BRIEFLY NOTED

The Menu Labeling Morass

BY IKE BRANNON AND SAM BATKINS

Why are Americans so fat? The federal government has concluded that it is due largely to a lack of information. It's tried to fill that lacuna as best it can, updating its food pyramid several times and mandating that food sold in stores have a nutritional label with the amount of calories, saturated fats, sodium, and various other components deemed hazardous to eaters.

This has done nothing to slow the increase in American obesity rates. That, in turn, has led to people asking why the new information hasn't helped. Some have suggested that obesity's chief cause has been the poverty in inner-city neighborhoods, which deters green grocers from operating there and leaving those denizens without ready access to healthier food options. It has also been observed that smoking, which is a well-known appetite suppressant, has tailed off dramatically over the past three decades, suggesting that people may be trading one vice for another.

But the federal government isn't giving up on us. Its latest plan is to extend the Food and Drug Administration's food labeling requirements to cover restaurants, grocery stores' prepared foods, and vending machines. Given that we are spending an increasing amount of our food dollars at restaurants or for prepared food, this seems like a natural next step.

The government's concern about our well-being and determination to save us from ourselves is touching. But what if the FDA's labeling actions have actually contributed to obesity? By focusing so much attention on factors that the latest science indicates contribute little to obesity, the last several decades' labels may have pushed people to eat other foods that do contribute to weight gain instead of foods that satisfy hunger and cravings without expanding the waistline. The evolution of our understanding of diet and obesity, still far from perfect, has led some to conclude that this is an issue worth examining before we expand our labeling regime.

Undaunted, the Obama administration has signaled that it will go full speed ahead with the new labeling mandates. These regulations will impose more than $1.5 billion in costs, according to the administration's ever-conservative estimates, while requiring approximately two million paperwork burden hours for businesses to comply with the directive.

We could excuse—somewhat—the urgency to complete this rule if there was good evidence that expanding food labeling would reduce obesity. However, that evidence is underwhelming.

Market failure? / Regulations, like taxes, are not borne by the companies on which they are imposed. Ultimately, they pass those costs along to consumers in some form. The administration, somewhat surprisingly, admits to this economic truth in its rulemaking, although not without the caveat that consumers "are generally willing to accept some degree of price increase in exchange for an increase in the nutrient content information." But if that caveat were the case, we would expect diners to be more willing to dine at restaurants providing such information, allowing them to charge a premium for the service and enticing their competitors to do the same.

It is unclear why the administration believes this lack of information is a market failure and not simply an example of a market failing to develop for something no one particularly values. The FDA's proposed rule offers no support or study proving that consumers willingly accept higher food costs in exchange for calorie information that is readily available for anyone who has access to the Internet. This is less of a "nudge" and more of an

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extraction of money for every consumer who purchases food.

Based on comment letters and anecdotal evidence, many stores will respond to the new labeling requirement by offering fewer choices for consumers. Salad bars and buffets will be replaced in some instances with standardized, pre-packaged food that already contains calorie information. In some instances, fresh items will probably no longer be offered. How this outcome will help reduce obesity has yet to be articulated.

Restaurants / Beyond the consumer impact lies the Rube Goldberg–like complexity of requiring something that, at first glance, would appear simple: include calorie labels for food. However, at 525 total pages, the two rules are anything but easy to understand. A pre-prepared sandwich must adhere to the rules, but a made-to-order sandwich that contains hundreds of different possible ingredients won't be covered explicitly—although retailers would still likely need to label all of the components. A daily special probably wouldn't be covered—unless the special occurs weekly or monthly, in which case it is shorn of its "special" status and covered by the rule.

For items that are covered, the rules are equally difficult. Covered establishments must provide:

- calorie information on menus and menu boards (including online)
- a statement on suggested daily calorie consumption
- a notice to customers that additional nutritional information is available

The Department of Health and Human Services, the FDA's parent agency, even mandates the font size, color, placement and wording ("calorie" or "cal") of the nutritional declarations.

But there's more: Calorie labels must be declared "to the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increments above 50 calories, except that amounts less than 5 calories may be expressed as zero." They must still provide any relevant "additional information," including data on calories from fat, saturated fat, trans fat, cholesterol, sodium, sugars, and protein.

This morass was explained in a 105-page rule, with an accompanying 133-page regulatory impact analysis. Regulators are likely to issue additional guidance documents as the final compliance date nears.

For retailers who fail to follow the new rules, there are stiff penalties—including the possibility of jail time. Under the Food, Drug, and Cosmetic Act, "misbranded" items carry a penalty of up to one year in prison or up to a $1,000 fine. For repeat offenders, the punishment of incorrectly displaying calorie information increases to three years in prison or $10,000. In addition, federal regulators can actually seize misbranded food in the stream of interstate commerce.

It is unclear why the administration believes this lack of information is a market failure and not simply something that no one particularly values.

Small business / Like most regulations, this one will affect small businesses more than their larger competitors. The HHS concedes the measures will have a "significant economic impact on a substantial number of small entities," and noted that approximately two-thirds of the regulated entities are small businesses, largely because of the prevalence of franchised entities in food service.

Based on the HHS's estimates, the menu labeling rule will impose per-entity costs ranging from $49,000 to $77,000. According to data from the Bureau of Labor Statistics, the typical food service employee earns $22,000 annually. Thus, the new rule essentially costs a business the equivalent of two to 3.5 employees, without doing a thing to increase sales or boost productivity.

Considering that half of all food service establishments employ fewer than 10 employees, and the historically low profit margins in the industry, the economic effect becomes clear. The food industry, which knows a bit more about its business than the HHS, projects costs eclipsing $120,000 per store, exclusive of levies for paperwork (for which the administration does not provide any cost estimate whatsoever). That implies an aggregate first-year cost approaching $1 billion.

Extending reach / The propagators of the regulatory state often appeal to the Precautionary Principle to defend their actions. This says that when there's even a small chance of an outcome that could potentially have a very large effect on the economy or some population in society, then the government should act out of an abundance of caution to reduce even this small risk.

There is a real possibility that the federal government, through its food labeling system, shares the blame for the rise in obesity over the last two decades. The current label nudges us to stay away from cholesterol by providing us with the proportion of the recommended daily allowance contained in each serving, and various edicts from the FDA have warned Americans to limit their intake of eggs for decades. We have listened; egg consumption has been falling since the 1940s and dipped sharply around the time we began food labeling.

Nutritionists have come to conclude that this effort has been mistaken. The relationship between cholesterol consumption and heart disease, never strong to begin with, now looks as if it doesn't exist. The Dietary Guidelines Advisory committee recently dropped its admonition that Americans limit their intake of eggs or other foods that are high in cholesterol.

It turns out we don't know nearly as much as we thought we did about how diet affects obesity. By encouraging people to eat less saturated fats, Americans have instead increased their consumption of

sugars and carbohydrates, which is looking like precisely the wrong thing to do if the goal is to control weight. Perhaps we should spend some more time researching what it is that we ought to be telling people about a healthy diet before we extend our nudging further.

The *Peoria* (Ill.) *Journal Star* recently published a photograph of the hosts of a local daytime children's television show from the 1970s, surrounded by a legion of erstwhile fans. The TV personalities—who went by the stage names of Captain Jinks and Salty Sam—were and remain icons throughout Central Illinois, and the article generated hundreds of online comments. Besides the plethora of wistful recollections about a show that was enormously popular was the simple observation that the Captain and his first mate—as well as the rest of the people in the picture—were so skinny compared to people today. What happened?

We don't fully know what happened is the short answer. But there are most likely multiple culprits to blame, and there's not a lot of evidence that the government's most prominent attempt to arrest this growth—putting calorie labels on food—had even a negligible positive effect in arresting the increase. In fact, there's reason to believe that labeling may have made matters worse. Expanding food labeling now, given our level of ignorance, is pure folly. R

Drugmakers' Unwelcome Surprise

BY THOMAS A. HEMPHILL

Last February, Hayman Capital Management hedge fund manager Kyle Bass, through his wholly owned subsidiary, the Coalition for Affordable Drugs, filed a patent review petition with the U.S. Patent and Trademark Office's Patent Trial and Appeals Board (PTAB). Bass seeks to invalidate two of the five patents held by pharmaceutical maker Acorda Therapeutics on its drug Amprya, which helps some multiple sclerosis patients to walk.

Explaining his petition, Bass said:

> A small minority of drug companies are abusing the patent system to sustain invalid patents that contain no meaningful innovations but serve to maintain their anti-competitive, high-price monopoly to the detriment of Americans suffering from illness. The beautiful thing is this will lower drug prices for everyone.

Pharmaceutical and biotechnology companies were quick to disparage this altruistic rhetoric. Said James C. Greenwood, chief executive officer of the Biotechnology Industry Organization (BIO), a D.C.-based trade association representing biotech firms and related entities, "There's nothing in this man's history to suggest he has any interest in lowering health care costs." Suspicions are that Bass is shorting Acordia (that is, betting that the stock price will fall as Acordia defends, and perhaps loses, its patents), or else he's betting on competing drug companies whose market positions would improve if Acordia's patents are revoked.

Amprya isn't the only drug in Bass's crosshairs. He subsequently filed petitions for biopharmaceutical maker Shire's drugs Lialda (a medicine for ulcerative colitis) and Gattex (for short bowel syndrome), and Jazz Pharmaceuticals' Xyrem (for narcolepsy). It's expected that more petitions are forthcoming.

Review procedures / Bass's moves have drug makers calling on federal lawmakers to tighten procedures for reviewing a patent's validity that were adopted as part of the America Invents Act of 2011 (AIA). The current regime was implemented out of concern that patents were being awarded too easily, resulting in successful, costly litigation against non-patent-holding firms that didn't seem to be unfairly infringing on a patent. Instead of the costly and intimidating process of going to court, many patent challengers could bring their complaints to the PTAB.

Under the AIA, the PTAB has greater jurisdiction than a previous Patent Office review panel to decide post-grant challenges and review patentability. It also has a lower burden of proof for patent invalidation and uses a shorter, more efficient review process—characteristics that are inviting to potential petitioners. According to Matthew Cutler, an attorney at the law firm Harness Dickey, a review can now cost about $300,000 and take up to 18 months to complete, as opposed to conventional patent litigation through the federal judiciary, which could cost $3 million or more and take several years before being resolved.

More galling to drug makers is the AIA adopted three different avenues through which petitioners can challenge a patent's validity. Two of those avenues—including the one used by Bass—permit the filing of petitions by entities that many drug makers believe shouldn't have standing. In the view of the drug makers, these two forms of review provide too many opportunities for nuisance petitions. BIO's Greenwood, thinking of Bass specifically, recently called on Congress to change the review system and stop him from "exploiting the ... patent challenge proceeding as part of his cynical short-selling strategy against innovative biotech companies that are delivering transformative therapies to patients in need." Pharmaceutical and biotech firms strongly recommend amending the AIA to eliminate the eligibility of "third party" petitioners to challenge patents.

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Results of reviews / Are the new AIA petition procedures providing avenues for abuse? A report compiled by Harness Dickey, *Harnessing Patent Office Litigation: Volume IX*, examined review petitions filed in the first 30 months (through last March 16) of the new regime and found that 383 "chemical or biotechnology" patent challenges had been filed. That represents just 15.1 percent of the 2,536 reviews that were instituted during that time period, behind "electrical and computer" patents (1,549) and "mechanical and transportation" patents (594) but ahead of "design" (10). The PTAB, in its final written decision, canceled patents in 84.8 percent of all cases, including 87 percent of the chemical or biotechnology patents. So, though relatively few of the challenged patents are for drugs and other chemicals, most of those challenges have been successful.

If those patents had been blocking the fair use of new drugs, their revocation should benefit both human health and the economy. The 87 percent rate of invalidation for chemical and biotech patents may accurately reflect exactly what Eric Spangenberg, an intellectual property consultant to Bass's Coalition for Affordable Drugs, said in a prepared statement: "A small minority of drug companies are abusing the patent system to sustain invalid patents."

Did Congress get the petition regime right? / So, if most cases of review are finding bad patents at relatively low cost, should we consider the AIA's patent review provision a legislative success story? Perhaps, though some would argue that petitions like Bass's are an unintended negative consequence. Patent attorney Gene Quinn, writing in *IP Watchdog* last April, reviewed the legislative history of the provision and its aftermath. According to Quinn:

> Post-grant procedures were designed to be an alternative to litigation, and Congress was well aware of at least some potential abuses of the new procedures. The intent was to give those with a justifiable grievance a cheaper, faster forum in which to challenge a patent. Likewise, the procedures were designed to the greatest extent possible to prevent abuse of process and/or harassment. The legislative history is silent with respect to the type of challenge Bass is bringing, although it stretches the imagination to believe that Congress intended to allow pharmaceutical companies to be subjected to a challenge by an individual or entity that would not have standing to sue in Federal District Court.

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So, perhaps patent challengers should be limited to only those with standing. But doing that would undermine one of the goals of the AIA, which is to allow entities to challenge "patent trolls."

Patent trolls are non-practicing entities (NPEs), which own patents but aren't actively using them in the production of some good. Instead, NPEs typically are investment firms that search for possible instances of infringement that could result in profitable litigation or settlement, and their preferred patents are in computing and communications. Congress passed the AIA out of concern that NPEs were impeding growth in the tech sector, an important growth sector of the American economy. That concern is reasonable: as James Bessen, Jennifer Ford, and Michael Meurer reported in these pages a few years ago, 75 percent of the NPE lawsuits they examined were initiated against firms in the computer and communications technology class ("The Private and Social Costs of Patent Trolls," Winter 2011–2012).

To make it as easy as possible for technology companies to invalidate NPE patents, Congress appears to have purposely chosen not to include standing as a requirement for two of the three review procedures. As Harness Dickey noted in its study, 61 percent of all reviews during the examined time period were for patents in the electrical and computer category. Three of the top four petition filers are from the electrical and computer technology category, with Apple at No. 1 (105 petitions), Google at No. 3 (68 petitions), and Microsoft at No. 4 (54 petitions).

But has the battle against patent trolls in the technology industry resulted in friendly fire casualties in the pharmaceutical industry? The early data on invalidation of pharmacologic and biologic patents have shown positive indicators that there are drugs vulnerable to successful post-grant review challenges. That is social and economic good news because it suggests the patents should not have been granted in the first place. That is, the petitions are making these advances more readily available for commercial exploitation and people's use.

On the side of the angels? / Of course, none of that means Bass's motivations match his altruistic rhetoric. After all, he has Spangenberg, through his firm nXn Partners, evaluate potential pharmaceutical targets using predictive analytics software to determine the strengths (and weaknesses) of certain pharmacologic or biologic patents. So it seems a lot more likely that Bass is motivated by financial advancement than health advancement.

Nonetheless, that doesn't mean Congress should "do something" about Bass and anyone else who follows his apparent strategy. After all, if the patents are weak and Bass challenges them, and the challenges result in greater availability of new pharmaceuticals, then the challenges are net beneficial regardless of Bass's motivations. So, until there is empirical evidence showing net harm, it seems unwise to change the current process.

Some critics of Bass's tactics may agree with this theoretical point. But, they say, if he and other entities continue filing petitions, the PTAB will become overwhelmed with less-than-credible patent challenge filings, slowing its work of ferreting out truly bad patents.

That concern has not yet materialized, but it could in the future. According to the Harness Dickey study:

> As the PTAB's workload has steadily increased, the time to a Decision to Initiate [a review] has gradually climbed as well. While the Board has statutorily been provided with three months to make that decision, it is taking *about two weeks less* (emphasis added) than the full statutory allotment to come to a Decision to Initiate.

However, until the PTAB does become overwhelmed, it seems unwise to change the current process. Much like Bass's tactics, we should wait for empirical evidence that change is needed.

And, for now at least, it seems politically unlikely that any change will occur. It would be a formidable legislative undertaking for pharmaceutical and biotechnology companies to motivate the 113th Congress to "change the [patent] review system," as BIO's Greenwood advocates. Biotech firms advocating change will find themselves confronted by technology companies adamantly opposed to limiting third-party challenges to post-grant review procedures.

Before Congress takes up the cause of restraining an onslaught of "reverse patent trolls"—as Bass has been described by his critics—who are assaulting pharmaceutical and biotech firms with "baseless" patent grant review challenges, lawmakers need to carefully evaluate the empirical data on review challenges *and* decisions against pharmaceutical and biotech patents. As for Bass, his five patent grant review challenges were just 1.3 percent of the 383 "chemical or biotechnology" patent challenges filed in the first 30 months since the inception of the review process—not exactly a giant troll. A "wait-and-see" approach is warranted for discerning whether Bass' success causes him to file further challenges and other hedge fund managers follow his lead. *R*

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The Promise and Peril of Retrospective Review

BY KEITH B. BELTON

Federal regulators spend much more time and energy writing new regulations than revising or rescinding old ones. Comparatively scant attention is spent evaluating older rules against their regulatory objective, with the primary aim of reducing the regulatory burden—an exercise referred to as "retrospective review."

The Obama administration has done more to advance retrospective review than previous administrations. It enforced a long-ignored section of a 1993 executive order requiring each regulatory agency to develop a plan for reviewing significant regulations. (Plans were first published in 2012 and include more than 500 ongoing or completed changes to existing regulations.) It set a schedule for agencies to update their plans every six months. (Plans were last updated and posted this past March 15th.) It urged independent regulatory commissions to follow suit (and they have). It required agencies to invite public nominations for reform (and most did). It required agencies to publicly release data and analysis from any retrospective reviews. It made clear that the emphasis is on reducing the regulatory burden (with special considerations for small business), including the cumulative burden. It set a goal of $20 billion in annual cost reductions associated with changing existing regulations, and identified a few regulatory changes that will count toward that figure.

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These administration activities have captured the attention of think tanks and other organizations focused on regulation. Michael Mandel and Diana Crew of the Progressive Policy Institute favor establishment of an independent commission to submit to Congress a list of regulations for elimination or modification, modeled after the successful Base Realignment and Closure (BRAC) process for identifying and closing military installations. Law professor Cary Coglianese, director of the University of Pennsylvania's Penn Program on Regulation, seeks a stronger role for the White House Office of Management and Budget: to issue guidelines to agencies on the conduct of retrospective review, to require that agencies plan for retrospective review in each regulatory impact analysis, and to recommend specific rules for agency review. The Administrative Conference of the United States, in an effort to "cultivate a culture" of retrospective review, emphasizes crafting new regulations with an eye toward future evaluation and then employing evaluators external to the agency to conduct the analysis.

Congress is also interested in retrospective review. Leading the charge is the Senate Homeland Security and Governmental Affairs Committee with its #CutRedTape Initiative, focused on reducing burdens associated with existing regulations. Last March, committee chair Ron Johnson (R–Wisc.) and ranking member Thomas R. Carper (D–Del.) sent letters to hundreds of interest groups seeking their top regulatory priorities and suggestions for improving the regulatory process. The committee established an online portal where citizens can share their stories about regulations. The committee's first hearing this year focused on regulatory reform, and the issue garnering the most attention was retrospective review. A series of additional hearings on regulation are planned for this year and next.

This interest by external parties may be having some effect on the administration. OMB leaders recently held a series of outreach meetings with various interest groups, seeking advice on how to "reinvigorate" their retrospective review efforts. The OMB has also requested "public engagement" plans to be completed by all agencies by May 1 and is tracking the agencies' progress in implementing their plans on a monthly basis. It is likely that any substantial changes to President Obama's initiative will become apparent when the next update of agency plans is posted in July or August.

Resistance from regulators / As promising as these developments appear, there is reason for pessimism about the administration's efforts: the exercise is agency-driven and regulators have strong incentives to resist retrospective review and preserve the status quo.

We should worry that regulators will ignore certain types of promising reforms or set a higher bar than necessary before making a change.

In his masterwork, *Bureaucracy*, public administration scholar James Q. Wilson argued that bureaucrats resist innovation that is at odds with their core task or mission, even if additional resources are provided to them. An agency whose core task is protecting consumers or workers can be expected to resist changing regulations that diminish protection, even if the resulting social benefits are large and the increased risk is slight.

An example of this can be found in the Department of Labor's retrospective review plan. The Occupational Safety and Health Administration will identify and remove unnecessary or duplicative provisions or paperwork requirements in workplace standards for construction. Administration officials are quick to point out that OSHA's efforts are focused on reducing burden "so long as the changes do not diminish employee protections." So no reduction of burden is considered worthwhile if worker risk increases even the tiniest little bit.

An additional factor affecting agencies also comes into play: the so-called "endowment effect." Behavioral economist Richard Thaler coined the term to describe the difficulty people have in giving up something, often requiring greater compensation than they would be willing to pay to obtain it. For example, if an agency believes it is "giving up" key information from regulated entities that enable it to fulfill its duties, it is likely to resist eliminating the information collection requirements unless it receives compensation in excess of its loss.

A good example of this effect comes from the Environmental Protection Agency's retrospective review plan. The EPA seeks to eliminate certain toxicity testing requirements for pesticide registration purposes. The current regulations require that pesticide manufacturers expose whole animals to an unrealistically high dose of a pesticide to elicit an adverse effect in order to determine a "safe dose" level for humans. This approach is costly, time-consuming, and involves a great deal of scientific uncertainty, especially when extrapolating data from high doses in animals to the lower doses expected in humans. In 2007, the National Research Council called for a shift to a new paradigm where human cells are exposed to an "environmentally relevant" (that is, likely) dose of a chemical. The cellular response from such in vitro assays, coupled with selective use of whole animal testing, can be used to evaluate chemicals more quickly, at less cost, and with fewer animals. Major scientific uncertainties are also reduced.

Despite the promise afforded by these new testing methods, the EPA has taken a stance that first requires proof that a new test provides at least the same information as the old test it may replace, even if the validity or relevance of the new test to human beings exceeds that of the old method. Should the EPA allow a new test to be used, it will require data from both

the old test and the new test for an indeterminate amount of time before it might decide to eliminate the requirement for the old test. In short, the agency is setting a much higher bar to replace a regulation than it did when setting it—the endowment effect at work.

To be fair, retrospective review plans include plenty of examples where there is significant alignment between regulators and the regulated. For example, the EPA aims to allow manufacturers to utilize modern optical imaging for detecting equipment leaks of air pollutants, a compliance option that is less costly and arguably more effective than current regulatory requirements. The Department of Labor plans to modernize its permanent labor certification process to make it easier for firms seeking to employ foreign workers permanently in the United States. The original regulations were established 10 years ago and have not been altered despite changes in the labor market.

We should not worry that regulators will ignore the president's initiative; they won't. We should, however, worry that regulators will ignore certain types of promising reforms or set a higher bar than necessary before making a change.

Regulated entities have their own reasons to be wary of retrospective review. For many if not most existing regulations that have been in place for a long time, compliance costs are greatest in the beginning, representing a sunk cost that cannot be returned. Compliance paths are relatively certain. A change in a long-established regulation would impose a new cost to change the established compliance path and would also create uncertainty over enforcement. As one retired compliance manager for a heavily regulated multinational company said, "Nothing good can come from opening up an old regulation." Perhaps this kind of thinking stems from experience with statutory requirements for periodic review of regulations, requirements that tend to add to—not subtract from—the regulatory burden (e.g., the Clean Air Act's mandate for the EPA to review the national ozone standard every five years).

Incremental versus significant progress / If there is reason for optimism, it stems from the fact that certain types of reforms—ones that do not threaten an agency's core task—should be welcome, or at least not resisted, by both regulators and the regulated. These reforms can be grouped into three categories:

- reforms that allow the use of new technologies or eliminate a requirement to use an out-of-date technology
- reforms driven by newly established scientific knowledge
- reforms that leverage information technology (e.g., in lieu of paper forms)

Nearly 50 percent of the listed regulations from a sample of retrospective review plans (from EPA, OSHA, and the Food and Drug Administration) involve these types of changes. There is no reason to believe the plans from other departments and agencies are any different. Admittedly, most of these types of reforms represent incremental improvements, the kinds of advances that continuously improve the efficiency and effectiveness of markets.

Unfortunately, even if the administration's efforts to "reinvigorate" retrospective review result in many more of these positive changes, success is likely to be relatively modest for two reasons.

First, regulatory priorities at many, if not most, federal agencies are driven by statutory mandates and court-imposed deadlines, lessening the time for agency discretionary activities like retrospective review. Only a tiny fraction of the future regulations listed in the latest semi-annual Unified Agenda (listing pending regulations in development across all federal agencies) are tagged with the "retrospective review" moniker.

Second, regulatory agencies cannot change bad regulations required or compelled by statute, and statutes establishing regulatory programs (especially in the last two decades) are notoriously prescriptive. Interestingly, Executive Order 12866 requires each agency to "identify any legislative mandates that require the agency to promulgate or continue to impose regulations that the agency believes are unnecessary or outdated by reason of changed circumstances." But despite this presidential requirement, agencies do not do this and OMB does not require that they do.

In the end, like every other proposal to reform the regulatory process, retrospective review is a second-best solution. The best solution can be found not on the back end, but on the front end: when Congress enacts or modifies statutes and when agencies craft regulations for a new regulatory program.

Congress is considering taking action. Two bills have been introduced to advance retrospective review; both build on Mandel's suggestion of having a politically appointed commission identify a package of regulations to be eliminated, subject to an up-or-down vote by Congress. Compared to the administration's initiative, in which the regulatory agencies determine which rules are to be eliminated or modified, Congress would be in the driver's seat.

The Obama administration deserves credit for bringing greater attention to retrospective review, but its efforts are likely to be incremental. The best way to eliminate a bad regulation is to avoid creating it in the first place. *R*

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THE AMERICAN DREAM

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BRIEFLY NOTED

How States Can Effectively End the Federal Income Tax—and Why They Should

BY RYAN H. MURPHY

Proponents of a more rational tax code may be feeling optimistic because of the Marco Rubio–Mike Lee proposal for tax reform. The senators' proposal would move the tax code closer to a tax on consumption, a policy that many economists have long argued would be conducive to economic growth. But the Rubio-Lee plan is a very watered down version of such a transition and likely would have to be watered down further in order to be enacted.

One alternative for achieving a genuine transition away from federal income taxation would be for state governments to de facto change the way federal taxes are collected. Such a change would profoundly improve the prospects for economic growth, even from the perspective of very orthodox economists. All that's needed is a state legislature daring enough to try it—a legislature like, say, Texas.

Lone Star pluck / In Texas, taxes on income are against the state constitution. However, Texans still pay the federal income tax.

In principle, the state could effectively end the federal income tax by using two surprisingly simple and straightforward legislative maneuvers—neither of which involves secession. Texas could choose to send its federal taxpayers a check in the form of a state tax credit equal to their federal income tax liability. It could then pay for the credit by increasing the state sales tax in a revenue-neutral way. Effectively, that would mean the end of all income taxes in the state while significantly raising sales taxes. This isn't about cutting taxes per se; rather, this is the tax swap to end all tax swaps.

Texas may be well-positioned to make such an extreme change because its population centers are distant from its borders with other states, which means most Texans would have difficulty arbitraging away from a higher sales tax. (Some other states may find that their citizens will cross borders to avoid paying significant sales taxes, but those states could pay for the income tax credit by raising the next least worst type of tax—perhaps the property tax. The arbitrage problem shouldn't be insurmountable for any state.)

A state could give its residents a tax credit equal to their federal income tax, and fund the credit by raising the state sales tax or the next least-worst tax.

The resulting inflow of investment from other states—and other countries—into Texas would be unprecedented. It could dwarf the recent "fracking" boom by an order of magnitude. Every firm in the world would eagerly seek to make a city in Texas home to its world headquarters.

Why do it? / This would constitute a drastic policy shift, but why not do it? The superiority of consumption taxes to income taxes has long been argued by many neoclassical economists.

The real difference between a consumption tax and an income tax is that a consumption tax encourages saving and thrift. We have good reason to believe that (relatively speaking) discouraging saving—and therefore investment—has significant negative effects on growth. There's no good reason to structure the tax code in such a way that it encourages using income on immediate consumption. If anything, we should raise revenues in such a way that *discourages* activities we think are harmful, not ones that are socially beneficial like saving.

The positive effects have been convincingly shown most recently by Jens Arnold, an economist with the Organization for Economic Cooperation and Development, who studied the effects of different tax policies on economic growth across OECD countries. Arnold's work indicates that consumption taxes and property taxes are distinctly superior to income taxes, especially to an income tax with high progressivity. William McBride of the Tax Foundation summarizes this in a 2012 study, "What Is the Evidence on Taxes and Growth?" What is clear is that a U.S. state that is willing to move its tax environment strongly in this direction would attract investment, entrepreneurs, and workers from the other 49 states.

This tax shift would implicitly allow states to unilaterally end one of the most pernicious parts of the federal tax code: the home mortgage interest deduction. While the economic effects of the deduction would cease to exist, the statute would still be on the books. A tax deduction that economists left and right agree is economically terrible would be erased, even though right now it is politically impossible to do so.

Other features of the federal tax code could be preserved, if a state wishes to do so explicitly. The information needed for charitable-giving subsidies or wage subsidies would still be contained in a filer's federal tax return. While we may or may not want to publicly subsidize such activities, we can agree it is more efficient to do so directly than to awkwardly build

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them into a progressive income taxation scheme.

Clearly, sales taxes are regressive, especially in comparison to progressive income taxes. But combating income inequality—or, far more importantly, poverty—should not impede this tax shift. Again, orthodox neoclassical welfare economics tells us to raise revenue in the most efficient way and to address distributional concerns in the most efficient way. That means consumption taxes followed by either wage subsidies or guaranteed minimum incomes for the poor.

Conclusion / Governments in "red" states face few impediments to enact policies conservatives want. From Georgia's so-called "Guns Everywhere" law to Right-to-Work becoming a reality in Michigan of all places, states have shifted policy significantly since the rise of the Tea Party. In contrast, even the most free-market states have tax policies to the left of the median economist—that is, if this tax-shift policy option is on the table.

Perhaps progressive jurists may challenge the legality of states effectively circumventing the desires of the federal government. I am not qualified to judge whether such a challenge would be successful. But beyond that, the only real obstacle to this policy change is the tyranny of the status quo. If states want to unilaterally end inefficient federal taxation from taking place within their borders, they can do it. R

READINGS

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Regulating Medical LDTs

BY HENRY I. MILLER

The U.S. Food and Drug Administration has announced that it will ease regulation of direct-to-consumer medical tests used to identify carriers of certain genetic diseases. These tests, which are used infrequently, will be classified as "Class 2"—low-to-moderate risk—medical devices and will thus be exempt from premarket review. With the announcement, regulators congratulated themselves for boosting innovation and benefiting consumers.

As with much regulatory policy in the Obama administration, however, even when there is some liberalization, it's often a case of one step forward, two (or more) steps back. A far more significant—and regressive—action by the FDA in the regulation of medical devices was a decision last October to begin regulating a class of products called "laboratory-developed tests" (LDTs). They are used to diagnose and treat a wide array of illnesses, from cancer and metabolic abnormalities to infections. These tests are often referred to as "home-brew" tests because they are developed and used in a single clinical laboratory rather than being manufactured and sold by big companies. There are an estimated 10,000 of them, produced by thousands of laboratories, that perform the tests on samples they receive.

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Why now? / Up to now, these tests have had little federal oversight. But that is about to change.

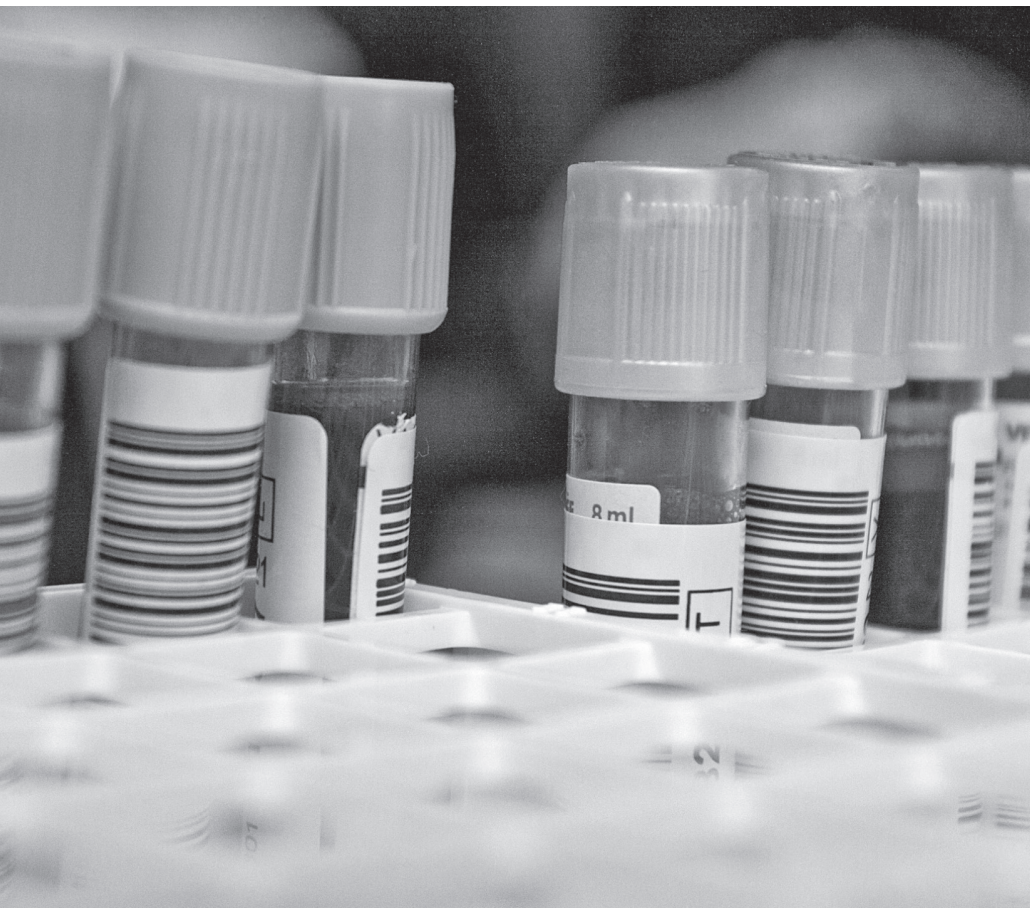
In 1976, Congress defined most diagnostic tests as "medical devices," which by definition fall under the purview of the FDA. But at the time, LDTs were not widely dispersed or commercialized. They tended to be relatively simple and their results were typically interpreted where the tests were performed. The FDA thus exercised "regulatory discretion," which is bureaucrat-speak for exempting the tests from regulation. Currently, the agency regulates diagnostic tests only if they are developed, sold, and distributed by device manufacturers as kits.

The FDA contends that LDTs have become much more complex and are used much more frequently and in higher-risk settings than they were decades ago. And, the agency says, some of the tests are defective and dangerous. Alberto Gutierrez, FDA director of in vitro diagnostics and radiological health, cites OvaSure, a test for early detection of ovarian cancer, which gave a high rate of false positives that in some cases led to operations to remove healthy ovaries.

In a guidance document published last October, the FDA announced that it intends to enforce certain device requirements "for laboratories that manufacture, prepare, propagate, compound, assemble, or process LDTs."

(It should be noted that, in the words of attorney David Hoffmeister of the firm of Wilson, Sonsini, Goodrich and Rosati, "LDTs are already regulated—by the Centers for Medicare and Medicaid Services (CMS) through the 1988 Clinical Laboratory Improvement Amendments (CLIA), which ensure that a test is performed properly and gives reproducible results." Specifically, CLIA regulations include requirements for establishing and maintaining quality laboratory operations and ensuring the lab is staffed by qualified personnel. However, the CMS's oversight does not extend to determining whether a test actually has clinical validity for the patient.)

Review process / There is significant uncertainty about what the FDA's LDT regulatory scheme ultimately will look like. It does appear that the agency intends high-risk LDTs to undergo internal review of their Premarketing Applications, which is the most stringent type of device marketing



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application required by the FDA. But most low- and moderate-risk LDTs will likely be eligible for third-party review, which is less rigorous, time consuming, and costly.

Such external review isn't new: the FDA's "Accredited Persons Program" was created by the FDA Modernization Act of 1997 to improve the efficiency and timeliness of the agency's 510(k) process, the pathway through which most medical devices receive marketing clearance in the United States. Under the program, the FDA has certified certain third parties, so-called "Accredited Persons," who are authorized to conduct the primary review of applications for eligible devices. The Accredited Person conducts the primary review of the 510(k) application and then forwards its review and recommendation to the FDA.

Nongovernmental, non-monopolistic regulation of consumer products operates efficiently and safely in the United States and abroad.

With the increasing complexity and use of medical diagnostics, an argument can be made for greater scrutiny of some of them, but this could be accomplished under the FDA's Accredited Persons Program. Under such a regime, the increased regulatory burden on the makers of LDTs would likely be tolerable and the medical community would benefit from greater confidence in the tests.

But there are even better options, which needn't involve the FDA in day-to-day regulation at all.

Although we tend to take government regulatory monopolies for granted, they are not sacrosanct. Nongovernmental, non-monopolistic regulation of consumer products operates efficiently and safely in the United States and abroad. In this country, Nationally Recognized Testing Laboratories, the prototype of which is Underwriters Laboratories, certify more than 20,000 categories of consumer products. Many of these products, such as electrical equipment, bulletproof glass, and fire-resistant building materials, present potential hazards if they are defective. Despite the lack of direct government involvement, there is considerable respect for the work of the testing laboratories.

Another model is the way medical devices are regulated in the European Union. There, there is heavy reliance on various sets of product standards, and oversight does not involve government regulators directly. For low-risk devices, such as tongue depressors or reflex hammers, manufacturers themselves are allowed to certify that their products meet the necessary standards. For higher-risk devices, manufacturers must obtain third-party reviews from private sector "notified bodies," which test products, inspect manufacturing systems, and verify that EU standards have been met. Following this certification, the products can be marketed.

Notified bodies are designated by the national regulatory authority (also known as the competent authority) of an EU member state to carry out one or more of the "conformity assessment procedures" required for approval of a device. Because these notified bodies compete with one another for business but need to maintain certification from a national authority, they have reason to be both expeditious and thorough. This system works well; approval of new medical devices in Europe takes only half as long as in the United States, shortening the development process by roughly two years without compromising safety.

Congress could mandate a system that more closely resembles Europe's. Sadly, the FDA and its boosters would likely fight such a proposal tooth and nail: it's in the DNA of regulators to oppose ceding any of their power. As former FDA commissioner Frank Young used to quip, "Dogs bark, cows moo, and regulators regulate." *R*