the-counter sale. A public health campaign promoting the drug as a preventative could improve and lengthen many lives. It is sad that there is a significant remedy for a condition that is often described as an "epidemic" and yet our regulatory institutions are such that no one is making an effort to use it. *R*

Tight Budgets Constrain Some Regulatory Agencies, But Not All

BY SUSAN E. DUDLEY AND MELINDA WARREN

Regulations are an increasingly important aspect of modern American life, and yet measuring regulatory activity is challenging. The cooperative effort between the George Washington University Regulatory Studies Center and Washington University in St. Louis's Weidenbaum Center on the Economy, Government, and Public Policy to track the trends in federal regulatory agencies' expenditures helps monitor one component of the impact of regulation: the direct taxpayer costs associated with developing, administering, and enforcing federal rules and regulations. Each year we examine the President's Proposed Budget of the United States to identify the outlays and staffing devoted to developing and enforcing federal regulations. This "regulators' budget" report covers agencies whose regulations primarily affect private-sector activities and expressly excludes budget and staffing associated with regulations that govern taxation, entitlement, procurement, subsidy, and credit functions.

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Our most recent report examines the requested budget outlays in fiscal year 2015 as well as estimated outlays for FY 2014. It also provides 56 years of data on annual outlays and staffing, from FY 1960 to the present. Those data reflect the on-budget costs of regulation and cannot inform analysts about the benefits regulations may convey. They also do not reflect full costs, as regulations impose social costs beyond the direct tax dollars spent to write and enforce them. An assessment of the full cost would not only calculate businesses' and individuals' costs associated with compliance, but also the loss of economic opportunities and choices available to individuals and organizations.

Despite those limitations, the time-series data on expenditures and staffing of federal regulatory agencies presented in the regulators' budget report offer a useful proxy of the size and growth in regulations that American businesses, workers, and consumers must follow. This information can serve as a barometer of regulatory activity, providing policymakers and analysts with useful insights into the composition and evolution of regulation over time.

Overall, this year's report finds that the regulators' budget continues to grow at a modest pace. The proposed budget for regulatory activities in FY 2015 is $60.9 billion (in nominal dollars), a real (inflation-adjusted) increase of 3.5 percent above estimated FY 2014 outlays. (See Figure 1.) The FY 2014 regulators' budget of $57.8 billion is 2 percent larger than FY 2013 regulatory agencies' outlays of $55.9 billion. The proposed budget also requests an increase in federal regulatory agency personnel of 0.8 percent in FY 2015, following an estimated 2.0 percent increase in FY 2014. (See Figure 2.)

FIGURE 1

BUDGETARY COSTS OF FEDERAL REGULATION

Adjusted for Inflation

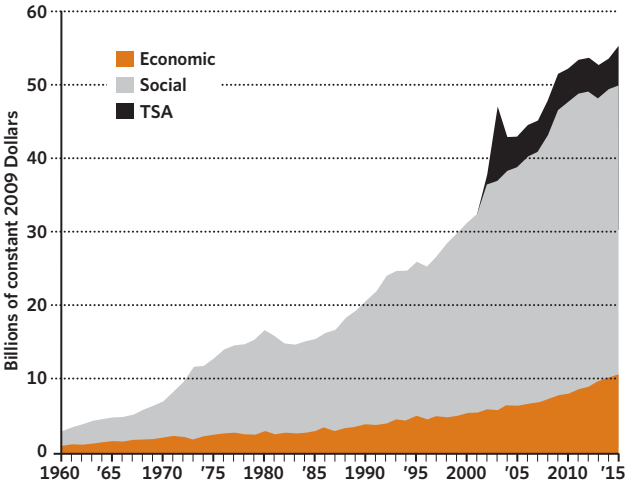
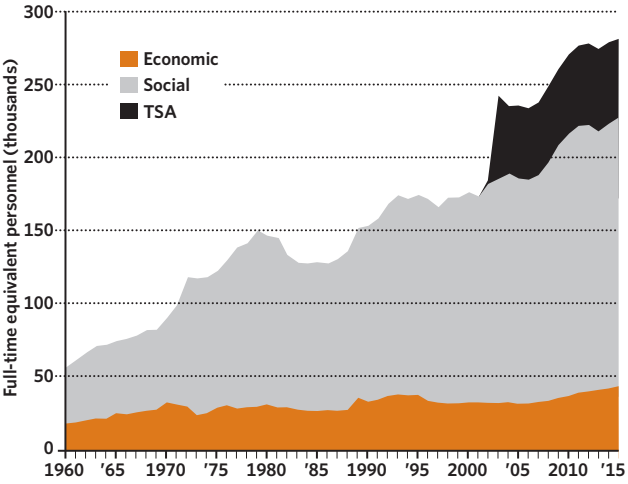


FIGURE 2

STAFFING OF FEDERAL REGULATORY AGENCIES

Full-time equivalent employees



SOURCE: Weidenbaum Center, Washington University in St. Louis, and the George Washington University Regulatory Studies Center. Derived from the Budget of the United States Government and related documents, various fiscal years.

One of the most interesting (though not surprising) findings of our analysis is that, while tight budgets are constraining regulatory spending at many federal agencies, those that are at least partially funded by fees on the entities they regulate are able to support substantial increases in regulatory outlays and staffing. For example, while the Environmental Protection Agency's outlays shrank by almost 4 percent in 2014, the Food and Drug Administration's budget grew by more than 29 percent. The Consumer Financial Protection Bureau's spending increased 33 percent in 2014 and outlays of both the Patent and Trademark Office and the Securities and Exchange Commission grew by more than 10 percent. The growth in spending and staffing at those agencies appears to reflect not only the increased scope of their regulatory activities, but a greater ability to finance those activities from revenue sources that are less affected by congressional spending limits.

This year's analysis also documents some interesting long-term shifts in regulatory spending patterns, including a trend in which overall outlays devoted to economic regulatory activities, including price, quality, and entry regulation, are increasing at a faster rate than those aimed at social regulatory activities such as environmental, safety, and health issues. This reverses a trend that began in the 1970s away from economic regulation of private-sector activities, and would likely be more dramatic if our data included agencies of the Department of Health and Human Services that pursue economic regulation of health insurance markets pursuant to the 2010 Patient Protection and Affordable Care Act. While the staffing and outlays devoted to these regulations do fit the criteria for inclusion in the regulators' budget report, the 2015 proposed budget did not allow us to distinguish between resources devoted to regulations that affect private-sector behavior (covered in the report) and those that affect entitlement spending (not included). This trend is worth watching because economic theory and empirical evidence suggest that the costs of economic types of regulation often outweigh the benefits. R

Regulating the Mobile App Market

BY LOGAN ALBRIGHT

The market for mobile apps on smartphones and other mobile devices has grown tremendously over the last few years. Indeed, it would be hard to find another sector that enjoys a similar level of creativity and innovation. Much of this vibrancy is driven by low barriers to entry and the fact that practically anyone with any level of programming savvy can try his or her hand at developing the next Angry Birds, with the hope of making millions.

Because of the highly decentralized and heterodox nature of this market, it is difficult to estimate its size. Various analyses have put it somewhere between $20.4 billion and $53 billion a year, with expectations that it will grow to between $63.5 billion and $143 billion by 2017.

That vibrancy has put apps under the scrutiny of state and federal regulators who worry about the effects of new technologies on the broader market. In many cases, the apps serve as a way of connecting users with services that have been around for a long time, but circumvent existing regulation of those services. Government agencies often see the apps as opening regulatory loopholes, and the agencies—often at the behest of incumbent firms that have long been bound by those regimes—are increasingly interested in finding ways to close them. Consider:

- In Virginia, the Department of Motor Vehicles recently issued a cease-and-desist letter to popular app-based ride sharing services Uber and Lyft, threatening to pull over and arrest drivers suspected of using the services. The Virginia action follows developments in other states and cities, as regulators argue that the services unjustly compete with the taxicab industry because they avoid highly restricted and expensive cab licenses. (See "Nashville's Competitive 'Black Car' Regulations," Summer 2013.)
- In New York, similar charges have been brought against Airbnb, an app that lets travelers find temporary lodging by paying to stay in people's empty apartments. The city claims that Airbnb violates hotel licensing laws and aims to shut down the service.
- A wide variety of food-based apps allow users to host dinner parties for strangers, offering the hungry and lonely a way to enjoy home-cooked meals and make new friends. The U.S. Food and Drug Administration, anxious about food being served for profit outside of rigorous local or state inspection procedures, is looking into ways to crack down on the service.
- The FDA is interested in other sorts of apps as well, with the burgeoning field of health care apps attracting the bulk of its attention. These programs range from diagnostic tools, to heart rate monitors, to dietary advice, to general sources of information like WebMD and even Wikipedia. Since the FDA currently has the authority to regulate medical devices, they are seeking to expand their powers to the app-based software available for smartphones, citing concerns over health and safety as its motive. (See "The FDA Allows Apps for That," Winter 2013–2014.)
- Finally, the U.S. Department of Transportation is seeking to apply current bans on cell phone use while driving to voice-activated navigation apps. There is undoubtedly a qualitative difference between a personal conversation and a hands-free device designed to aid driving and eliminate the need for bulky paper maps, but it is the DOT's position that a phone is a phone, regardless of how it is used.

Rent-seeking / What is notable in all those cases is the way in which innovation has allowed entrepreneurs to find ways around existing regulations—at least temporarily—and that many of the industries in question have been cartelized thanks to the government erecting substantial barriers to entry. Those industries are now pushing back against the apps.

Taxi companies want to prevent ride-sharing services because the current "taxi medallion" regulatory regime means that only a very few are able to compete, keeping prices high for incumbent firms. Hotels dislike Airbnb for the same reason. Restaurants feel cheated by apps allowing private dinner party organization, doctors and medical device makers want to keep patients coming to them instead of self-diagnosing, and the manufacturers of navigation systems fear obsolescence at the hands of mobile competitors.

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The aim of regulators in most of these cases, with the notable exception of Uber and Airbnb, is not to eliminate the app-driven service entirely, but to subject it to the same kind of regulatory oversight as the cartelized incumbents. But what about the lost benefits to consumers, forgone economic activity, lost revenue, and the diminished incentives for innovation that result from regulating or prohibiting the app-driven services?

We can attempt to quantify a portion of those lost benefits by examining just the effect of delays necessary for regulatory review. Let us assume an average of one year for a new app to apply for and receive approval from the necessary government agency—probably a generous assumption given the current lack of personnel dedicated to such a purpose. The largest purveyor of mobile apps, Apple, enjoys an average of 40,000 downloads per app at an average revenue of 10 cents for each purchase. The Apple App Store adds about 20,000 new apps each month, totaling 240,000 a year. Thus, a one-year delay for all apps pending regulatory review would cost the economy an average of nearly $1 billion annually. Data for other app providers are unavailable, but it is safe to assume this would be just a fraction of the total cost of regulating apps. Furthermore, these numbers do not account for the disincentive effect a lengthy review process would have on the development of new apps, nor the unquantifiable benefits from the apps themselves, such as better health or safer driving, nor the cost to taxpayers of expanding the regulatory apparatus to monitor this new industry.

Uneven burden / As irksome as they seem, the complaints of lobbyists for existing businesses are not wholly without merit. It is true that there is currently an unequal burden of regulation, with those operating via mobile app interface escaping the rules that govern the rest of the industry. So what should be done to rectify this?

There are three potential options for regulators. First, the existing regulatory structure can be made to apply equally to all firms in an industry, whether they operate via mobile app or not. Existing cartels typically advocate this method because it allows them to preserve their position as privileged incumbents while forcing start-up competition out of the market. It may sound like the "fairest" solution, but the costs, as we have seen, are enormous.

Second, the current regulatory regime could be eliminated, applying the current model for mobile apps to other firms as well. Consumers would enjoy the gains of increased competition, lower prices, and more choice. And the cartelized incumbents would lose whatever benefits were provided by existing regulations. However, the practical (read: political) challenges of repealing such a broad array of regulations may be insurmountable, at least in the short term.

The third option is to leave things as they currently stand, with new technologies escaping the regulatory burden and slowly chipping away at the old regime. While this may seem like the least fair of the three options because it treats some firms differently than others, for the advocate of limited government it has some advantages.

Allowing new business models to escape regulation not only offers the benefit of more innovation and consumer choice, but it gradually incentivizes more and more firms to change the way they do business. As more companies alter their services in order to avoid existing regulations, the regulatory hold on the economy as a whole gradually and inexorably shrinks without the political difficulties of repealing dozens of individual laws. Over time, more and more firms will come to operate under the new models and the regulatory regime will have been all but demolished, all without the government having to lift a finger—a practical means to an idealistic end.

What needs to be determined is whether we are willing to tolerate a certain inequality in regulations in order to ultimately reduce the burden on everyone, or if equity considerations alone justify imposing the costs of current regulations on everyone. R

Australia's Regulatory 'Bonfire'

BY JEFF BENNETT AND SUSAN E. DUDLEY

The World Economic Forum ranks Australia 128th in the world in terms of the burden of government regulation. According to the group's latest analysis, Australia's "business community cites labor regulations and bureaucratic red tape as being, respectively, the first and second most problematic factor for doing business in their country." Concerns over regulatory burden have resonated with the Australian coalition government elected last September, which committed to "building a stronger, more productive, and diverse economy with lower taxes, more efficient government, and more competitive businesses ... by reducing the regulatory burden that is strangling Australia's economic prosperity and development."

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Repeal Day / With that goal in mind, Prime Minister Tony Abbott announced March 26, 2014 as the Parliament's "first ever Repeal Day: to abolish regulation and legislation that's outlived its usefulness or is doing more harm than good." Committing to create "the biggest bonfire of regulations in our country's history," Abbott promised legislation on Repeal Day to remove "more than 9,500 unnecessary or counterproductive regulations and 1,000

redundant acts of Parliament," and "more than 50,000 pages ... from the statute books," saving "individuals and organizations over $700 million" annually.

Some Repeal Day legislation immediately passed both houses of Parliament, including streamlined environmental approvals for major developments, limiting paperwork requirements related to approval mechanisms for agricultural chemicals and veterinary medicines, and the elimination of several redundant or dubious acts, such as "the 1970s conversion from imperial to metric measurement." Other initiatives, such as reduced paperwork requirements for universities and employment agencies, were enacted without the need for Parliamentary approval.

When announcing the Repeal Day initiative, Abbott listed a number of regulatory targets. Many of those proposed reforms await debate and approval in one or both houses of Parliament, including:

- Abolishing the Australian Charities and Not-for-Profits Commission and Independent National Security Legislation Monitor.
- Changing the film classification system so that films will only need to be classified once—not again and again when they are reissued in DVD, Blu-ray, or 3-D format.
- Repealing the requirement that businesses administer the former government's paid parental leave scheme.

Initially, some of the more significant proposals failed to pass Australia's Senate, where the coalition government does not hold the balance of power. Those proposals included repeal of the Carbon Tax (a levy of $25 per ton of carbon-equivalent emissions imposed primarily on coal-fired power stations) and repeal of the Mining Tax (a resource rent tax). However, subsequent parliamentary negotiations have seen the Carbon Tax repealed and the significant reform of regulations regarding the provision of financial advice. The Abbott government estimates those initiatives will provide annual cost savings of around $300 million.

Future repeals / Prime Minister Abbott has committed to holding at least two Repeal Days each year and has formed deregulation units within each regulatory portfolio, noting, "It's sometimes more important to repeal old laws than to pass new ones." The next is scheduled for October 29th. Proposed initiatives include:

- Cessation of the obligation for some small businesses to lodge quarterly Business Activity Statements.
- Abolition of energy efficiency reporting requirements.
- Reforms arising from regulatory audits conducted for every government department.

The Productivity Commission is developing metrics by which to evaluate cost reductions and each "department and agency is conducting a comprehensive audit of the costs it puts on individuals and entities so that it can put a dollar figure on the cost of compliance and reporting and start reducing it every year." Through these efforts, the coalition government commits to $1 billion in "red tape cost savings" each year. In addition, the government is reemphasizing the importance of producing a Regulation Impact Statement for newly proposed regulations, "developed early in the policy making process ... to encourage rigour, innovation, and better policy outcomes from the beginning."

The *Australian Government Guide to Regulation*, released in the spring of 2014, identifies 10 regulatory reform principles for policymakers (see sidebar below).

Conclusion / The ongoing success of the regulatory reform agenda will depend on actions of the often hostile Senate. In addition, the coalition government's appetite for taking an aggressive stance on reform will be tested given the strident vested interest group protests they weathered on the first Repeal Day. The fiercest of those protests were over the proposals to abolish the Australian Charities and Not-for-profit Commission, repeal the Carbon Tax, and reform restraints on the provision of financial advice by those selling finance products. Tellingly, the issue identified as providing the greatest restraint to Australia's international competitive position—labor market regulation—remains off the political agenda.

Nevertheless, the two-pronged focus on repealing ineffective regulations and taking care to consider consequences when developing new regulation is an important first step in Australian regulatory reform. The world will watch with interest the effect of these actions on Australia's rankings in global indexes such as the World Economic Forum's, as well as the nation's economic growth and global competitiveness. *R*

Ten Principles for Australian Government Policymakers

From the *Spring 2014 Australian Government Guide to Regulation*

1. Regulation should not be the default option for policymakers; the policy option offering the greatest net benefit should always be the recommended option.
2. Regulation should be imposed only when it can be shown to offer an overall net benefit.
3. The cost burden of new regulation must be fully offset by reductions in existing regulatory burden.
4. Every substantive regulatory policy change must be the subject of a Regulation Impact Statement.
5. Policymakers should consult in a genuine and timely way with affected businesses, community organizations, and individuals.
6. Policymakers must consult with each other to avoid creating cumulative or overlapping regulatory burdens.
7. The information upon which policymakers base their decisions must be published at the earliest opportunity.
8. Regulators must implement regulation with common sense, empathy, and respect.
9. All regulation must be periodically reviewed to test its continuing relevance.
10. Policymakers must work closely with their portfolio Deregulation Units throughout the policymaking process.