
Briefly Noted

Too Many Commissioners?

BY NANCY A. NORD

Congress has created many independent multi-member commissions—including the U.S. Consumer Product Safety Commission—on the theory that their independence from the administration and the commissioners' staggered terms would enable the agencies to rise above politics and address crucial problems. Based on my experience, though, politics is precisely what the American public gets.

My experiences during three key periods at the CPSC shed light on the causes and effects of this partisanship. The first period happened immediately after a sweeping reform law passed, when there were two sitting commissioners; the second, after the president filled all five seats on the commission; and the third, when one commissioner's departure left the CPSC equally divided again. During the first period, commissioners cooperated and accomplished many big tasks. During the second period, when the commission was split 3-2 along party lines, controversy was common and key policies were determined with little regard to minority concerns. During the third period, cooperation again occurred, but it was not very deep and did not extend to truly controversial issues. And rather than resolve those controversial issues, they were put off until a partisan majority returned in October of this year.

The political and personal disagreements are the inevitable result of partisan multi-member commissions. But with good data and analysis, a single administrator can make decisions as good as or better than a commission, while avoiding the perils of partisanship. Drawing on the lessons of these experiences, I make a modest proposal: replace the five-member CPSC with a single administrator.

Two commissioners | The CPSC is an independent regulatory agency that was created 40 years ago during the Nixon administration to regulate unsafe consumer products. Originally, it had five members. But in the early 1980s, to save money, two commissioner spots were effectively wiped out by not appropriating money for them. The arrangement, effectively blessed by Congress, continued through the Clinton and both Bush administrations.

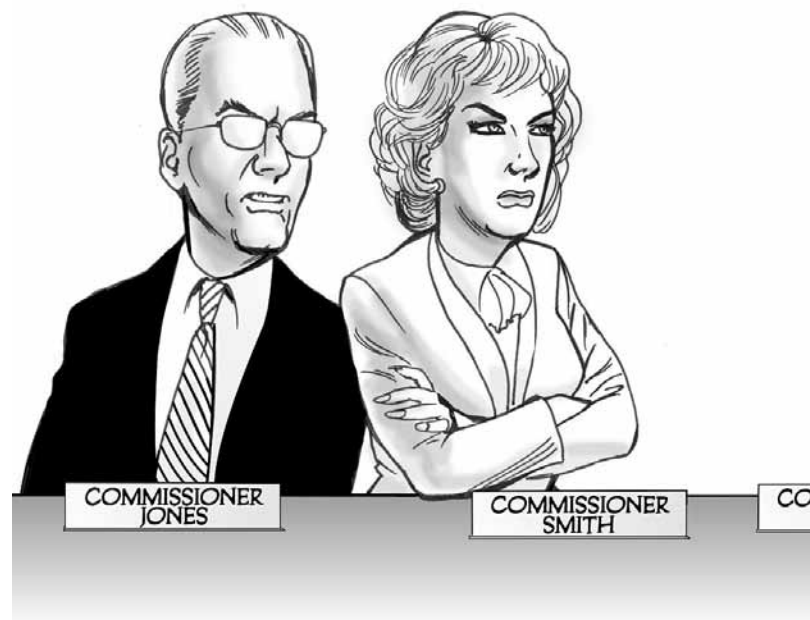
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In 2006, a vacancy arose on the three-seat commission. That left only two commissioners—a Democrat and me, a Republican—whose views often diverged. Then, in 2008, Congress passed legislation that immensely increased our authority but also our obligations, directing us to issue many regulations on an impossibly short timeline while giving us no new resources to accomplish the tasks.

Facing a long to-do list with only two commissioners, the options were for us to disagree and let the agency's work slow or stop, or to figure out where we could agree and implement the new law (while continuing our usual work as much as possible). I am pleased that my colleague and I took the latter approach. Even with our differences, we were able to find middle ground and get the job done. Frankly, we had to. No other course was open to us as responsible commissioners, and we both knew that. We put out over 25 rules and other significant regulatory actions in nine months. Considering the agency's typical pace, that was extraordinary.

Five commissioners | Contrast that to the period after the Obama administration arrived, when the president and Congress filled all of the open seats, including the two that had been reauthorized in recent legislation. This created a commission with five commissioners: three Democrats and two Republicans.

The result is unsurprising. Important policy issues routinely were decided on a 3-2 vote. Effectively, the three Democrats would



determine policy and then announce it to the Republicans. We did have conversations, and sometimes the minority even won a point or two. But these wins generally were on side issues, not central policies.

We in the minority did not sit idly by. Watching the majority use the agency's extensive communications tools to trumpet flawed policies, we went public with our concerns about the disputed decisions. On top of the traditional commissioners' statements attached to votes on rules and policies, I created a blog, *nancynord.net*, and began regularly posting my positions and rationales. My Republican colleague, Anne Northup, did the same. In our written statements, blog posts, tweets, and comments at public meetings, we have each been critical of the majority's decisions and the process leading to them.

Was this excessive partisanship by the majority or the minority? No; it was the result of elections, which have consequences. Presidents put their people into positions of power, and those appointees perform their duties according to their own understandings of their duties. On a commission with a required partisan split, disagreements about the way to perform duties are bound to come up.

Four commissioners | After the departure of a Democratic commissioner in the fall of 2011, things changed yet again. Some policy decisions were made unanimously. Though the process of achieving unanimity was long and often tedious, the results were generally reasonable. Consensus on important issues gives the public more confidence in those decisions. It is true that we

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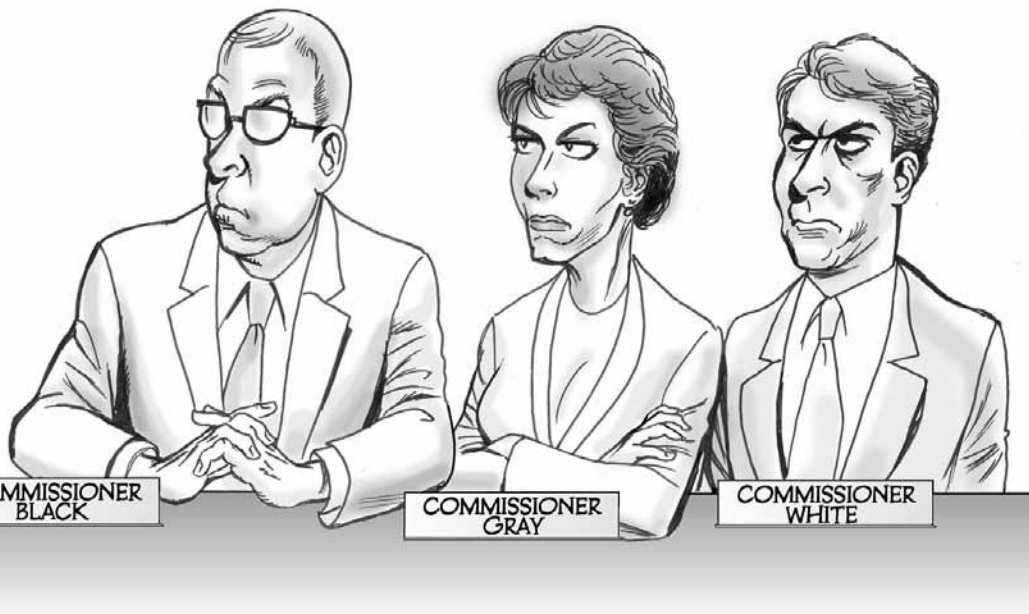
seemed to be working together because we had to, just as was the case in 2006–2009 when there were two commissioners. So if we are going to have a commission, making it equally divided appears to make members work together. But is that the answer?

Look underneath the cooperation and you will find that the consensus on many of these issues was thin and truly contentious issues were generally put off. In one recent instance, the commission appeared to agree unanimously on a modest set of improvements to a very divisive rule, but the agreement only extended to *considering* improvements and doing so at some uncertain future date. In another instance, the commission simply deadlocked 2–2, then later, under a new 2–1 Democratic majority, dusted off its failed proposal with no effort to address the concerns that had caused the deadlock. A quick turnaround from agreement to disagreement demonstrates that the consensus was not only the offspring of circumstance, but a rather sickly one at that.

Instead of hoping for clearheaded bipartisanship (or non-partisanship), I suggest that we re-examine the decision to put a multi-member body in charge of the CPSC. A well-informed single administrator with sole accountability for decisions, I have come to believe, is a better way to achieve underlying policy goals. Since decisions under the current structure are no less subject to political forces than they would be with a single administrator, we would lose no political independence, just a lot of political shouting.

Independence and reasoned analysis | The justification for these multi-member bodies is that they are independent because they have members from different political parties and backgrounds who serve staggered terms that bridge elections. But my experience at the CPSC indicates that commissioners' independence is more hope than reality. In non-unanimous votes, crossing party lines is rare. Only rarely during my tenure has it happened in a sharply contested matter, and in one instance the commissioner who joined the opposite party recanted that vote, citing a change of heart that came only after a concerted effort by forces outside the CPSC to change the result.

The occasions when independent agencies claim their prerogatives the most vigorously are, however, instructive. In response to presidential initiatives in the form of executive orders, agencies carefully deny any obligation to comply, but



they say they will voluntarily cooperate. This had been the standard practice at the CPSC, but a more dismissive tone seems to be emerging. When President Obama issued Executive Order 13579 last year, it was met not with the CPSC's typical obliging spirit, but with words of cooperation and actions of disregard.

Crucially, that order proposes using an important tool that a majority of commissioners have declined to use unless specifically required to do so by statute: cost-benefit analysis. This analysis has become increasingly important and accepted in the last four decades, embraced by Republican and Democratic administrations alike for its help in ensuring that regulations are effective but minimally burdensome. But for many of the CPSC's key recent regulations, no cost-benefit analysis was done. The majority essentially concluded that cost-benefit analysis was too onerous and time-consuming. They further pointed to the absence of a requirement to perform it (for certain rules) as an argument against doing it. Thus, when the CPSC approved two rules in the last two years with economic effects well over the \$100 million legal threshold for "major rules," it performed no cost-benefit analysis. They were only the second and third major rules in the history of the agency, but the majority refused to analyse their costs and benefits, and the results are significant rules with significant flaws.

A single administrator | If independent agencies were required to do cost-benefit analysis, compare the various regulatory options, and better justify their regulatory decisions with science and economics, would we need multi-member bodies like the CPSC? The hoped-for independence of commissioners seems unnecessary when considering other factors that contribute to modern rulemaking. First, good data and analysis—economic and scientific—should guide reasoned decisionmakers. Second, thorough review and analysis by the White House Office of Information and Regulatory Affairs can ensure that a rule fits within the larger federal regulatory program. Third, effective public notice and comment should help an agency appreciate the likely consequences of its rules and correct missteps before they happen. If all these processes are followed in developing a rule, then a decisionmaker will have the information needed to analyze and make an appropriate decision. If these procedures are followed, the single decisionmaker is likely to make a good decision without the personal and political wrangling common on a committee.

Granted, a single decisionmaker could make the wrong decision. That is what judicial review is for. But when a single decisionmaker stumbles, he or she can be held accountable. By contrast, on a multi-member commission, a good rule will have many fathers, while a bad one is always an orphan.

Let me close by quoting the first chairman of the CPSC, Richard Simpson, who also identified this problem: "[I]f you must manage and make decisions by committee, then the committee should have an odd number of members, and three is too many." I did not agree with Dick on many things, but on that one I've come around. **R**

Shareholder Proxy Access: The Results of Private Ordering

BY THOMAS A. HEMPHILL

The Securities and Exchange Commission, the federal agency responsible for protecting the nation's investors, first proposed proxy access rules in May 2009 in order to give shareholders of publicly traded corporations the right to nominate directors on the company ballot. After the subsequent enactment of the Dodd-Frank Wall Street Reform and Consumer Protection Act, the SEC was granted explicit authority under Section 971 of the act to amend Section 14a of the Securities and Exchange Act of 1934 in order to implement access requirements. The SEC, in a 3–2 vote on August 25, 2010, approved the Exchange Act Rule 14a-11 mandating that shareholders of corporations be eligible to have their nominee listed in proxy materials if they owned a minimum of 3 percent of common shares for at least three prior years.

Following the adoption of the rule, the Business Roundtable and the U.S. Chamber of Commerce filed a petition with the U.S. Court of Appeals for the District of Columbia challenging the rule's legality. The D.C. Circuit, in a July 22, 2011 decision, vacated the rule, saying that the SEC failed to analyze its costs and benefits as required by Congress. In writing for the Court, Judge Douglas H. Ginsburg held:

[T]he Commission acted arbitrarily and capriciously for having failed once again—as it did most recently in *American Equity Life Insurance Company v. SEC*..., and before that in *Chamber of Commerce*...—adequately to assess the economic effects of a new rule. Here the Commission inconsistently and opportunistically framed the costs and benefits of the rule; failed adequately to quantify the certain costs or to explain why those costs could not be quantified; neglected to support its predictive judgments; contradicted itself; and failed to respond to substantial problems raised by commentators.

Despite its continuing commitment to finding a means of facilitating shareholder director nominations, the SEC formally announced on September 6, 2011 that it would not seek immediate review of the Court's decision, an indication that it took the Court's harsh criticism as final. Furthermore, when questioned on April 25, 2012 before the House Committee on Financial Services, SEC chair Mary Schapiro answered that proposing a revised mandatory rule on shareholder access to company proxy materials is "not on the commission's immediate agenda," although she did indicate that it was an issue that the SEC will "continue to look at over time."

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Private ordering of proxy access | The Court's decision to vacate the rule did not affect the SEC's amendments to Rule 14a-8(i)8 (adopted in conjunction with Rule 14a-11) facilitating "private ordering" in proxy access, since it was not the subject of the litigation. Many corporate governance reform advocates had supported this private ordering (versus a mandatory rule) to the existing shareholder proposal rule during the course of the original SEC rulemaking process.

Under the amendments to Rule 14a-8(i)8, a corporation may no longer exclude a proposal that would amend or request that a corporation consider amending governing proxy materials to facilitate director nominations by shareholders, or disclosures related to shareholder nominations, as long as such a proposal is not otherwise excludable under some other procedural or substantive basis. Thus, since September 13, 2011, shareholders have had the opportunity to establish proxy access standards on an individual corporate basis, rather than the "universal" requirement instituted under the vacated Rule 14a-11.

Sullivan and Cromwell, a global law firm headquartered in New York City, recently issued a memorandum that compiled data on proxy access proposals submitted through June 30, 2012 to companies in Standard and Poor's 500-firm index. The data were compiled by corporate governance research and consulting firms FactSet, SharkRepellent, and Institutional Shareholder Services, as well as Sullivan and Cromwell's own review of public filings. The results of their study show that 23 proxy access proposals were submitted during the last proxy season, with only nine actually being voted on. Of the 14 proposals not voted on, eight were deemed "excludable" after review by SEC staff—because of "multiple proposals submitted" (when only one is allowed per voting session) or "vague due to 14a-8 reference" (a procedural or substantive issue)—with the remainder either withdrawn (two), pending for a future meeting (two), not voted on (one), or not presented at the annual meeting (one).

Of the nine proposals voted on, only two nonbinding on the board passed with over 50 percent of shareholders' support: Chesapeake Energy, with 60 percent shareholder support, and Nabors Industries, with 56 percent shareholder support. Both Chesapeake Energy's and Nabors Industries' proposals were for a minimum of 3 percent of common shares for at least three prior years, identical to the vacated "Exchange Act Rule 14a-11." Those seven proposals not passed with a majority of shareholder support were for a minimum of 1 percent of common shares for at least one year (four firms); a minimum of 1 percent of common shares for at least two years (two firms); or a minimum of 2 percent of common shares for at least one year (one firm).

The 2013 proxy season | With such a small number of proxy access proposals submitted, and an even smaller number voted on, tentative conclusions can be inferred from the first year's data of the amended Rule 14a-8(i)8.

First, if there was hesitation on the part of shareholder activists to submit proxy access proposals with S&P 500 firms during the past year—because they were expecting a renewed effort to

institute a revised rule that would pass scrutiny with the D.C. Circuit—that expectation was dashed by Schapiro's statement that a mandatory rule consideration is "not on the Commission's immediate agenda." This statement will certainly energize the shareholder activist community's efforts to increase the number of proxy access proposals in the 2013 proxy season.

Second, studying issues arising from SEC staff review exclusions of proxy access proposals will be a steep, yet attainable, learning curve for shareholder activists. Therefore, this challenge should not be a formidable barrier to shareholders actually voting on such proposals in the upcoming year.

Third, the results of the first-year proxy access proposal votes found that no binding proposal garnered majority shareholder support. If shareholders want to grant specified proxy access to nominate directors, will they want binding or non-binding proxy access?

Last, the issue of acceptable proxy minimum thresholds remains unresolved. While the two nonbinding proxy access proposals that passed with majority shareholder support mirrored the SEC's percentage of minimum outstanding shares (3 percent) and holding periods (three years), many corporations lobbied for a 5 percent minimum threshold of outstanding shares, while other investors recommended only a 1 percent minimum threshold of outstanding shares during the SEC's Exchange Act Rule 14a-11 rulemaking process.

Is proxy access a burning issue with U.S. shareholders? This question is still to be resolved. In the short term, however, a renewed effort by knowledgeable shareholder activists to significantly increase the number of proxy access votes is on tap for the upcoming season of annual board meetings. Furthermore, the next proxy season should be a harbinger for what proxy access thresholds will emerge when actively exercised through the private ordering process. R

Examining the U.S. Regulatory 'Budget'

BY SAM BATKINS AND IKE BRANNON

The nation's federal budget deficit gets a lot of attention from policy wonks and political commentators, and for good reason. Most people agree that the rapid rise in deficit spending in the last several years represents a genuine threat to our long-term economic well-being. But government affects the economy not only by taxing, borrowing, and spending, but also by telling businesses how they need to spend *their* money, via the issuance of regulations. This can have just as much of an effect on the economy as the government's fiscal policies. And just like government spending, the cost to the economy from

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the expanding regulatory state has been steadily increasing as well. In the last decade, regulations issued by the federal government have forced businesses, individuals, and various state and local governments to spend at least \$570 billion on compliance—and probably a lot more.

While that number by itself is instructive, it's even more illustrative to look at *where* regulations direct private spending. We examined 10 years of data and more than 230 regulations issued during that period, and we found that the bulk of the costs of regulations involve mandates to improve energy efficiency, with various environmental edicts coming in second place. Together, these two categories account for roughly two-thirds of the economy-wide cost of complying with various federal regulations.

The data | For the costs of various regulations, we compiled the regulatory costs reported in the *Federal Register*, which is the most inclusive source that exists for federal government regulatory activity. However, it does have a couple of important holes.

For starters, independent federal agencies routinely omit quantified cost-benefit analyses in their regulations. They are free to do this because Executive Order 12866, which mandates that executive branch agencies conduct such analyses for “economically significant” regulations, does not apply to independent agencies. This omission results in some obvious lacunae; for instance, the reported costs of complying with various financial regulations comprise only \$24.9 billion, or less than 5 percent of the total regulatory compliance costs. The Federal Communications Commission, Consumer Product Safety Commission, Office of the Comptroller of the Currency, and the new Consumer Financial Protection Bureau are among the independent agencies that do not have to estimate the costs imposed by their regulations.

The other problem is that the agencies issuing the regulations are the ones tasked with estimating the costs and benefits. Given that the Office of Information and Regulatory Affairs has the power to return proposed rules to the agency and request that changes be made, the agencies have an incentive to do everything they can to inflate benefits and deflate costs to keep that from occurring. Thus, we suspect that a wholly inclusive, objective analysis of the costs of regulation would be significantly larger and skew more toward those areas of the economy that our government largely regulates through independent agencies.

And while we include the costs that regulations impose on federal, state, and local governments to implement new regulations,

FIGURE 1
U.S. Regulatory Costs Breakdown

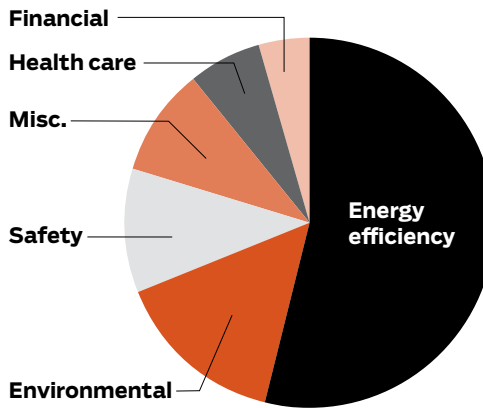


TABLE 1
U.S. Regulatory Costs by Category

Energy efficiency	\$310.7 billion
Environmental	\$86.8 billion
Safety	\$61.1 billion
Miscellaneous	\$55.5 billion
Health care	\$37.2 billion
Financial	\$24.9 billion
Total	\$576.4 billion

we do not consider the cost of maintaining the bureaucracy that creates those regulations in the first place—a cost that is not trivial. Susan Dudley of George Washington University and Melinda Warren of Washington University in St. Louis estimate that cost as roughly \$59 billion, or enough to support nearly 300,000 regulators.

Below, we divide the regulations that we examined into six categories and rank the categories by aggregate cost.

Energy efficiency | It might surprise some readers that energy efficiency regulations, including several recent changes to the Corporate Average Fuel Economy (CAFE) standards, provide the top regulatory cost burden, especially given that the recently passed Affordable Care Act (ACA) and Dodd-Frank finance law promise to significantly increase regulatory compliance costs for businesses in the health care and financial services industries. These latter laws are just now being implemented and, so far, have had a relatively small effect on our list. The

energy efficiency legislation is more mature and its costs are better measured.

The combined cost of the last four increases in the CAFE standards alone eclipses \$250 billion. The Regulatory Impact Analyses (RIAs) for the legislation note that these costs are initially borne by manufacturers, but are ultimately passed down to consumers. For example, for the 2017–2025 CAFE standards, the “technology costs” to producers will top \$121 billion. Consumers will thus see higher vehicle costs as a result of the manufacturers’ regulatory compliance. By 2025, the average cost per vehicle will have increased by more than \$2,200, for a total economy-wide cost of \$154 billion.

Environment | Regulatory authorities estimated that various environmental regulations mandated more than \$86 billion in compliance costs across the economy during the last 10 years. For example, the Environmental Protection Agency’s Utility Maximum Achievable Control Technology rule, which regulates mercury and other acid gas emissions, is one of the largest cost drivers, at approximately \$10 billion. Federal regulators acknowledged the regulation would result in the closure of numerous coal-fired power plants. Nevertheless, the EPA concluded that the actual consumer impact would be minimal.

The agency did concede—with some nudging from various affected entities—that consumers would be forced to pay \$700 million in higher energy prices as a result of the Cross-State Air

Pollution Rule, which was recently struck down by the U.S. Court of Appeals for the District of Columbia. If implemented, the rule would have cost approximately \$2.7 billion.

Safety | The bevy of rules passed in order to compel businesses to improve the safety of their operations for workers or consumers will add more than \$61 billion in costs, according to RIAs produced by various government agencies. The actual cost of all the safety regulations implemented over the past decade is probably much higher than this estimate, because many of the post-9/11 emergency regulations were never quantified. (Their approvals were expedited on an “emergency” basis, which precluded any cost analysis.) The Department of Homeland Security, the CPSC, and the Federal Aviation Administration issued most of the regulations that make up this category.

Miscellaneous | A few regulations do not fit neatly into the other five categories but, with a cost totaling \$55 billion, they merit inclusion and a brief comment. Many of these rules are unfunded mandates on state and local governments. For example, new federal school lunch standards will cost local governments \$3.2 billion, while new prison reform regulations will add nearly \$6.9 billion.

There are also countless rules designed to benefit favored political classes. In 2011, the National Labor Relations Board passed a regulation forcing employers to post notices about unionization rights. Although the NLRB conducted no formal cost-benefit analysis, it did note that more than 6 million employers would each incur costs of \$64 during the first year of implementation, for a combined 12 million hours of impact on the economy. Two federal courts have stayed implementation of the new standards.

Health care | Before implementation of the ACA, health care regulations were often simply “transfer” rules that dictated how federal funds were to be allocated to states or health care providers. However, the implementation of the ACA will boost the long-term costs to states and the private sector by more than \$27 billion alone, excluding federal transfers. Many of these burdens are ultimately passed to consumers. For example, a recent rule issued under the title “Adoption of a Standard for a Unique Health Plan” under the ACA will require physicians and hospitals to use new standard transaction formats, with a full implementation cost of approximately \$450 million.

Financial regulation | At \$24 billion, financial regulation could take a higher spot on the list of affected industries if independent agencies were not exempt from conducting cost-benefit analyses under Executive Orders 12866 and 13563.

The Dodd-Frank law is, of course, contributing to the surge in costs. To date, the law has imposed \$14 billion in costs, but few agencies have examined the impact on entities other than large financial institutions. Former Congressional Budget Office director Douglas Holtz-Eakin has estimated that new capital requirements for banks may result in 20 percent fewer loans and 600,000

fewer home sales. By his analysis, the new rules could result in 1 million fewer housing starts by 2015, almost 4 million fewer jobs, and subtract more than 1 percentage point from GDP.

Conclusion | The implementation of federal regulation is still somewhat of a gray analytical area. With dozens of agencies, differing legal standards, and more than 3,000 rules each year, a detailed examination of everything is nearly impossible. Thus, it is difficult for those in the regulatory community to get a clear picture of the true economic impact of the spending mandated by our regulatory bureaucracy.

This snapshot of regulatory costs during the last 10 years reveals the federal government has placed a priority on energy conservation and tougher environmental standards. At a cost to the economy of close to \$400 billion between these two efforts, this impact is historic in proportion.

However, it’s important to note that this snapshot is woefully imprecise, owing to the fact that independent agencies do not need to perform cost-benefit analyses of their rules. Other executive branch agencies that are not exempt from this requirement have every incentive to produce an analysis that omits as many costs as they can get away with. The reality is that the true costs of our nation’s regulations greatly exceed our own estimates. **R**

READINGS

■ “Regulators’ Budget Rising,” by Susan E. Dudley and Melinda Warren. George Washington University, May 18, 2010.

■ “Regulatory Reform and Housing Finance: Putting the ‘Cost’ Back in Benefit-Cost,” by Douglas Holtz-Eakin, Cameron Smith, and Andrew Winkler. American Action Forum, October 2012.

The Ripple Effects of Flawed Agbiotech Regulation

BY GREGORY CONKO AND HENRY I. MILLER

The modern techniques of genetic engineering—also known as biotechnology, recombinant DNA technology, or genetic modification (GM)—offer plant breeders the tools to make old crop plants do spectacular new things. In about three dozen countries worldwide, more than 17 million farmers are using genetically engineered crop varieties to produce more consistent yields with lower inputs and reduced environmental impact. Most of these new varieties are designed to be resistant to pests and diseases that ravage crops or to be

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resistant to herbicides so that farmers can more effectively control weeds while adopting more environment-friendly no-till farming practices and herbicides.

Over many millennia, there has been a virtually seamless continuum of genetic improvement of crops using increasingly sophisticated techniques. The modern era of genetic engineering emerged during the 1970s as part of this progression of technologies. Thus, because genetic modification has been with us for centuries, the term “genetically modified organism” and its abbreviation “GMO”—commonly used nomenclature—are unfortunate, confusing choices of terminology. “GMO” is often used arbitrarily to mean organisms containing genes transferred across species lines when accomplished (only) by recombinant DNA techniques, but this usage ignores the fact that genetic modification has been achieved using many technologies and that recombinant organisms are not in any way a meaningful “category.”

Since the first market introduction of crops engineered with molecular techniques in 1994, farmers have found that the new varieties reduce overall costs, deliver important environmental benefits, and increase per-acre profitability. Although farmers who choose these genetically engineered seeds find them worth their higher prices, many are eagerly awaiting the expiration of the patents on popular biotech traits in the next few years, hoping that prices will fall.

The patent on Monsanto’s Roundup Ready soybean trait (herbicide-resistance)—the most widely adopted crop biotechnology product in the world—and the patents covering another 22 biotech traits and processes are expected to expire over the next decade. Such patent expirations should make it possible for plant breeders to sell “generic” versions of these seeds, resulting in greater competition and lower prices.

Unfortunately, a quirk in the way biotech crops are regulated in the United States and other countries poses several challenges that may make it difficult for breeders to develop a generic seed industry.

Regulators treat these important products as though they pose uniquely worrisome risks, in spite of a longstanding consensus in the scientific community that the newer techniques are essentially an extension of more primitive ones. Federal regulation discriminates against the most precise and predictable techniques for genetic improvement, requiring endless, redundant case-by-case reviews of plants crafted with those techniques. By contrast, the testing and commercialization of similar seeds and crops made with less precise, less predictable techniques are usually subject to no regulation at all.

Re-registration | Federal regulators’ approach to biotech oversight violates two fundamental principles of regulation: similar things should be regulated in similar ways, and the degree of oversight should be proportional to the expected degree of risk. Regulators have, in fact, turned the second principle on its head, with more precisely and predictably crafted products subjected to the most expansive and costly regulatory requirements.

Both biotech and non-biotech crop varieties can be, and



routinely are, patented. But when the intellectual property rights protecting biotech plant traits expire, prospective generic breeders need to ensure that growers and end users have legal permission to sell the seeds and to grow and sell the harvested crops, respectively. A complicating factor is that the genetic constructs of most biotech seeds—known as “transformation events,” or simply “events”—must be periodically “re-registered” for commercial sale by regulatory authorities in the United States and abroad. In key markets, this can be a lengthy, expensive, and politically unpredictable process that requires access to the proprietary testing data held by the original developers of the approved events.

For example, a common bacterium called *Bacillus thuringiensis* (or *Bt*) produces proteins that are toxic to certain insects but safe for humans and other animals. When one or more of the *Bt* genes that express this protein are inserted into a specific corn variety, it makes the corn plant insect-resistant, reducing the need to spray chemical pesticides. But each time one of these genes is spliced into a different corn variety, that insertion creates a new “transformation event” that must be approved and re-registered separately. U.S. farmers can choose from more than 15 different transformation events of corn and dozens more of soy, rice, cotton, canola, and several fruits and vegetables. However, in order to export any of these crops, each event must be

re-registered repeatedly in various foreign countries as often as every three to five years.

The unrenewed expiration of the registration of any transformation event in an important export market could result in entire bulk shipments containing even relatively small percentages of that crop being rejected by the government of an importing country. Such an occurrence would have tremendous negative economic effects that would ripple throughout the food supply chain. This means that as long as biotech traits must be re-registered every few years, those who sell or buy genetically engineered seeds will have to bear the burden of meeting these ongoing stewardship obligations and will experience some degree of uncertainty and financial risk. The heightened costs associated with re-registration could erase a substantial portion of the economic gains ordinarily associated with patent expirations and the subsequent development and sale of generic products.

The re-registration requirement cannot be justified scientifically and is needlessly complex. For 30 years, there has been broad agreement among plant scientists that using genetic engineering to develop new plant varieties presents no new or unique risks compared to conventional breeding using techniques such as hybridization or irradiation mutagenesis. Scientific bodies around the world, ranging from the U.S. National Academy of Sciences to the United Nations' Food and Agricultural Organization, have concluded that there is no scientific justification for regulating the use of genetic engineering techniques, as opposed to regulating certain traits that may be associated with heightened risk. Thus, there is no justification for subjecting all genetically engineered crop plants to special pre-market approvals or to periodic re-registration.

Agency fiction | Adding further cost and complexity to re-registration is the required resubmission of—or legal access to—the original safety testing data submitted for the initial approval, along with whatever new testing and monitoring information regulatory authorities may require. Governments treat the data in approval applications as confidential business information or protected trade secrets because the data often contain information about the innovator's development and production processes, quality control and management programs, and other details that would be of significant value to potential competitors.

When considering approval applications from developers of generic versions of innovator products, regulators generally are not permitted to rely on data in the innovator's application to evaluate the follow-on products. However, while there are good reasons why regulators should maintain the confidentiality of an innovator's data, there is no good reason for regulatory regimes

to require follow-on producers to have access to the original developer's proprietary data in the first place. After all, regulators need not evaluate a dossier submitted for re-registration of a biotech transformation event de novo. For a biotech event to have been granted market approval in the first place, regulatory scientists would have already examined submitted data and arrived at a judgment that the product is safe enough for commercial use. In other words, one can rely on a principle of transitivity that says that if the application for the original product was evaluated and approved for marketing on the basis of submitted data, and the follow-on product contains the same transformation event, the follow-on product is equivalent to the original product and should be approved.

The simplest solution to this problem is for governments to eliminate the unjustifiable, unnecessary re-registration requirement. Alternatively, regulatory agencies should, at the very least, eliminate the legal fiction that agency scientists have not already examined the original data and reached the conclusion that the product is safe for consumers and the environment. In other

words, there should be no need for breeders to submit or have access to original safety data when seeking a re-registration.

There appears to be little political support, however, in either the United States or abroad, for the reform of biotech crop regulation. Regulators are resistant to relinquishing their perks, budgets, and

bureaucratic empires. As a workaround of the flaws in the regulatory system, seed breeders and the biotechnology industry have begun to cooperate on a voluntary, contractual arrangement that will help to address some of these problems. Under the terms of this "Accord Agreement," participating developers will agree to maintain registrations for their transformation events for a limited time after the expiration of the patents. Developers and generic breeders would then be able to make binding contractual agreements to share needed regulatory data and to hand off long-term regulatory stewardship obligations, thereby facilitating a seamless transition to the post-patent regulatory regime.

Private contractual arrangements that would permit post-patent generic versions of biotech crop varieties should begin to address some of the regulatory and legal challenges that stand in the way of a seamless transition to a post-patent generic seed industry. But any wholly private effort can at best be expected to ameliorate the problem rather than to solve it entirely because the existing regulatory requirements—which defy both sound science and common sense—must still be met. The continuing presence of discriminatory regulation will make it difficult for small breeders (particularly public sector breeders and small firms in less developed countries) to take advantage of off-patent traits. The ripple effects of a quarter-century of flawed agbiotech regulation have been wide, deep, and damaging. **R**

Scientific bodies around the world have concluded that there is no scientific justification for regulating the use of genetic engineering techniques, as opposed to regulating certain risky traits.