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REGULATION was first published in July 1977 "because the extension of regulation is piecemeal, the sources and targets diverse, the language complex and often opaque, and the volume overwhelming." REGULATION is devoted to analyzing the implications of government regulatory policy and its effects on our public and private endeavors.

Ethanol 2.0

BY ROBERT EARLE AND AHMAD FARUQUI
The Brattle Group

For almost a decade now, some people have held up biofuels (such as corn-based ethanol) as providing a pathway to energy independence. Congress has instituted subsidies to bring that vision to fruition.

Recent empirical work has called both the vision of energy independence and the subsidies for biofuels into question. It has questioned the efficacy of biofuels in displacing imported oil, reducing carbon emissions, and ameliorating fuel prices. A central concern is that biofuels are driving up food prices by shifting rightward the demand function for items such as ethanol, palm oil, and rapeseed oil. This effect has been observed in the United States and Europe. While there is disagreement about the precise magnitude of the hike in food prices that has resulted from the increased use of food as energy feedstock (the World Bank calculates that 75 percent of the recent increase in food prices is attributable to biofuels while the U.S. Department of Agriculture puts that figure at only 3 percent), there is little doubt that biofuels have played a role that is expected to grow in the future as biofuel use increases in accordance with government mandates.

To get out of the food trap, biofuel advocates look to "second-generation" biofuels made from such non-food sources as jatropha and algae. To size up the economics of these new biofuels, we reviewed the professional and trade literature and conducted telephone interviews with a dozen energy experts at universities, commodity trading firms, environmental groups, and in the U.S. government. By and large, they told us that there are no definitive assessments of costs and prices on the subject of second-generation biofuels.

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The opinions expressed in this article are those of the authors and do not necessarily represent The Brattle Group.

THE NEXT GENERATION Two of the oft-mentioned sources of second generation biofuels are jatropha and algae. How close are these biofuels to large-scale production? And what is the status of some other candidates?

Jatropha (*Jatropha curcas*), also known as physic nut, is a perennial poisonous shrub belonging to the Euphorbiaceae, or spurge, family. It is indigenous to Central America, but can be cultivated in subtropical and tropical regions. The seed is used for biodiesel production. Oil content varies from 25 percent to 45 percent, with extraction rates running as high as 95 percent. Estimates of yield vary from four to seven barrels per acre. Conversion of jatropha to biofuel is at an embryonic stage of development, with some relatively extensive testing carried out in India, and that research has yielded mixed results. Because it is poisonous, use of jatropha as a feedstock may require additional investment in transportation infrastructure. There is little consistent information about the cost of production, with much uncertainty about water, fertilizer, and other inputs needed to achieve commercial production levels. In addition, there is some uncertainty about jatropha's combustion properties, which makes it difficult to quantify its fuel content.

Algae are grown on a commercial basis for food consumption as an ingredient in products such as ice cream. As a potential biofuel feedstock, algae have attracted attention because of yields reaching 150 to 2,600 gallons per acre or from two to over 15 times the productivity of palm oil. Producing biofuels from algae is currently in the early testing stages of development, and is being funded by major oil companies such as Chevron and Shell. Fundamental research in the biological sciences needs to be done before commercial production can begin. Our panel of experts is of the opinion that algae-based fuels are at least a decade away.

The wide range of estimates for pro-

KEVIN TUMA (4)

ductivity for algae is typical for new technologies. Technologies follow a development lifecycle that starts with theory and then moves to testing in a laboratory, testing in pilot programs, and then ultimately to commercialization. As commercialization reaches sufficient concentration, new products reach a level of market participation of sufficient level that the product becomes an alternative to others on the market.

Given the uncertainty as to the productivity and costs of various second-generation biofuels, where do they line up in the technology development lifecycle? Table 1 shows the collective judgment from our experts on a variety of biofuel feedstocks. Palm oil is the most advanced, with commercial availability (when the price was low enough that the biodiesel produced from palm oil could compete with petrodiesel). Jatropha is arguably at the lab testing or, at best, pilot stage, with plans in many locations for large growing experiments, commercialization, and marketing. Algae-based fuels remain in the lab stage, with important trials in Arizona (as a carbon sequestration mechanism) and Hawaii. Another next-generation source of biofuel, the Fischer-Tropsch process of converting vegetable matter to liquid hydrocarbons of various forms, has existed for decades but it is still in the lab testing stage.

DEMAND FOR LAND One of the problems with biofuel as a solution to provision of energy is the competition that most biofuels have for agricultural land. As noted in a recent *Regulation* article ("Neither Renewable Nor Reliable," Fall 2007), if all the corn grown in the United States were devoted to producing ethanol, it would only displace about 3.5 percent of current gasoline consumption. Along with the competition for food, another concern about biofuel crops is their impact on the environment. Increased demand for biodiesel in Europe has helped to increase the demand for palm oil, which is turned into biodiesel. As a result, virgin rain forest is replaced by cropland for palm oil, resulting in huge releases of carbon dioxide into the atmosphere. That release is partly due to the burning of the forest in order to clear it and partly due to the plowing of fresh agricultural land.

The Round Table on Sustainable Palm Oil has created a voluntary certification program with over 200 participating companies in an effort to build a market for sustainable palm oil. While the price of palm oil has risen in the past year so that biodiesel from palm oil is no longer competitive with petroleum, efforts to prevent the demand for biodiesel from causing environmental harm and food price increases are instructive because the palm oil efforts will undoubtedly be repeated as other biofuel crops emerge.

A basic problem with the certification of palm oil as "sustainable" is that there is more than one market for the product. To simplify a bit, there are two main markets: one for food and the other for fuel. In the food market, there is little significant demand for sustainability. But there is significant demand for sustainability in the palm oil fuels market. The rational response of producers of palm oil is to reclassify existing production as "sustainable." If the food demand for palm oil is increasing to the degree that there is pressure to open up new forest land for cropping purposes,

Table 1

Energy Independence at Hand? Lifecycle development for selected biofuels

Stage of development	Palm Oil	Jatropha	Algae	Fischer Tropsch
Theory	*	*	*	*
Lab testing	*	*	Old Dominion University, Va.	*
Pilot program	*	Xenerga (Fla.) to produce plants with higher-octane oil	Solex Biofuels (Colo.), Xcel (Minn.), Shell (Hawaii), PetroSun (Ariz., Texas, N.M.)	Bio feedstock: VTT (Finland), GTI (U.S.)
Commercial availability	*	Indonesia, Malaysia, India, China, Africa, Mexico and Brazil	PetroSun, Green Fuel Technologies	Bio feedstock: Siemens (Netherlands), Shell-Choren (Germany), Vamamo (Sweden)
Market penetration	Widely used as an edible oil; produced mainly in Malaysia and Indonesia	D1 Oils (UK), Mission Biofuels (Australia), ESV Bio (Africa), Duelco (S. Africa)		Gas feedstock: Shell, Sasol

the new land will be cleared to provide for the food market, and land already under palm oil cultivation will be designated "sustainable" and used for biofuel. In addition, because of its fungibility — palm oil for food does not differ from that for fuel — efforts to track which oil comes from which land will incur considerable expense. It is probably impracticable to verify the origins of the oil.

In the case of crops such as jatropha where the oil from the plant is not edible, it might be argued that restricting the crop to "marginal" land that was not used for other purposes will avoid the deleterious impacts and ineffectiveness of sustainability restrictions on food/fuel feedstocks. Abandoned agricultural land, for instance, is seen as ideal for cultivating jatropha. The difficulty with this approach is that while jatropha can grow on marginal land with few nutrients or much water, its yields on such land are very low, making the economics of using jatropha as a fuel feedstock tenuous. It is precisely the land that is more suitable for agriculture for food crops that provides good conditions for growing jatropha.

Biofuels are thus subject to a sort of Gresham's Law, except that instead of bad money chasing out good, environmentally harmful uses of the plants will replace sustainable uses. And true across-the-board sustainability restrictions, to the extent they are possible, will drive up the price of both the fuel feedstock and the food.

ONE PRICE Many advocate the use of biofuels as a way to end the grip that petroleum prices have on consumers. But under reasonable assumptions, this "energy independence" is not possible. Initially, palm oil producers will set their price to be close to crude petroleum, less the cost of turning the palm oil into a crude petroleum equivalent. That may generate excess profits for palm oil producers. If so, entry will occur until risk-adjusted profits in palm oil do not differ from profits in other sectors of the economy, including petroleum.

But in equilibrium, we do not believe that the price of biofuels will ever be lower than the price of petroleum. If the world really implemented a binding sustainability mandate, the restrictions on land inputs would restrict output and increase the price until the biofuel price equaled petroleum. And the owners of land would receive rents. But even if the market segmented and the sustainability constraint was not binding, the use of less and less productive land to make biofuels would increase the cost to petroleum levels long before petroleum was replaced. For example, in 2006 and 2007 palm oil was refined into biodiesel by a number of producers in Southeast Asia. A significant surge in palm oil prices followed, starting in March of 2007. As the price exceeded the equivalent oil price, the palm oil refineries shut down. A portion of the price hike may be transitory, attributable to the failure of the rapeseed crop in China, but our interviews with experts suggest that the price trend is long-term and driven by demand caused by a rising population that is increasingly affluent and health conscious and views palm oil as superior to animal fat for cooking.

CONCLUSION Demand for first-generation biofuels such as ethanol has put significant upward pressure on food prices. Emphasis in the biofuel community has shifted to second-generation biofuels as a means of dealing with imminent climate change regulations and the increased drive for energy independence. However, it is clear that second-generation biofuels have a long way to go in their development.

Moreover, even if they become commercialized, the new biofuels will not be available at prices that are lower than the prevailing price of petroleum because both will be substitutes for each other. Some have argued that second-generation biofuels may help bring down the price of petroleum, but we believe that productive land will become scarce long before sufficient biofuel supply exists to bring down the price of world oil. And we know of no method to prevent biofuel use from increasing food prices. Even jatropha and algae — never likely to become major food crops — compete for the same natural resources as food crops. R

Readings

- "Growing Energy: How Biofuels Can Help End America's Oil Dependence," by Nathaniel Greene. Natural Resources Defense Council, December 2004.
- "Neither Renewable Nor Reliable," by James Eaves and Stephen Eaves. *Regulation*, Vol. 30, No. 3 (Fall 2007).
- "Review of Environmental, Economic, and Policy Aspects of Biofuels," by Deepak Rajagopal and David Zilberman. The World Bank, September 2007.

An Accountability Agenda

By Jerry Brito and Jerry Ellig

Mercatus Center

The 2008 financial crisis has propelled politicians in both political parties to call for increased regulation. Democrats wave a bloody shirt called "deregulation" the way 19th-century Republicans blamed Democrats for the Civil War. President Bush, meanwhile, has presided over a massive increase in the power of the Federal Reserve and Treasury Department to underwrite bad investments and supervise financial firms. We've even received inquiries from news reporters asking if the "death of deregulation" in the financial sphere also presages new waves of health, safety, and environmental regulation.

Another political trend, however, offers hope that new regulatory initiatives could be better designed, more effective in producing public benefits, and less costly to the economy. Initia-

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tives to promote transparency, accountability, and improved government performance have the potential to expand the role of social science in making regulation more rational. And we have some very specific suggestions for how the Obama administration could more closely align regulatory analysis with government performance management.

TWO INITIATIVES Both regulatory analysis and government performance management seek to identify the nature of the problems government is trying to solve, develop alternative solutions, and evaluate the effectiveness and costs of the alternatives. Both require measurement of costs and outcomes. Both involve rigorous analysis to identify whether, and to what extent, government actions cause particular results to occur. Their analytical methods can be used *ex ante* to evaluate alternative prospective courses of action, or *ex post* to assess what consequences actually flowed from the alternative that was chosen and identify opportunities for improvement.

Nevertheless, scholars who specialize in performance management tend to be in public administration or policy analysis departments; scholars who focus on regulatory analysis tend to be economists or lawyers. Ideologically, performance management is usually viewed as a means of making government more effective and customer-focused; regulatory analysis is often characterized as an attempt to throw sand in the gears of the regulatory state.

For the U.S. government, the most prominent performance management directive is the Government Performance and Results Act of 1993 (GPRA). The principal source of regulatory analysis mandates is President Bill Clinton's Executive Order 12,866. In federal agencies, the plans and reports mandated by GPRA are usually the responsibility of the chief financial officer or a senior official in charge of management. Regulatory analysis is usually the responsibility of a policy office that writes regulations or an economic analysis division. Even in the President's Office of Management and Budget, which oversees both performance management and regulatory analysis, responsibility is divided. GPRA guidance and other performance-related initiatives are under the OMB's deputy director for management. Regulatory analysis is overseen by the Office of Information and Regulatory Affairs (OIRA).

REVIEW Some of the most senseless aspects of regulatory policy stem from the federal government's failure to apply basic principles of transparency and performance management to regulation.

The subprime lending crisis, for example, arose in large part because federal regulation of lenders sought to pursue two contradictory outcomes: safety and soundness, and encouraging homeownership through extension of credit to risky borrowers. Politicians wanted to promote affordable housing for low-income households, but they hid the risks (temporarily) by pushing banks to make subprime loans and pushing the government-sponsored mortgage giants Fannie Mae and Freddie Mac to buy subprime loans. A transparent policy to assist low-income borrowers without jeopardizing the safety of the financial system would have directly subsidized interest rate buy-downs, thus giving low-income borrowers mortgages they could afford without pushing excessive risks onto the financial system.

The Federal Communications Commission's universal service programs that subsidize phone service in rural communities provide another example. Essentially, the programs tax all telephone customers to subsidize a subset of customers. The Telecommunications Act of 1996 states that universal service programs are supposed to make telecommunications services in rural areas available at prices reasonably comparable to those in urban areas. In July 2008, a Government Accountability Office report pointed out that the FCC has disbursed $30 billion in subsidies for rural and high-cost areas without ever measuring the outcomes the program is supposed to achieve. Simply put, we do not know whether, or how much, the availability and affordability of telecommunications service in rural areas have improved as a result of the $30 billion in expenditures. (In September, the FCC launched a Notice of Inquiry asking how it should measure outcomes for the programs.)

More generally, EO 12,866 and a host of legislative mandates require agencies to perform retroactive review of regulations to assess what needs to be modified and/or repealed. In the absence of well-defined outcome measures and data, however, agencies cannot even know whether regulations are accomplishing their intended goals.

The OMB's annual report on the costs and benefits of federal regulations relies largely upon estimates that agencies produce in their Regulatory Impact Analyses prior to adoption of the regulations. A 2007 GAO report found that nine federal agencies conducted more than 1,300 regulatory reviews between 2001 and 2006, of widely varying scope. The report notes, "Our limited review of agency summaries and reports on completed retrospective reviews revealed that agencies' reviews more often attempted to assess the effectiveness of their implementation of the regulation rather than the effectiveness of the regulation in achieving its goal." In other words, regulators are trying to steer while looking in

the rearview mirror, but in fact the rearview mirror is missing.

A colleague of ours who served as chief economist at a federal agency once noted, "You could always identify the newly-hired economist. That was the guy running down the hall screaming, 'I can't believe they're trying to do this!'" The examples we cite should of course make students of benefit-cost analysis recoil in horror. But they should also disturb anyone genuinely concerned about effective, performance-based governance. Rationality makes strange bedfellows.

PROPOSALS The OMB guidance documents — notably EO 12,866 and Circular A-11 (which includes GPRA guidance) — incorporate many key principles of performance management and regulatory analysis that are well grounded in scholarly literature. Yet no administration has fully exploited the potential synergies. Revising the documents would help ensure that federal regulatory analysis more fully reflects best practices in performance management, and that federal performance management more fully reflects best practices in regulatory analysis.

Concerning EO 12,866, we recommend the following revisions:

■ **Incorporate GPRA-style performance measurement into proposed regulations**. Intuition and evidence both suggest that much of the value of strategic planning and performance measurement stems from what managers learn from going through the measurement process, rather than the value of the plan or report after it is written. As Dwight Eisenhower remarked, "Plans are useless, but planning is indispensable." Agency efforts have greater focus, direction, and effectiveness when a tangible outcome is defined, measures are identified, and goals are set. There is no reason regulators would not benefit from such an improved focus when writing regulations. Therefore, EO 12,866 should explicitly require agencies to identify the specific outcomes of value to the public that the regulation is supposed to produce, explain how those outcomes are related to one or more strategic goals in the agency's GPRA-mandated strategic plan, and identify what indicators the agency will use to measure progress toward the outcomes. The proposed outcomes, goals, and measures should be included in any Notice of Proposed Rulemaking so that the public has an opportunity to comment on them.

■ **Require independent annual retrospective cost and benefit estimates.** EO 12,866 requires agencies to periodically review significant regulations to determine whether they should be modified or eliminated. Apparently, few agencies have done extensive retrospective analysis. To remedy that problem, the executive order should be amended to require agencies to arrange for and publicly release independent annual assessments of the *ex post* costs and benefits of existing regulations.

GPRA requires agencies to produce strategic plans, annual performance plans, and annual performance reports. It does not explicitly require agencies to do sound strategic planning or use the plans and reports to guide action. Yet GPRA's Statement of Purpose, as well as the Senate Government Affairs Committee's report on GPRA, indicate that the spirit of the law goes beyond reporting to include action. In light of that, we recommend the following revisions to Circular A-11:

■ **Require analysis of alternatives in strategic planning and performance reporting.** Consideration of alternatives is a critical element of sound decision-making. "Steer, don't row" was one of the fundamental credos of the "reinventing government" movement that spawned GPRA. The OMB could promote consideration of alternatives through two changes to Circular A-11. First, the circular should instruct agencies to include in their strategic plans a discussion of the benefits and costs of alternative ways of accomplishing their goals — much like EO 12,866 requires agencies to consider a wide range of alternative regulations and alternatives to regulation. Second, the circular should instruct agencies to include in their annual performance reports a discussion of alternative approaches to remedy performance shortfalls (failures to meet goals). Because Circular A-11 applies to independent as well as executive agencies, our proposed changes would encourage independent agencies to consider a wide range of alternatives — something they do not currently have to do unless required by specific legislative mandates.

■ **Require assessment of costs and benefits of regulation in performance reports.** Since regulatory agencies accomplish their goals through regulation, they should be expected to understand and report on the results produced by their regulations. A GPRA performance report is the appropriate place for agencies to report on the benefits and costs that result from all the regulations that substantially advance their strategic goals. Circular A-11 should require agencies to enumerate in their performance reports the primary regulations or groups of regulations that contribute to the accomplishment of each strategic goal, along with an assessment of outcomes and costs. If a regulatory agency truly understands how its major regulations or groups of regulations accomplish its goals, this should not be hard to do. For independent agencies, this change to Circular A-11 might provide the primary motivation to conduct retrospective analysis of actual benefits and costs produced by regulation.

■ **Require regulatory agencies to**

report on opportunity costs. GPRA authorized experiments in performance-based budgeting. The OMB advanced the concept further in Circular A-11 by directing agencies to prepare performance-based budgets in order to satisfy GPRA's requirement for annual performance plans. For many types of federal programs, comparing outcomes with the cost to the federal treasury should provide a reasonable means of assessing benefits and costs. But regulation is different. Regulatory agencies accomplish outcomes not by spending federal tax dollars, but by directing citizens to do specific things with their own resources. These mandates do not just impose monetary costs; they also alter prices in ways that distort decisions and give rise to additional social costs — the forgone value that economists call "deadweight loss." Enhanced airport security after the 9/11 terrorist attacks, for instance, did not just increase monetary costs and passenger waiting times; it also prompted some passengers to forgo flying. One back-of-the-envelope calculation suggests that the additional cost of federalized airport screening generated a deadweight loss almost as large as the revenues raised by the "9/11 fee" that funds the screening. In addition, a November 2007 study published in the *Journal of Law and Economics* estimated that enhanced airport security led to 129 more highway fatalities in the fourth quarter of 2002 because passengers substituted driving for flying on short trips. Opportunity costs of regulation can be large. Therefore, Circular A-11 should explicitly direct agencies to report on the opportunity cost to society of regulations related to their strategic goals, not just their expenditures to promulgate and enforce regulations.

ENFORCEMENT Agency regulatory analysis is a creature of the executive branch that has its roots in Richard Nixon's "Quality of Life" review process, and that is now embodied in EO 12,866. Expanding its scope to include some performance management practices is completely within the president's power. OIRA is currently charged with checking that agencies have complied with the executive order and it could also be tasked with performance management requirements.

The executive order, however, does not apply to independent commissions. That said, the president could appoint only commissioners and chairpersons that agree with him on the importance of performance management. Additionally, GPRA does apply to independent commissions and the OMB is tasked with interpreting the act and giving agencies and commissions compliance guidance. The president could try to make independent agencies engage in some regulatory review by inserting a requirement in Circular A-11. However, there is no procedural check like the one OIRA provides for executive agency regulatory analysis. It would be up to Congress to enforce a requirement.

CONCLUSION Effective performance management of regulatory agencies requires regulatory analysis. Conversely, regulatory analysis is nothing more than sound strategic planning and performance management applied to regulation. The changes we suggest would go a long way toward integrating and strengthening performance management and regulatory analysis in regulatory agencies. R

Doctors for Gun Control

By Robert A. Levy
Cato Institute

Just weeks after the Supreme Court issued its blockbuster opinion in the landmark Second Amendment case *District of Columbia v. Heller,* two prominent medical journals were in print with an editorial and two articles asserting that guns at home are a major public health problem.

First off the press was the July 31, 2008, *New England Journal of Medicine* editorial "Guns and Health," citing statistics from the Centers for Disease Control and Prevention on the number of injuries and deaths from handgun use. Five weeks later, the same journal published "Guns and Suicides in the United States," by the Harvard School of Public Health's Matthew Miller and David Hemenway, summarizing studies purporting to establish a direct relationship between suicides and household gun ownership. Four weeks later, Georgetown University law professor Lawrence Gostin expanded on the guns-cause-violence theme in "The Right to Bear Arms," a brief paper on gun control law and politics that appeared in *JAMA: The Journal of the American Medical Association.*

The articles and editorial raise two important questions: Is there persuasive empirical data that lawful gun ownership makes the public less safe? If so, would public safety be enhanced by tighter gun controls? There is a rich academic literature examining those questions, and the literature indicates "No" for both questions.

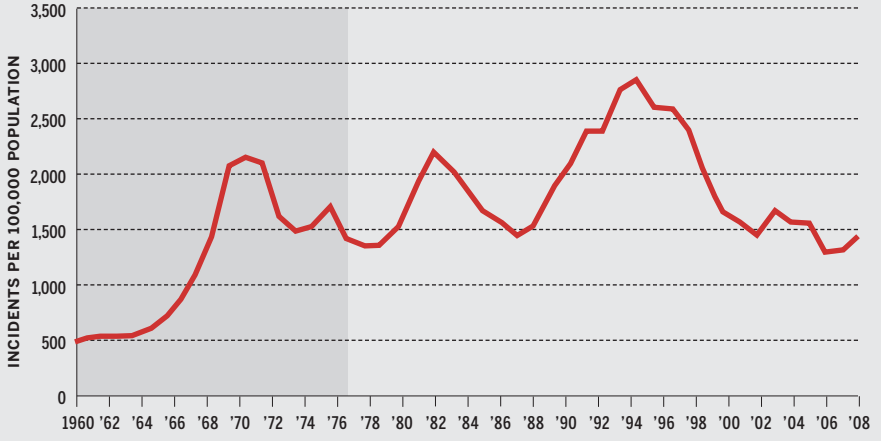
Disappointingly, neither the *NEJM* nor *JAMA* wants to discuss those peer-reviewed studies. Indeed, when I offered to write a short article in response to the *NEJM* editorial, my offer was declined. When I volunteered to convert the short article into an even shorter letter-to-the-editor, that too was declined. Other lawyers have written for the *NEJM*, but none represented Mr. Heller before the Supreme Court as I did. Perhaps view-

Robert A. Levy is incoming chairman of the board of the Cato Institute. He was co-counsel to Dick Heller in *District of Columbia v. Heller.*

Figure 1

District of Columbia Violent Crime Rate

Gun ban implemented September 24, 1976

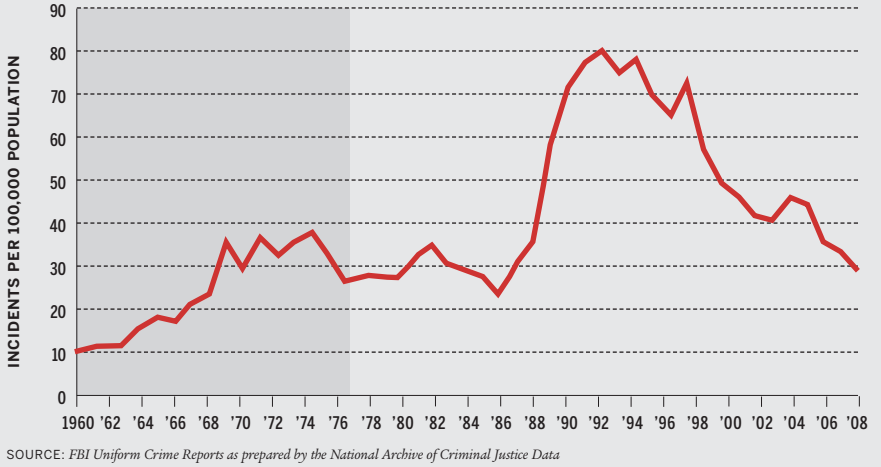


SOURCE: *FBI Uniform Crime Reports as prepared by the National Archive of Criminal Justice Data*

Figure 2

District of Columbia Homicide Rate

Gun ban implemented September 24, 1976



SOURCE: *FBI Uniform Crime Reports as prepared by the National Archive of Criminal Justice Data*

point discrimination explains the one-sided coverage of this issue by both the *NEJM* and *JAMA*. So I will share a few of those counter-arguments here.

GUNS AND SAFETY The *NEJM's* editors cite, with justifiable concern, CDC data on handgun-related injuries and deaths. But the editors ignore a comprehensive 2003 CDC report on the efficacy of firearms and ammunition bans, restrictions on acquisition, waiting periods, registration, licensing, child access prevention laws, and zero tolerance laws. The report's conclusion: There is "insufficient evidence to determine the effectiveness of any of the firearms laws or combinations of laws reviewed on violent outcomes."

"Research has shown," the *NEJM* editorial claims, "that fewer restrictions on handguns will result in a substantial increase in injury and death." To the contrary: a 2004 National Academy of Sciences review of 253 journal articles, 99 books, and 43 government publications evaluating 80 gun-control measures concluded that "existing research studies ... do not credibly demonstrate a causal relationship between the ownership of firearms and the causes or prevention of criminal violence or suicide."

The *NEJM* editorial writer does offer one citation to specific data on the relationship between guns and public health: a 1991 *NEJM* article ostensibly documenting a 25 percent decline in gun-related homicides and suicides immediately after the District of Columbia enacted its 1976 gun ban. But that study has been discredited for its biased selection of comparable jurisdictions, failure to adjust for D.C.'s declining population, disregard of other explanatory variables, and selective choice of time periods. Further, a 1996 paper in the *Law and Society Review* found that if the study, which ended in 1987, had been extended by just two years, the observed decline would have disappeared.

Interestingly, the District exempted pre-existing handguns from its 1976 ban. If handgun availability were positively linked to suicides, one would expect suicides to decline progressively as owners gradually sold, discarded, or removed pre-1976 guns from the city. But the suicide rate was the same in 1998 (7.6 per 100,000) as it was in 1981, and ranged from 4.9 to 11.8 during the intervening period. The decline in suicides reported in the 1991 *NEJM* article was a temporary, random phenomenon.

Looking at suicide data cross-sectionally — e.g., comparing states having the highest rates of gun ownership with states having the lowest rates — Miller and Hemenway conclude in their *NEJM* article that high gun ownership goes hand-in-hand with high rates of firearm suicide and overall suicide. But numerous studies, not cited in their article, have concluded otherwise. Florida State University criminologist Gary Kleck, for example, cites studies based on local, national, and international data showing that nations with fewer guns do not have fewer suicides. New York University law professor James B. Jacobs confirms that the U.S. suicide rate is equal to the average for industrialized nations, despite America's higher rate of gun ownership.

Correlation studies between suicide rates and gun ownership are further complicated by confounding variables — including differences in the percentages of single-parent households, the portion of the population that hunts, and the preponderance of selected racial and ethnic groups (most importantly, African-Americans, who have a much lower suicide rate than whites). The association of confounding variables with both suicide and gun ownership can make it appear

that suicide and gun ownership are themselves correlated, when they are not.

REGULATION AND SAFETY Even if it could be shown that suicides, crime, or accidents increase as gun ownership increases, the preventive or remedial effect of gun control must also be demonstrated. On that question, the *NEJM* editorial simply asserts that the problem of firearm injuries "seems certain to be exacerbated with less handgun regulation." That is a gross and careless overstatement. There is little reliable evidence — much less certainty — of a statistically significant inverse relationship between handgun regulations and firearms injuries. In fact, much of the evidence points to a direct relationship: more regulations limit the deterrent effect of defensive firearms and lead, therefore, to more injuries.

Washington, D.C., affords a crystalline example: Since implementation of the District's ban, the city's murder rate has fallen only once below what it was in 1976. The overall violent crime rate in D.C. dropped below its 1976 level in only four years during the three ensuing decades. Most distressing, the District has ranked first or second in yearly murders 15 times since the ban has been in place. FBI data for 2006 indicate that the District's murder rate was more than five times higher than the national average, and more than double the rate in comparably sized cities — none of which had gun laws as restrictive as the District's.

Perhaps recognizing that crime data provide compelling support for the proposition that gun control doesn't work, Gostin's article in *JAMA* highlights accident statistics. "A gun in the home is far more likely to be involved in killing a family member than an intruder," insists Gostin. Even if true, the point is irrelevant. The benefit of a gun in the home is not to shoot bad guys; that rarely happens. The real benefit is the deterrent effect on the commission of crime. Peer-reviewed studies indicate that guns are used defensively — almost always brandished, not fired — five times more often than they are involved in violent acts. More important, the *JAMA* article does not consider the countless instances of violent acts *not* undertaken because the potential victims might be able to defend themselves with suitable firearms.

BURDEN OF PROOF One final point: A few seemingly sophisticated statistical analyses suggest that more firearms mean more gun violence, and more gun regulations will alleviate the problem. But many more analyses suggest the opposite. How then should a court, considering the tradeoff between public health and the Second Amendment, weigh the evidence? Do the regulators or the firearms rights advocates have the burden of proof? That is a legal, not social science, question.

When courts review regulations to determine whether they pass constitutional muster, judges must first decide how rigorously they will scrutinize enactments of the legislative branch. Under so-called rational basis scrutiny, courts typically rubber-stamp whatever the legislature passes as long as the judge can conceive of a legitimate justification for the law. Challengers face a heavy burden in showing that no rational basis exists. At the other extreme is "strict scrutiny," whereby courts will demand proof from government that state interests are compelling and the regulation is no more restrictive than necessary to attain the desired goal.

In *District of Columbia v. Heller*, the Supreme Court categorically rejected rational basis scrutiny for the review of firearms laws. Something higher is demanded, said Justice Antonin Scalia, when an express constitutional right is at issue; the District's ban on all functional firearms in the home was unconstitutional "under any of the standards of scrutiny the Court has applied to enumerated constitutional rights." Although the Court did not explicitly adopt strict scrutiny, it certainly moved in that direction.

It is clear, post-*Heller*, that government has the burden of proof in justifying gun regulations that might infringe on Second Amendment rights. It is equally clear — notwithstanding the predisposition of the *NEJM* and *JAMA* — that the regulators have not met their burden. R

Readings

- "A Reassessment of the D.C. Gun Law: Some Cautionary Notes on the Use of Interrupted Time Series Designs for Policy Impact Assessment," by Chester L. Britt, Gary Kleck, and David J. Bordua. *Law and Society Review*, Vol. 30 (1996).
- *Firearms and Violence: A Critical Review*, edited by Charles F. Wellford, John V. Pepper, and Carol V. Petrie. National Academy of Sciences, 2004.
- "First Reports Evaluating the Effectiveness of Strategies for Preventing Violence: Firearms Laws," by Robert A. Hahn, O. Bilukha, A. Crosby, et al. Centers for Disease Control and Prevention, October 3, 2003.

Harming Patients' Condition

By Henry I. Miller

Hoover Institution

One of the cornerstones of American medicine is the flexibility of physicians to prescribe drugs for "off-label" uses that have not yet been approved by the Food and Drug Administration. Instead, the prescriptions are based on doctors' reading of the medical literature and their own professional judgment. This "practice of medicine" traditionally has not been constrained by federal drug regulators. With the exception of certain "controlled substances" such as narcotics, drugs generally may be freely prescribed and advertised.

During the past several years, however, the increasingly risk-averse Congress and FDA have been gradually moving

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toward what amounts to "conditional" or limited approvals of new drugs that place various restrictions on their prescribing, distribution, sale, and advertising. At the same time, they have imposed additional requirements for the demonstration of safety and efficacy in order to obtain even those limited approvals. That has delivered a devastating double-whammy to patients and has damaged one of the nation's most innovative and critical industries.

As a result, at a time when drug development should have been spurred by huge increases in research and development expenditures — which tripled to more than $45 billion between 1995 and 2007 — and by the exploitation of numerous new technologies, drug approvals have actually dropped. The 19 approvals in 2007 were the lowest in 24 years, and 2008's figures are running behind last year's.

NO DRUGS, NO PROBLEMS Bringing a new drug to market now requires, on average, 12–15 years and costs more than $1.2 billion in direct and indirect expenses. Several recent developments at the FDA will further increase the time and cost of drug development — bad news for the developers of medicines and for the sick and infirm who need new therapies.

One such development is a Memorandum of Agreement between two groups within the FDA's Center for Drug Evaluation and Research. It specifies that the drug review and drug safety offices will have equal responsibility on "significant safety issues" for medicines that are under review or already have been approved for marketing. Examples include:

- changes in labeling that pertain to safety;
- the establishment or revision of a drug's risk management plan (which can range from educational programs for physicians and pharmacists, to highly restrictive limits on prescribing and advertising);
- withdrawal of a drug from the market; and
- the requirement for post-approval clinical trials or epidemiological studies.

To those unfamiliar with the nuances of drug regulation, the implications of this development will likely be obscure, but they are important. The officials in the FDA's Office of Surveillance and Epidemiology (OSE) are focused so narrowly on "safety" that they ignore the fact that because all drugs have side-effects, safety cannot be evaluated in a vacuum but must be part of a complex cost-benefit judgment. Their motto might be, "If you don't approve any new drugs, you don't have any safety problems."

Worse still, some of them are true-believers — not in the need for new drugs, but in the venality of drug companies and the inherent dangers of their products. Former FDA senior official and former Wyeth vice president D. Bruce Burlington described succinctly the inherent bias of the drug safety minions: "OSE has a vested interest in finding problems." Up to now, the drug safety staff has had an advisory, largely subordinate role, but the new arrangement compounds the already high risk aversion of the FDA's new drug review divisions with the blinkered, safety-obsessed views of the OSE.

How does this affect regulated industry? Former deputy FDA commissioner Mary Pendergast, now a regulatory consultant, tells the story of one of her clients who had an agreement on safety issues with the Office of New Drugs, only to have it overruled by the OSE. There are other, similar examples.

Another troubling development, related to the first, is that the 2007 FDA Amendments Act gave the agency new authority to act on drugs under review or already marketed, including the ability to require Risk Evaluation and Mitigation Plans (REMS). REMS can include a Medication Guide, Patient Package Insert, communication plan, an implementation system, and also must include a timetable for assessment of the REMS. Another required component is "elements to assure safe use," which may include strict restriction of the drug to specified patient populations, distribution only by certain specialty pharmacies, required laboratory findings and/or monitoring, advertising permitted only to certain physician specialists, and patient enrollment in a central registry. Those limitations and requirements, in effect, constitute "conditional" approvals that create new obstacles to patients' getting needed medicines.

A third development is an FDA advisory panel's recommendation that regulators require studies of the long-term cardiovascular risks of new diabetes drugs before they can be marketed, even if they

show no sign of such problems in the usual large trials performed to demonstrate safety and efficacy. If regulators accept this recommendation, it would add tens of millions of dollars and years of delay to drug development. Ira Loss, who tracks the drug industry for Washington Analysis Corp., an independent investment research firm, was quoted in a Bloomberg wire article as predicting a major impact on research and development of new diabetes drugs: "It would be a major setback to drug development. Anybody who is developing a drug for diabetes is at risk. If they put new burdens on the industry, it could in the worst case bring to a halt any new diabetes drugs for some time." And diabetes drugs are only a microcosm of the universe of all medicines in development.

Fourth, the advisory panel recommendation follows recent guidance by the FDA to two drug companies that their new lipid-lowering drugs would need to show not only the ability to exert a favorable effect on laboratory values — such as lowering LDL cholesterol — but that clinical trials would also need to show a positive effect on "genuine" clinical outcomes, such as fewer heart attacks and strokes, or even lengthened survival.

Even critical cancer drugs have been treated shabbily by regulators. In a 2007 commentary in the *Wall Street Journal*, oncologist Richard A. Miller decried the FDA's unwillingness to grant even limited approvals to five potentially important cancer drugs that had shown significant evidence of efficacy. "In each case, the FDA overlooked substantial evidence of the drug's positive impact in slowing the progression of killer cancers and improving quality of life — evidence that should have been at least sufficient to warrant conditional approvals under established regulations that have been eroded by the Agency's bureaucratic intransigence."

These new standards for drugs' efficacy remind me of a cartoon that shows two researchers in the laboratory, one of whom is holding a flask. He says to his colleague, "Well, it looks as though we've finally done it — discovered a drug that will confer immortality. The only trouble is, it will take forever to test it."

Instead of checking the FDA's excesses using its role of oversight over federal agencies, Congress has thrown gasoline on the conflagration. Rep. Rosa DeLauro (D-Conn.) has proposed legislation that would establish a three-year moratorium on direct-to-consumer advertising, because "we must ensure consumers know what they are getting, and drug makers know what they are promising." This new limitation on newly approved drugs, yet another element of a "conditional" approval, is unnecessary and unwise because studies show that newer drugs are, on average, better at saving lives than older ones, and that direct-to-consumer advertising induces patients to seek professional help for their ailments earlier than they would otherwise. Moreover, this measure would make it even less likely that drug companies could recoup their development costs on a drug before its patent runs out. (As it is, only 20 percent of approved drugs garner sufficient revenues to recoup the research and development costs for the manufacturer.)

Intimidated by such proposals and other forms of relentless pressure from Congress, in June 2007, the pharmaceutical giants Merck, Schering-Plough, Johnson and Johnson, and Pfizer announced a six-month moratorium on direct-to-consumer ads for new drugs and volunteered to limit how they would use doctors in their ads. The advertising moratorium is only the beginning of what will likely be a long period of debilitating capitulation to anti-innovative, anti-patient regulatory policies. The drug industry's primary trade association, the Pharmaceutical Research and Manufacturers of America (headed by former congressman Billy Tauzin), has begun to formulate an appeasement plan for "regulatory reform" — reform of the kind that will make drug development even slower, more expensive, and more uncertain than it is currently. There is nothing on the horizon that can slow the regulatory juggernaut.

The bottom line is that the new conditional approvals will worsen the condition of patients and drug companies. At a time when the U.S. population is aging and needs innovative new medicines for a wide spectrum of degenerative and infectious diseases, the changes are not what the doctor ordered. R

Legislating Life's Value

Robert Hahn, *American Enterprise Institute*
and Peter Passell, *Milken Institute*

Back in 2005, the White House Council on Environmental Quality was roundly criticized for censoring government scientists' latest warnings about climate change. Republicans, it was claimed, were breaching a carefully preserved wall between science and ideology. Yet, in a little noticed move, Senate Democrats led by Barbara Boxer of California are breaching the same wall by trying to bar the Environmental Protection Agency from making scientifically objective calculations of what economists call the "value of a statistical life" (VSL).

The Boxer assault on scientific method is no small matter. A dozen federal agencies use VSL calculations in deciding everything from mandates for new safety equipment in airliners to acceptable levels of toxic chemicals in drinking water. And without the anchor of objective measurements of how much people are prepared to pay to avoid small chances of catastrophe in everyday life, decisions about which

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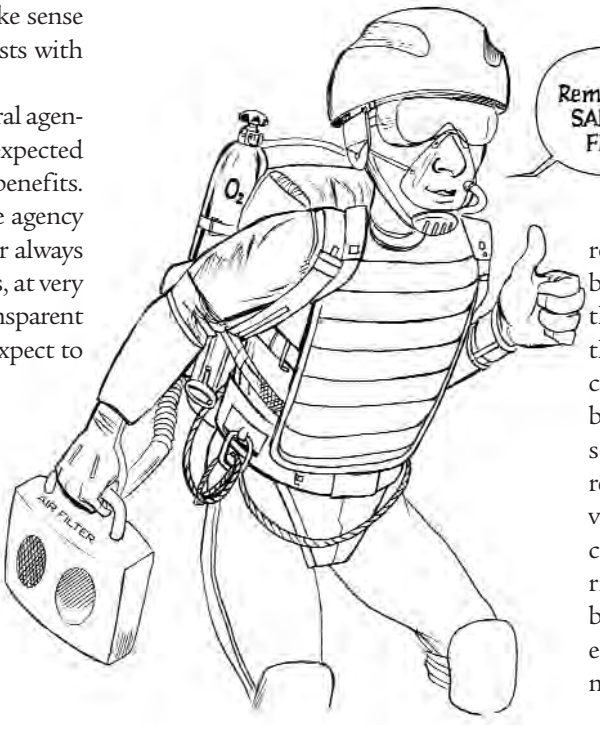
costly life-saving regulations make sense will largely devolve to the lobbyists with the most muscle.

Some background: Most federal agencies are required to weigh the expected costs of a rule against its likely benefits. That's surely a good thing; while agency methods are neither uniform nor always reasonable, the requirement does, at very least, force regulators to make transparent assessments of both what they expect to achieve and what will be sacrificed in the process.

But many federal regulations are aimed at saving lives. How can the bean counters possibly put a price tag on that most precious, intangible benefit?



It is not enough to say that life is infinitely valuable. By that logic, all the benefits derived from using cars or electricity or swimming pools wouldn't be worth the risk of a single fatal accident, and those modern conveniences should be done away with. Nor is it enough to say that the value of life simply can't be quantified; we make rough quantifications everyday when we decide whether the purchase of various safety features or devices is worthwhile, given our limited financial resources. The same is true with policymaking; one way or another, someone is implicitly valuing life in deciding whether to mandate spending an extra billion dollars on liver transplants or air bags.

CALCULATING VSL Economists have a way around the quantification problem: infer the value of life from the way ordinary people trade off safety against other goods and services. Practically everyone, it is safe to say, would spend all they have to escape certain death if trapped in a burning house. But how much are they willing to spend on smoke detectors that reduce the risk of dying at home from, say, one chance in 10,000 to one chance in 100,000? If we can measure that figure, then we can turn the calculation on its head and place a number on the value people implicitly place on their own lives.

A dozen objections no doubt come to mind. Do people really know how useful smoke detectors (or mammograms, or lightning rods) are when they contemplate their purchases? Does the value to the consumer accurately incorporate the value to family and friends who may also benefit? Can we legitimately infer the value of life to a hunter wintering in rural Alaska from the consumer behavior of Los Angeles suburbanites?

But the core concept certainly passes the sniff test — who, after all, better knows the value of life than the person at risk? And in dozens of studies over the past few decades, researchers have found sufficient consistency (and a narrow enough range) in the estimates to make a reasonable case for the numbers. Accordingly, agencies ranging from the Mine Safety and Health Administration to the Food and Drug Administration have been pressured by both the Clinton and Bush administrations to use VSL estimates in their calculations of benefits and costs.

KERFUFFLE Why, then, the current controversy? One reason is that few people buy the idea of VSL on first sight — the notion that analysts somehow assign a monetary value to life and make policy decisions based on that value seems offensive. And officials serving at the pleasure of politicians are hardly eager to take the heat for using it. For example, back in 2003, then-EPA administrator Christine Todd Whitman backed away from applying a discount to VSL calculations for the very old, once she'd gotten an earful from seniors in Tampa.

Equally to the point, VSL estimates can make a big difference in which proposed rules are promulgated and how they are written. Environmental groups are most concerned because many reject the very premise that the value of life should be compared to the value of workaday pleasures. But VSL calculations can cut both ways, offending business interests, too. Or even national security hawks: one analysis by researchers at Ohio State and the University of Newcastle concluded that the current pattern of U.S. Homeland Security outlays would save lives at a cost between $64 million and $600 million each —far in excess of the maximum $10 million VSL used by federal agencies.

The latest kerfuffle stems from a recent decision by the EPA to pare its VSL from $7.4 million (estimated in 1999 and subsequently adjusted for inflation) to $6.6 million. The new number (like the old) is based on a synthesis of dozens of independent studies of people's personal decisions in trading off the costs and benefits of risk reduction — this time updated to include current research. There is no evidence of hanky-panky here, no fingerprints of K Street lobbyists. But highly partisan wrangling over environmental regulation in recent years has injected a whiff of paranoia in reactions to almost every EPA decision. And last month, the Boxer-led Senate Environment and Public Works Committee reported out a bill freezing the agency's VSL at the old figure.

This is unfortunate because there is every reason to give the benefit of the doubt to EPA technocrats who are simply trying to take advantage of the latest scientific evidence. But the very fact that influential senators are willing to muscle scientists to come to conclusions more to their liking is bad news.

Congress rightly has the last word on agency-created regulations, and exercises it frequently. But there is a big difference between making public policy and undermining the integrity of objective government analysis that is vital to assessing policy. The distrust and cynicism created by crossing that line corrodes government — and democracy. R