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REDUCING UNNECESSARY AND COSTLY RED TAPE THROUGH SMARTER REGULATION

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CONTENTS

Opening Statements of Members

Hon. Kevin Brady, Chairman, a U.S. Representative from Texas 1
Hon. Amy Klobuchar, Vice Chair, a U.S. Senator from Minnesota 3

Witnesses

Professor Susan Dudley, Director, Regulatory Studies, The George Washington University, Washington, DC 6
Dr. Michael Greenstone, 3M Professor of Environmental Economics, Massachusetts Institute of Technology, Director of the Hamilton Project and a Senior Fellow at the Brookings Institution, Cambridge, MA, and Washington, DC 8
Dr. Jerry Ellig, Senior Research Fellow, Mercatus Center, George Mason University, Arlington, VA 10
Dr. Robert Kieval, Executive Vice President and Chief Technology Officer, CVRx, Inc., Minneapolis, MN 12

Submissions for the Record

Prepared statement of Chairman Brady 30
Prepared statement of Professor Susan Dudley 32
Prepared statement of Dr. Michael Greenstone 47
Prepared statement of Dr. Jerry Ellig 51
Prepared statement of Dr. Robert Kieval 84

REDUCING UNNECESSARY AND COSTLY RED TAPE THROUGH SMARTER REGULATION

WEDNESDAY, JUNE 26, 2013

CONGRESS OF THE UNITED STATES,
JOINT ECONOMIC COMMITTEE,
Washington, DC.

The committee met, pursuant to call, at 9:55 a.m. in Room G–50 of the Dirksen Senate Office Building, the Honorable Kevin Brady, Chairman, presiding.

Representatives present: Brady, Paulsen, Hanna, Maloney, and Delaney.

Senators present: Klobuchar, Murphy, Coats, and Toomey.

Staff present: Gabriel Adler, Ted Boll, Hank Butler, Colleen Healy, Conor Carroll, Gail Cohen, Connie Foster, Niles Godes, Patrick Miller, and Robert O'Quinn.

OPENING STATEMENT OF HON. KEVIN BRADY, CHAIRMAN, A U.S. REPRESENTATIVE FROM TEXAS

Chairman Brady. Good morning, everyone. We are going to do something unusual and start ahead of time. So we will see if that works in Washington.

This month the current recovery celebrates its fourth anniversary. Now is a good time to assess how the U.S. economy is performing.

Unfortunately, for American families the current recovery remains the weakest since World War II. There is a troubling Growth Gap in economic performance between this recovery and the average of post-war recoveries, leaving our economy 4 million private sector jobs short and $1.2 trillion missing from the economy. While Wall Street is booming, every man, woman, and child in America is missing nearly $3,000 in real disposable income due to the Growth Gap.

During this Congress, the Joint Economic Committee has been examining the causes of the Growth Gap and the types of alternative policies to close that gap. The Joint Economic Committee has studied how current fiscal and monetary policies have held back this recovery. Today, the JEC will explore regulatory policy.

From town hall meetings with my constituents in Texas, to conversations with business leaders and economists across America, there is one consistent message: Uncertainty over the costs of new regulations in healthcare, the environment, labor issues, and financial services is suppressing business investment and the creation of new jobs along Main Street.

The burden of federal regulations is large. At year-end 2012, the Code of Federal Regulations had 238 volumes and 174,000 pages.

That burden is growing. In 2012, the Federal Register—which publishes proposed new rules and regulations, final rules, and changes to existing regulations—totalled 78,961 pages. Three of the four highest page counts since the Federal Register began publication have occurred during the current presidency.

And that burden is costly. NERA Economic Consulting, in a study last year commissioned by Manufacturers Alliance for Productivity and Innovation, estimates the current direct cost of compliance with "major" regulations—that is, those with an estimated cost greater than $100 million a year—issued between 1993 and 2011 to be between $265 billion and $726 billion every year. Clyde Wayne Crews of the Competitive Enterprise Institute estimates the total cost of regulation in America approaches $1.8 trillion annually, or nearly 12 percent of our Nation's economy.

Given this historically weak recovery, the rise of technology to help us meet regulatory goals more cheaply, and a shared belief that America should continue progress on a clean environment and safe workplace, when regulations are necessary doesn't the public deserve the most effective regulation at the least cost?

Smart regulations that improve the market process and its incentive structure to accelerate progress rather than dictate particular outcomes will prove superior to tens of thousands of pages of mandated rules and micro-managed instructions.

Devising process-enhancing rules that engage the private sector's versatility and creativity requires objective upfront analysis and thoughtful design.

Yet federal agencies often do things the other way around: deciding first what they want to do, and then using whatever analysis is performed to justify their preconceived "solution." This abuse must stop.

In 1981, President Reagan issued an Executive Order requiring Executive Branch agencies to conduct Regulatory Impact Analysis, commonly known as cost-benefit analysis, before issuing major new regulations. This first step toward smarter regulation had its limitations.

An executive order affects only Executive Branch regulatory agencies and therefore does not affect independent regulatory agencies such as the Consumer Product Safety Commission, the Federal Trade Commission, the Federal Reserve, and the Consumer Financial Protection Board.

Over the years, Congress has exempted broad swaths of federal regulation from the scrutiny of cost-benefit analysis through provisions of the Clean Air Act, for example. While there are government-wide "best practice" standards on how agencies should conduct cost-benefit analysis, they are not uniformly applied and are not legally binding. So the quality of agency cost-benefit analyses varies greatly.

Agency bureaucrats, as you would imagine, are naturally biased toward their proposed regulation and have learned how to manipulate cost-benefit analysis to justify whatever new regulations they wish to issue.

For example, former Administrator of the Office of Information and Regulatory Affairs, Professor John Graham, closely examined CAFE, the Corporate Average Fuel Economy standards for trucks in his testimony before the House Committee on Oversight and Government Reform in September 2011 and found that to inflate the benefits of their new rule regulators had cut the discount rate and the so-called "rebound effect" of increased driving with better mileage to half or less. He also found that they failed to carefully consider the rule's effects on vehicle size, performance, and safety.

In other words, today too few proposed rules are fully analyzed. There are too many loopholes, no uniform requirement across all agencies, a lack of standards with which to conduct the analysis, no check-and-balance against agency bias, no comparison of past analysis to real-life impacts, and little recognition of the total burdens on the economy of regulation.

We must do better. The purpose of this hearing is to discover ways in which Congress can make the regulatory process "smarter," more cost-effective, and better designed to accomplish the goals without damaging the economy.

In particular, the Committee hopes to hear from today's witnesses about the deficiencies in cost-benefit analysis as it is now practiced, and how agencies can do a better job of quantifying and measuring the costs and the benefits of both proposed and existing regulations.

I look forward to the testimonies, and I recognize our Vice Chair, Senator Klobuchar, for her opening remarks.

[The prepared statement of Chairman Brady appears in the Submissions for the Record on page 30.]

OPENING STATEMENT OF HON. AMY KLOBUCHAR, VICE CHAIR, A U.S. SENATOR FROM MINNESOTA

Vice Chair Klobuchar. Well thank you very much, Mr. Chairman, and thank you for holding this hearing, and thank you to all the witnesses.

I particularly wanted to recognize two witnesses I invited, Dr. Greenstone and also Dr. Kieval, who heads up a company in Minnesota, CVRx, Inc., which is a medical device company. And I know that Representative Paulsen welcomes him, as well, as we both have done a lot of work—Representative Paulsen and myself—in the area of medical device regulation to make things a little easier, and also trying to get the medical device tax repealed.

This hearing is especially important to me because, before coming to the U.S. Senate I spent 13 years representing companies in regulatory areas, doing everything from trying to get competitive telecom carriers into the telecommunications local market, to helping Dairy Queen get their 2-for-1 Sundae deal approved in every state in the Union.

I know you're curious about which the last state was that was willing to approve it. That would be Louisiana, not really a surprise.

Americans expect and deserve a common-sense approach to regulation, one that protects consumers and the public interest, without stifling innovation and economic growth. And this means doing sensible things that advance technology and global competitive-

ness, while also maintaining safety and security standards. And that is the way I look at this.

At the same time, I would agree with the Chairman that we should be open to change. I believe we need to be a country that makes stuff again, invents things, exports to the world, and for that we need a competitive agenda. Which means building our work skills. Which means building on exports. Which means reducing our debt in a balanced way. Doing comprehensive tax reform. Bringing down that business tax rate, and paying for it by closing loopholes and other things.

But this also means cutting down on red tape. One example that we will talk about today is medical device. My State has a long history of leadership in medical device manufacturing. The story of Earl Bakken tinkering around in his garage and launching Medtronic is the stuff of legends, but it is not just big companies like Medtronic that keep this industry running. It is the small- and medium-sized medical tech companies.

I recently visited one that actually got its start in a chickencoop. The U.S. is the largest net exporter of medical devices in the world, enjoying a trade surplus of $5 billion a year. Yet we've seen a decline in venture capital funding largely due to delays in the approval process.

According to one study, venture capital investment in the medical device and equipment industry fell 20 percent from the first quarter of 2012 to the first quarter of 2013.

It is critical that we prevent regulatory burdens from interfering with the delivery of life-saving products. We recently passed MDFA/PDFA bills out of this Congress, signed into law, that contain some really good things, including bills that I introduced and Representative Paulsen and others worked on, the agency's least-burdensome principles, which have been continuously ignored by the FDA reviewers, improving the conflict-of-interest provisions making it easier for the FDA to recruit top-line experts to take part in the review process, and requiring the FDA to use an independent contractor to assess the management processes.

This is just one example. Another that I've worked on a lot is tourism. And I personally believe that one way we can do this, in addition to looking at some of the cost/benefit analysis, is looking industry by industry and figuring out what are things that we can do that we could actually get through Congress, or that the Administration could do on its own without Congress, to reduce some of these regulatory burdens and make things work for today.

One of my best examples is tourism. Since 9/11, through two Administrations, we lost 16 percent of the international tourism market. Every point that we gained back is 161,000 jobs. A lot of that had to do with slowdown of the approval of the visa process.

Senator Blunt and I worked on this together. We have seen dramatic changes in China now. We were unable to compete with Chinese wanting to go to England. We are now in the game, competing in terms of the wait times for those visas.

Brazil is down to two days in several cities. That is simply because we move people around, realizing this was a profit center for our government, and did this without legislation.

Now we also can do more things legislatively with visa waivers. That is why I am so excited in part about the immigration bill. There are some really good things in there, like the JOLT Act that will help with that. And Senator Blunt and I, along with Representative Walz, passed last December the no-hassle flying act, which was about not doing double screening of luggage. As minor as it might sound, it makes a huge difference when you're on the Canadian Border in Minnesota when you have airports that are already up to our standards for screening.

Exports are another example. As we see the defense industry being hit by sequestration and other things, and some reduction in our work overseas, we have to try to keep those jobs in America. And part of this is going to be having to look at the export rules and make the defense export system more efficient by creating a unified list of restrictive items at one agency, rather than having lists at multiple agencies.

This will help defense subcontractors and other businesses that make parts that are used in military equipment but are not exclusively military products. So we have to look at this export control list and make it work better.

Agriculture is something we care a lot about in our State. We have seen a number of rules from the EPA that have come out, and then later been rejected, whether it's milk spills being regulated as oil spills, or other things, where I think we can be smarter about how we do that.

I actually had a bill that I had with Senator Lugar that I will be introducing again to try to get people with agriculture backgrounds on the EPA rulemaking group so that we can try to get that interest represented and stop things from happening that do not make sense.

The Chairman mentioned the tax issues. I truly believe that we need comprehensive tax reform. After immigration, I would love it if that was the next issue that we went to, in addition to trying to work out a bipartisan agreement. Our Tax Code, as we all know, is too complicated. And while we have made some inroads like repealing the 1099 reporting requirement, I think there's others we can do.

That being said, we have to remember our economy is stable. We have seen improvements. In Minnesota we're down to 5.3 percent unemployment. And so I want to keep on that road, not doing anything to interfere with safety or security but look at this red tape as part of the solution to improving even more.

Thank you, Mr. Chairman.

Chairman Brady. We have a terrific panel of witnesses today. I appreciate each of you being here today and look forward to your testimony. Let me introduce each of them.

Ms. Dudley, Professor Dudley, directs the George Washington University's Regulatory Studies Center, which she founded in 2009 to focus on high-quality research in regulatory policy. She has previously served as Administrator of the Office of Information and Regulatory Affairs of the U.S. Office of Management and Budget. She has also directed and taught the Regulatory Studies Program at the Mercatus Center at George Mason. She holds a Master's Degree from MIT's Sloan School of Management, and a Bachelor's De-

gree in Resource Economics from the University of Massachusetts at Amherst.

Mr. Greenstone, Dr. Greenstone, is the 3M Professor of Environmental Economics in the Department of Economics at MIT. He is on the MIT Energy Initiatives Council, and on their Environmental Research Council. He also serves as a Senior Fellow at the Brookings Institution, and a Research Associate at the National Bureau of Economic Research. Previously he served as the Chief Economist for President Obama's Council of Economic Advisors. He holds a Ph.D. in Economics from Princeton, and a B.A. in Economics from Swarthmore College. Welcome, Doctor.

Dr. Ellig is a Senior Research Fellow at the Mercatus Center at George Mason University, as well, focusing on the federal regulatory process, economic regulation, and telecommunications regulation. Previously he served as Deputy Director and Acting Director of the Office of Policy Planning at the Federal Trade Commission, and has also served as a senior economist for this Committee. Welcome. Dr. Ellig received his Doctorate and Masters in Economics from George Mason, and his B.A. in Economics from Xavier University.

Dr. Kieval is founder and Chief Technology Officer of CVRx, a private medical device company located in Minnesota whose State has currently taken over the Joint Economic Committee.

[Laughter.]

He is over—much to my dismay—he has over 16 years of medical device industry experience, including being named Innovator of The Year by Twin Cities Finance and Commerce. He currently serves on the board of the Medical Device Manufacturers Association. He completed his undergraduate and graduate training at the University of Pennsylvania, where he received Doctorate Degrees in Veterinary Medicine and in Psychology.

Welcome to each of the panelists today. I think this is a very important topic, and certainly our businesses large and small have raised regulatory concerns as their number one and number two concerns about their ability to hire.

So just a nuts and bolts discussion on how we can achieve our regulatory goals in a smarter, cheaper, more cost-effective way by doing analysis up front is really critical.

So, Professor Dudley, we have reserved five minutes for your oral remarks. Your statement will be made a part of the record. Please go ahead. Can you get that mic?

STATEMENT OF PROFESSOR SUSAN DUDLEY, DIRECTOR, REGULATORY STUDIES CENTER, THE GEORGE WASHINGTON UNIVERSITY, WASHINGTON, DC

Professor Dudley. Thank you, Chairman Brady, and Vice Chair Klobuchar. I really enjoyed your opening statements, and I am pleased that the Committee is holding this hearing.

I would like to talk about the importance of Regulatory Impact Analysis, but also the need for institutional change to provide better incentives for ensuring better regulatory outcomes.

While Regulatory Impact Analysis is widely accepted by practitioners and academics, and every modern President has endorsed its use, too many regulations are still being issued without mean-

ingful analysis of the likely consequences of alternative actions. And you mentioned this in your opening remarks, Chairman Brady.

First, many statutes preclude agencies from considering important tradeoffs when developing regulations. Now fixing that problem would likely require amending language in existing statutes, but also ensuring that new legislation requires agencies to weigh regulatory effects and provides them with adequate time to do the research, to deliberate, and to consult with the public before they issue new regulations.

The other constraint, as you mentioned, is that independent regulatory agencies have not been subject to executive oversight, and they have been less than rigorous in their analysis.

Now Senator Warner, who is a member of this Committee, has proposed legislation, co-sponsored with Senators Portman and Collins, that would subject independent agencies to regulatory analysis and oversight. And I think that is important.

But even when it is conducted, regulatory analysis is not the silver bullet guaranteeing smarter regulation, as you both mentioned. Ex ante analysis necessarily rests on hypotheses of how regulatory action will alter outcomes and what it will cost.

So even the most carefully analyzed regulations may result in unanticipated changes in behavior that undermine their desired effects.

Compounding this problem is—and I feel like I'm saying everything that you said—is that agencies have strong incentives to demonstrate that their desired regulations will have benefits that exceed their costs.

Regulatory impact analyses are often done after the decision is made to justify, rather than to inform, the decision.

Agency staff are smart and motivated, but like everyone else they are susceptible to the confirmation bias. And their single-mission focus often leads them to discount data, research, values, and perspectives that do not support their preferred regulatory alternative.

Institutional changes that provide more effective checks and balances and engage the wisdom of crowds are needed to counter these natural incentives. Judicial oversight provides an important Constitutional check, but courts defer to agency expertise when evaluating regulatory records and requirements, and Presidential Executive Orders are not enforceable by law.

There are some promising legislative initiatives that would make Regulatory Impact Analysis judicially reviewable, and others that would alter the deference that courts give to agencies.

Congress could also provide more checks and balances by voting on new regulations before they're issued. It could also assign responsibility for evaluating regulatory bills and regulations to a Congressional office.

Just as the CBO provides independent estimates of the on-budget cost of legislation and federal programs, a staff of Congressional regulatory experts could provide Congress and the public independent analysis regarding the likely off-budget effects of legislation and regulation.

And then the American public can provide checks and balances, too. Recognizing that not all problems require a regulatory solution is an important first step. Requiring earlier disclosure of key information could also engage broad public input, long before any policy decisions are formed and could bring greater transparency to the rationale behind regulatory decisions.

Regulations also lack accountability because once they're in place agencies seldom look back to evaluate whether they are having their intended effects.

Initiatives to require ex poste evaluation of regulations have met with limited success largely because they did not change the underlying incentives.

Two ideas that have the potential to impose needed discipline on regulatory agencies, and to generate a constructive debate on the real impacts of regulation, are a regulatory improvement commission that operates like the BRAC, and a policy similar to the UK's one-in-one-out approach that requires agencies to make trade-offs when issuing new regulations.

So in closing, Regulatory Impact Analysis is a longstanding and important element of U.S. regulatory policy, but a variety of institutional obstacles prevent it from being a silver bullet for producing smarter regulation.

Greater Congressional oversight, judicial oversight, and opportunities for public involvement could provide better accountability and improve the reasoning underlying regulatory decisions, as well as the decisions themselves.

[The prepared statement of Professor Susan Dudley appears in the Submissions for the Record on page 32.]

Chairman Brady. Thank you, Professor. And don't worry about agreeing with Senator Klobuchar and I. It rarely happens. We're glad to hear that happened.

[Laughter.]

So, Dr. Greenstone.

STATEMENT OF DR. MICHAEL GREENSTONE, DIRECTOR, HAMILTON PROJECT, 3M PROFESSOR OF ECONOMICS, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, WASHINGTON, DC, AND CAMBRIDGE, MA

Dr. Greenstone. Thank you, Chairman Brady, Vice Chair Klobuchar, and Members of the Joint Economic Committee, for inviting me to speak today about opportunities to improve the government's regulatory system.

American government, as all of you know, at every level regulates a broad array of social and economic life. Regulatory policy determines the air we breathe, the quality of the water we drink, the safety of our workplaces, the investments we make, and so much more.

Government regulates these activities because, in cases of market failure, for example, our free market system does not create the necessary incentives for businesses and individuals to protect the public good.

The challenge for regulators is to consistently set rules with benefits that exceed their costs, or otherwise achieve their statutory objectives. However, an important weakness in our regulatory sys-

tem is that we generally don't have the information to make these judgments over the long haul.

This is because our evaluations are done before the regulations are enacted, and are almost entirely based on a regulation's likely benefits and likely costs. Of course this is the point when we know the absolute least, precisely because the regulations are untested.

Once a regulation passes this ex ante test, it goes on the books and generally stays there unexamined for years, and in many cases decades. In practice, some regulations work out exactly as intended, but others do not.

For example, an air pollutant may prove to be more harmful than was originally understood; or innovation may lead to new and less expensive pollution abatement technology.

President Obama's Executive Orders 13563 and 13610 spell out what I think is a potentially revolutionary step forward in regulatory policy. Specifically, they require that agencies routinely revisit the measurement of costs and benefits of existing regulations, and identify the least costly ways to achieve a regulation's goals.

In the remainder of my testimony I am going to identify two further changes that I think would increase the chances that our regulatory system consistently produces rules with benefits that exceed costs.

The first change is to make three reforms that build on the President's recent Executive Orders.

First, I recommend institutionalizing the retrospective review of economically significant rules so that these reviews are automatic. Depending on the particulars of the rules, the reviews should be completed within a prespecified period—say 5 to 10 years.

In addition, the relevant agency would be required to prespecify the expected benefits—for example, reduced child mortality rates—and expected costs: say reduced business profits, so that the terms of the subsequent review would be known in advance and could not be changed later.

Second, the relevant agency should commit to undertaking a new rulemaking when the results from the retrospective analysis differ from the benefits and costs that were expected prior to the regulation's implementation. The new rulemaking should also operate under a time limit.

Third, these efforts would be strengthened if they were accompanied by triggers to ensure that they are undertaken within a prescribed time period. One approach would be for agencies to post on their website the deadline for a rule's review and reconsideration. A stronger approach would be to enable the Judiciary to compel reviews and new rulemakings in cases where an agency has failed to comply with the review timeline, or to act upon its results.

There are some difficulties with this approach I have just outlined. Many agencies do not have the staff, expertise, or resources necessary to undertake these reviews.

Further, as Dr. Dudley has pointed out, the process of self-evaluation is challenging for all organizations as it requires complete objectivity.

My recommendation is to establish a new, independent body for regulatory review. This body could be housed within the Legislative

Branch and modeled after the Congressional Budget Office—or even become a division within the existing CBO.

As you know, before the CBO was established only the President had a ready source of budgetary and economic data and analysis. The entire budget process has benefitted from CBO's existence and its independence.

Budgetary analyses and proposals throughout Washington are now created to a higher standard, knowing that they must ultimately face scrutiny by the nonpartisan CBO.

My recommendation would be to place this new organization in the Legislative Branch and make it avowedly nonpartisan, just like the CBO. The organization would be charged with conducting independent regulatory impact evaluations.

Of course the creation of such a body would require resources. My best estimate is that such an organization could be funded for less than $15 to $20 million annually. This is a modest amount of money when compared to the hundreds of billions of dollars of costs and benefits that regulations introduce in our economy.

My judgment is that it is very likely that such an office would pay for itself many times over.

To quickly summarize, I propose two key reforms:

One, institutionalize a process by which agencies automatically undertake retrospective reviews of regulations, and initiate a new rulemaking when the results from the retrospective analysis differ from the expected benefits and costs.

Two, create a new independent body for rigorous, objective regulatory review that is modeled on the Congressional Budget Office.

We live in a rapidly changing economy and need a regulatory review structure that evolves to meet the new and different needs of our society. The reforms that I have outlined here would give policymakers tools for protecting those regulations with great benefits for our society, reforming those regulations that impose unnecessary costs, and culling those that no longer serve their purpose.

That would be good for our well-being and good for the American economy.

Thank you, once again, for inviting me to participate and I will gladly respond to any questions.

[The prepared statement of Dr. Michael Greenstone appears in the Submissions for the Record on page 47.]

Chairman Brady. Great. Thank you, Doctor. Dr. Ellig.

STATEMENT OF DR. JERRY ELLIG, SENIOR RESEARCH FELLOW, MERCATUS CENTER, GEORGE MASON UNIVERSITY, ARLINGTON, VA

Dr. Ellig. Well, Chairman Brady, Vice Chair Klobuchar, Members of the Committee, I would like to thank you for the opportunity to testify here today.

If I could summarize my testimony in a nutshell, it's this: Regulatory Impact Analysis is critically important for making sensible regulatory decisions. A lot of times it is not done very well, or it does not appear to have much of an effect on decisions, and improvement in that is probably going to require legislation.

Let me elaborate on each of these three points.

First, why is Regulatory Impact Analysis important? Well one of my favorite old Calvin & Hobbs cartoons starts with the little boy, Calvin, holding a water balloon saying,

"I'm going to prove that there is no moral law governing the universe. I will throw this water balloon at Suzy Dirkens, unless the universe gives me a sign that that would be wrong in the next 10 seconds."

So he counts down. He says, "Nope, no sign." Throws the water balloon.

She chases him. Beats him up. In the last panel of the cartoon, he's lying on the ground saying:

"Why does the universe always give you the sign after you do it?"

[Laughter.]

That is why we need high-quality Regulatory Impact Analysis to inform regulatory decisions.

We expect regulation to accomplish a lot of really important things. We expect regulation to protect us from financial fraud; to keep the air clean; keep the water clean; in the case of my old agency, the Federal Trade Commission, we expect regulation to prevent telemarketers from bothering us at home when we don't want to be bothered. All of those kinds of good things.

In order to get those good things, we usually have to give something up. Sometimes it's money. Things cost more. Sometimes we have to give up privacy. We give up convenience. We give up dignity. We give up liberty. Regulation tells us what we may do, what we may not do, and sometimes what we must do.

And if government is going to tell us what we may, may not, and must do, government has a moral responsibility to understand the likely consequences of regulation, to understand the likely consequences of alternatives, and to understand those things ahead of time before it makes decisions.

And a good Regulatory Impact Analysis provides that kind of information. Regulatory Impact Analysis is a structured framework for comparing the potential results of different courses of action, and it is also a structured framework for assessing the nature of the problem we're trying to solve so we can pick a solution that will actually work.

Now Presidents have recognized this. For more than three decades, Presidents have directed Executive Branch agencies to conduct Regulatory Impact Analysis for important regulations.

Unfortunately, we find that often Regulatory Impact Analysis is not done very well, or is not used very much in decisions. The most recent piece of research that looks at that is a project at the Mercatus Center that we call "The Regulatory Report Card."

We have a team of economics professors around the country who evaluate the economically significant regulations. Those are the ones that have an economic impact above $100 million. It is kind of a giant exercise in grading papers. We have done this for—from 2008 to 2012, looking at the quality of the analysis and the extent to which it is used; evaluating them based on criteria that are in the Executive Order that governs regulatory analysis and review.

And the result of this is that over the past five years on average regulations have earned about half of the available points that they

could earn on our grading scale. For me, 50 percent is about good enough for an "F."

The best we have ever seen earns about 80 percent of the possible points on our grading scale, so that might be a B-. These results are consistent with what other researchers find when they have looked at the quality of Regulatory Impact Analysis and when they have looked at the use of Regulatory Impact Analysis.

We certainly do find some best practices, and we do find cases where the analysis seems to have affected decisions, but those are exceptions rather than the rule.

So how could the U.S. Government improve the use of Regulatory Impact Analysis? Well the first step toward that is understanding that no single Administration, and no single political party, is to blame for this problem.

We looked at regulations in the Bush Administration and the Obama Administration. On average, there was no difference in quality. On average, there was no difference in the extent to which the analysis was used. Other researchers have found the same thing when they compared the quality of Regulatory Impact Analysis across Administrations of different parties.

It is not a partisan problem, or a problem with a particular Administration; it is an institutional problem that requires institutional solutions.

The most logical obvious institutional solution is a legislative requirement that all agencies conduct Regulatory Impact Analysis for regulations of a certain level of importance combined with Judicial review to ensure that the analysis meets a certain standard of quality, and that the agency explained how the analysis affected its decision.

In short, regulation is too important to be based just on good intentions. We need to actually know what we are doing before we do it.

[The prepared statement of Dr. Jerry Ellig appears in the Submissions for the Record on page 51.]

Chairman Brady. Great. Thank you, Dr. Ellig.

Dr. Kieval.

STATEMENT OF DR. ROBERT KIEVAL, EXECUTIVE VICE PRESIDENT AND CHIEF TECHNOLOGY OFFICER, CVRx, INC., MINNEAPOLIS, MN

Dr. Kieval. Thank you, and good morning.

Chairman Brady. Can you hit that (microphone).

Dr. Kieval. Got it. Good morning, Chairman Brady, Vice Chair Klobuchar, Members of the Committee. It is an honor to have this opportunity to address you today. I will focus my remarks on the impact of regulation on medical technology and innovation.

As you have heard, I am the founder and Chief Technology Officer of CVRx, a Minneapolis-based medical device company. I have worked in the medical technology industry throughout my entire career, with experience both at a large manufacturer, and also in the start-up environment.

In addition to serving on the board of the Medical Device Manufacturers Association here in Washington, I also serve on the board of our local industry organization, LifeScience Alley in Minneapolis.

CVRx is now about 11 years old. We remain pre-revenue here in the United States, and are in early commercialization outside the U.S.

The U.S. med tech industry supports at least 400,000 jobs, with nearly 2 million more in adjacent sectors. It is one of the few American industries that is a net exporter and we are the global leader.

Small businesses like CVRx, often with fewer than 50 employees, are a vital source of innovation and comprise approximately 80 percent of the industry. Companies like ours, with a single product and no alternative revenue streams, depend on outside investment.

Investors require assurance of a reasonable and predictable path to product approval. Ambiguous or overly burdensome approval thresholds can fatally inhibit investment in a company and prevent development of what could be a very meaningful new therapy.

Since 2005, the time and capital required by a company to get a clear determination of its regulatory pathway, to negotiate clinical trial requirements, and to obtain a product approval decision have risen dramatically.

The approval process itself has become increasingly inefficient, inconsistent, and unpredictable. This has led patients—excuse me, this has led to patients outside the U.S. frequently getting access to American innovations an average of two years before American patients do.

In many cases, jobs and R&D have also moved overseas, weakening our industry's competitiveness.

This is also the case for CVRx. While we work through the approval process here, our product is treating patients in Germany, Italy, the Netherlands, Hungary, and Turkey. I just returned from Europe where I heard from doctors how patients there are benefitting from our technology. As a result, the jobs that we are adding are also largely overseas.

The FDA has a crucial mission to protect the public health. Clearly this means providing reasonable assurance that products are safe before they are approved. However, it also means that patients should not be unduly deprived of innovations because of inefficient or overly burdensome approval processes.

Finally, the medical device tax, a tax on revenues irrespective of a company's earnings, further increases financial pressure and compounds these difficulties. For larger companies, these challenges often represent issues of profitability; for smaller companies like CVRx, they may be issues of survivability.

In the first quarter of this year, first-time financings in the life sciences dropped dramatically to $98 million, the lowest quarterly amount since 1996. By comparison, in 2007 alone, start-up device companies raised over $700 million in initial financing. These early stage investments are a clear leading indicator of future innovations. So this does not bode well for patients.

Federal regulators and policymakers are working to address these issues. Our industry appreciates the bipartisan support for the Food and Drug Administration's Safety and Innovation Act of 2012. This reauthorized the medical device user fee program, and includes reforms that, if implemented as intended, will really benefit patients, innovation, and our economy.

These include earlier substantive interactions between FDA and industry shared outcome goals that track performance in calendar days clarification of least-burdensome language provisions regarding conflict of interest and management review.

On a personal note, I would like to thank yet again my home State Members and the Minnesota Delegation for their tireless work on these issues.

The Medical Device Innovation Consortium, a public/private partnership that had roots in Minnesota but is now a national program, is a promising example of government and industry working collaboratively to identify and improve regulatory inefficiencies.

Also encouraging are reports that FDA is concentrating on three highly practical priorities: Improving efficiency in clinical trials; balancing the pre- and post-market process; and identifying ways to shorten the lag between FDA product approval and reimbursement approval by CMS.

In closing, capitalizing on many of these opportunities will require effective collaboration between patients, industry, and the FDA. However, Congress can play an important role as well by ensuring that all parties continue to work toward these goals in a highly constructive manner.

Thank you very much for your attention.

[The prepared statement of Dr. Robert Kieval appears in the Submissions for the Record on page 84.]

Chairman Brady. Thank you, Dr. Kieval. And don't keep giving the Minnesota Delegation a bigger head, please.

[Laughter.]

It's tough enough to deal with these guys.

I want to talk real quickly—ask, real quickly, about the loopholes at the agencies that are not part of the requirement, standards and review, looking back. But before I do that, you know our businesses really are concerned about the level of implementation of regulation.

OIRA, looking at 2011, looked at 3,500 rules and regulations that year. About 58 of them were major rules. Only 13 underwent complete cost-benefit analysis. That seems like an awfully small amount of scrutiny and cost-benefit analysis ahead of an awful lot of regulation.

I have adopted the Papa John's motto "Better Ingredients, Better Pizza." Better analysis means better regulation, when it's done ahead of time.

So I want to ask: Is it the belief of the panel that we ought to close the loopholes to ensure that independent regulatory agencies also conduct a net cost-benefit analysis up front?

Dr. Ellig, you were at the FTC. They would be included in there. Do you agree?

Dr. Ellig. I agree that it is important to have all agencies under the same set of requirements. I think there really are two loopholes.

The one loophole is independent agencies that are not covered by the Executive Orders and do not have a separate Legislative requirement for cost/benefit analysis don't have to do it.

The other kind of loophole is, under the current set of institutions we have agencies analyzing their own regulations. We have

economists in the Executive Branch agencies who are expected to analyze basically their boss' decisions——

Chairman Brady. Yes.

Dr. Ellig [continuing]. And render an impartial verdict on that.

And then we have OIRA (Office of Information and Regulatory Affairs), which is inside the Administration, you know, assessing what the agencies are doing. And I think we get better results with that than if we didn't have those requirements and didn't have OIRA, but we still have a lot of folks who are issuing regulations and essentially in charge of reviewing what they themselves are doing.

So it would be nice to have, for the Executive Branch agencies, a more independent look at the quality of their analysis. And that is one of the things that some kind of Judicial review would accomplish.

Chairman Brady. Great. To that point, standards, the transparency on those cost-benefit analyses ahead of time, where the public can comment. You can see what ingredients go into the cake ahead of time, the analysis.

Professor Dudley, you were at OIRA. I know they have a best practices, best standards' type approach, but statutorily should we set up some process where there are standards, where agencies can develop them publicly, you know, tailored to their regulatory challenges; they can be commented on and reviewed as part of setting appropriate standards up front?

Professor Dudley. Yes, I do think it would be valuable to have a statutory standard that supercedes other authorities. I think a lot of the problem is, as you mentioned in your opening remarks, there are some statutes that direct agencies not to consider, or at least have been interpreted by the courts as telling agencies they can't consider things that any sensible person would want to consider in making a decision.

Chairman Brady. On the look-back, it seems common sense would be to review, as a number of you proposed, a regular process to look back and compare the actual real-life impact versus the original analysis, when it is done.

In general—how best do we accomplish that? Is that a statutory change that requires it to be done? Is it including frequent Judicial review as part of the process?

Dr. Kieval, sort of going backward—you know, you deal with the FDA in heading this way on the panel—your views? Because you see it in your industry, obviously, with regulations. Good goals, you know, shared goals, how those regulations are implemented create, as you say, huge impacts on patients, the economy, and industries like yours.

Dr. Kieval. Yes. Absolutely. We have spent upwards of two years negotiating the latest MDUFA agreements with the FDA. And so I think there's a shared sense that if we are able to meet those goals, then that will be to the tremendous benefit of patients.

Certainly within industry we do look-backs and post-mortems on our programs and our processes with great regularity. One of the challenges that we have working with the agency is that sometimes the people who are present at the end of the project are not the

same people that were present at the beginning of the project. So better continuity of oversight of our projects would be very helpful.

Chairman Brady. Dr. Ellig, your point was, you know, standards up ahead. Make sure you address the issue of agency bias, but look-back gives you a chance to really look at the quality of the impact? Is that your position?

Dr. Ellig. Oh, yes, definitely. And I agree with Dr. Greenstone that the ideal look-back is done by someone other than the agency itself, to give kind of an independent view.

Chairman Brady. And, Dr. Greenstone, what is the best way to create that process? Because if you do it independently and objectively, I would think it would help. This is not a partisan issue. This is really a smarter way to hit a goal.

Dr. Greenstone. This is exactly an issue of how to best serve the American people. I think it would be good to embed in the process the agencies themselves, to engage in look-back. But I think it is very hard for people to be completely objective.

I find it hard to be objective about myself sometimes, and I think having my wife around to tell me the truth sometimes is useful. Sometimes painful, but useful. And I think having an outside agency or institution, a CBO-like thing for regulation, would be really quite effective and would help even improve the analyses that agencies do themselves.

Chairman Brady. My wife's look-back on me is a continual improvement process.

[Laughter.]

And very timely, let me add. Thank you all, very much. Senator Klobuchar.

Vice Chair Klobuchar. Thank you very much, all of you.

Dr. Greenstone, just to follow up on the Chairman's question there with your idea of having this automatic review, which I think is a good one, you would see this—you suggested it possibly could be each agency, but there are concerns that they would not probably be able to unmoor themselves from their closeness to having to enforce the regulation. So do you think it would be something that Congress would set up, then, to look back at it?

And how do we do it efficiently? You know, my concern is we are going to have new regulations that come out as we confront new problems as a Nation, and you want to make sure that those get done in a speedy manner instead of people getting hung out to dry for years. So how would we be able to do this efficiently?

Dr. Greenstone. With respect to creating an independent body to do this, I think it would really take a very small amount of money to set up a regulatory look-back organization say that could be housed in CBO, or it could be independent, but modeled after the CBO.

My own view is that that should be combined with increased look-backs within government itself. And so one way to do that would be to build on the Executive Orders that the President put out. I assume that there's also a Legislative way to mandate that.

In forcing agencies to do it themselves, I think there is a little bit of the mañana problem, they will always want to do it tomorrow. And I think putting some trigger in there to force them to comply by a certain period I think would be effective.

Vice Chair Klobuchar. Very good. The World Bank produces their annual report about doing business. They actually look at 185 of the world's economies, and they look at their ease of doing business, their regulatory environments.

In 2013, as well as 2012, the U.S. ranked 4th in ease of doing business, and 13th in ease of starting businesses. So we are doing some things right.

However, when you look at our tax system, with the fact that we play red light/green light, that it is too complex, we actually rank 69th out of 185 in that subcategory.

And I continually get complaints—as I know everyone up here—not only about paying taxes, obviously, but also about the fact that no one knows what is going to happen year in and year out, and that it is too complex.

Dr. Greenstone, just following up, do you think simplifying our Tax Code would benefit economic growth in the long run?

Dr. Greenstone. I think there are excellent opportunities to do some simplification. And I think simplification might put some tax lawyers out of business, but I think it would probably be good for the overall economy and lead to greater growth.

Vice Chair Klobuchar. Professor Dudley.

Professor Dudley. Well, I am not a tax expert, so I would answer that question as a regular person, and concur with both of you.

But if I could add something to your previous question?

Vice Chair Klobuchar. Sure, the question the Chairman led with, yes.

Professor Dudley. I agree with everything that my colleagues have said, because I really do think a Congressional office of regulatory oversight would be valuable for many, many different things.

But I also think there needs to be a change in the default that triggers review. We already have statutes that say look back at your regulations. The Regulatory Flexibility Act does. And yet meaningful retrospective review does not happen for all the reasons that Michael mentioned.

So the default somehow needs to change so that a regulation will expire unless you have shown it is having the effect it should have.

Vice Chair Klobuchar. Okay. Thank you.

Dr. Kieval, thanks again for coming and giving us some practical perspective on all of this. I also note, in addition to Representative Paulsen, Senator Coats is here. We co-chair the Medical Device Caucus in the U.S. Senate and he has done a lot of work in this area.

Could you speak, Dr. Kieval, to the FDA's culture and regulatory climate in recent years? You mentioned some proposals you had, but where have you seen improvement? And where do you—if you could just run it, where do you think we could see the most dramatic improvements?

Dr. Kieval. Well I think the regulatory climate has become more challenging over the past several years. And I think that is reflected in the financing climate becoming more challenging, as well, because investors often cite regulatory concerns as some of the biggest inhibitors of their investment.

So, clearly the FDA has a focus on ensuring patients' safety, and you can never be too sure that a product is safe, and that is an important part of the mission, but another important part of the mission is making sure that promising new products do reach patients in a timely manner. And we think that there are opportunities to continue to focus on that side of the equation.

The agreements in MDUFA we think are going to increase greatly the efficiency, which is going to translate into tremendous cost savings for industry. And I think what Congress can do is just keep both parties accountable to the goals that have been set under MDUFA and FDASIA, and I think that will be to our mutual advantage.

Vice Chair Klobuchar. In looking at the Medical Device Tax issue, and we are obviously, many of us up here would like to see it repealed and have been working—Senator Hatch and I have a working group working on how we could pay for that, and figuring out some practical ways it could actually get through Congress.

Is it true that Excise Taxes are applied to the sales of medical device firms whether they are profitable or not? And doesn't that mean that these companies may be forced to pay federal taxes even though they are not making a profit in many cases because in this area where the up-front costs are so high they have put a lot of money into research and development?

Dr. Kieval. Yes, that is absolutely true. Our company has raised about $200 million of capital that we have invested and continue to invest in research and development and clinical trials. We probably will not reach profitability until we are gaining revenues of, you know, $70 to $100 million per year, as we recoup that investment and defray our ongoing costs. Yet we would be responsible to start paying the taxes as soon as the first U.S. dollar [of revenue] crosses the threshold.

So as we think about continued investments in innovation, expanding manufacturing capabilities, and keeping high-paying jobs, we are already planning for the impact of the device tax that that is going to have on us.

Vice Chair Klobuchar. Thank you, very much.

Chairman Brady. Thank you.

Representative Paulsen.

Representative Paulsen. Thank you, Mr. Chairman.

I will just follow up a little. I will start out by mentioning that, boy, when I'm in Minnesota I get a chance to tour a lot of Minnesota companies, and Senator Klobuchar and I have been quite frequently visiting our medical device companies in particular.

And at a lot of these companies we get a chance to tour. They're small business. They're manufacturers. And so I have had a chance to talk with floor managers, the sea-level folks working on the floor, as well as the business owners. And the issue about uncertainty and the increasing regulatory burden comes up frequently as a part of those conversations.

In fact, there was a recent study that was just done on the state of manufacturing in Minnesota on a survey that was done: 60 percent of businesses in manufacturing are very concerned about government policies and regulations. So it is not just even concerning the tax side of the equation, but it's the regulatory environment.

So having that fear of onerous regulation does not create an environment that allows companies to invest with certainty in their people or their equipment, certainly. And that is definitely one factor that is a part of this Growth Gap which the Joint Economic Committee is focused on.

Mr. Kieval, I just want to follow up. The medical device industry is absolutely an American success story. You know that. Senator Klobuchar and I both know it. Senator Coats knows that. And we represent heavy sectors in that area.

But at the same time, I think we know that that leadership is threatened. And in particular, as Senator Klobuchar noted and you mentioned in your testimony, there is a recent study with the U.S. Venture Capital. Funding has declined and it continues to decline today. So it essentially is going to mean more movement towards Europe, or toward other countries for these new start-ups for break-through technologies. That harms patients, obviously.

So knowing that the trend is going in that direction, and knowing that medical devices and technology get approved in Europe faster than it gets approved here, what are some ways as a technology officer, for instance, that maybe we should be looking down the road for, how can technology play a role in making sure we are doing regulation smarter from a technology perspective, and at the same time protecting from a safety perspective?

Dr. Kieval. These are a part of the realities of what we are dealing with on a daily basis. And we, under the guidance of our boards of directors and our investors, have to make these investment decisions very carefully about whether to pursue products in the U.S. or outside the U.S.

You know, we've been able to garner our leadership position by attracting top talent, and retaining top talent with high-paying jobs, and investing heavily in ongoing innovation and expansion of manufacturing capabilities. And, with the time and amount of capital required to get our products across the approval threshold in the U.S., there is just less money to devote to those value-add activities.

On top of that, the Medical Device Tax is going to continue to divert precious capital away from ongoing innovation and U.S. jobs.

So I think ensuring that the agreements under MDUFA are met—and I think we all expect clinical as well as economic benefits to come out of those—but as we have talked about, I think repealing the Medical Device Tax would also go a long way to freeing up the greatly needed capital to help us maintain our leadership position.

Representative Paulsen. Dr. Ellig, I was going to ask a question. Because among the initiatives to assess the quality of federal regulation systematically is the Mercatus Regulatory Report Card as probably the most comprehensive.

Your testimony lists a lot of different criteria as a part of that Report Card. What is the most important criteria, and why?

Dr. Ellig. Oh, the most important criterion for a regulatory impact analysis is analysis of the systemic problem that the agency is trying to solve. Answering questions like:

Is there a problem?

Is it a system-wide problem that you might be able to solve through a change in the rules of the game?

Or is it just some bad behavior by particular bad actors where you might take more of a law enforcement approach rather than a regulatory approach?

Is there a problem at all?

And what is the nature of the problem so that we can then tailor a solution that would actually take care of the problem but also take care of the problem at minimum cost?

Representative Paulsen. You have also used the term "Regulatory Impact Analysis." Is that the same thing as cost/benefit analysis? Or does it mean something else?

Dr. Ellig. Regulatory Impact Analysis is really broader. Regulatory Impact Analysis is an overall analysis that summarizes a lot of information about the nature of the problem, the alternative solutions to the problem, and the costs and benefits of the alternative solution.

So really the cost/benefit analysis is one piece of a Regulatory Impact Analysis, and it would include economic analysis, but also any other science that goes into understanding the problem, understanding the harm, understanding what we are trying to do.

Representative Paulsen. Well, Mr. Chairman, I know we are going to have a lot more conversation about regulatory policies, given the President's proposed some new suggestions on the regulatory environment with energy, for instance, and this is something I think this Committee is going to continue to tackle. So I yield back.

Chairman Brady. Thank you.

Senator Coats.

Senator Coats. Thank you, Mr. Chairman.

And thanks to all the witnesses here for your presentations to us. I think it is an extremely important issue. I agree with my colleagues here. I think on a bipartisan basis if we are going to address our current economic malaise, or much lower and slower growth than we would like to see at this particular point in time in our economy, regulatory reform has to be an essential component of that, along with tax reform and budget reform, and particularly entitlement reform.

And so I appreciate your contribution. I want to state that, the panel here is kind of weighted toward the medical device issue. And I enjoy co-chairing that Caucus with my colleagues from Minnesota on medical devices. So rather than be repetitive, let me just say Indiana says ditto to everything that Senator Klobuchar has said, and Congressman Paulsen has said, relative to medical devices.

We have a big stake in that in Indiana, and it is one of the most, no pun intended, cutting-edge industries in our State, providing a glimpse into the future of the kind of technology innovation that we can accomplish here in the United States, and we don't want to see that shipped overseas on the basis of an egregious tax, or failure to bring about some sensible regulations.

Secondly, I also want to note for the record—and this is pretty startling; I don't know that you need to comment on this—but the Small Business Administration a few years ago estimated that the

cost of complying with federal regulations exceeded $1.75 trillion every year—nearly 12 percent of the total GDP.

Now if that is only half right, we are looking at a staggering cost here. And so the application of impact analysis, and sound examination of how we go forward before we regulate is extremely important.

I want to just ask a couple of questions. Dr. Ellig, I will direct this to you: the President's announcement yesterday relative to moving forward on climate control initiatives of course has a dramatic effect on regulations coming out of the EPA.

What measurements and analysis have you done, if any, relative to EPA? And do you have any thoughts at this particular point as to where this agency would fall in terms of regulatory impact—sound regulatory impact analysis?

Too often I think ideology tends to drive agency regulatory decisions, as opposed to sound analysis. I am not trying to make a political point here; I am just simply saying if we are going to address these problems we need to be more rational and more scientifically oriented in terms of making some of these decisions.

So do you have any thoughts or comments on that?

Dr. Ellig. Well, in the Regulatory Report Card the environmental regulations actually often tend to rank in about the top half. But what that is telling us, since the average is about—the average score is about 50 percent—what that is telling us is that the EPA, the Department of Energy, some of the other entities that issue environmental regulations, have made an investment in Regulatory Impact Analysis and are producing documents that are at least, you know, trying to appear to comply.

In comparison with some other agencies where you read the Regulatory Impact Analysis and you say, ayah, they are not even trying. So sometimes they are some of the better ones, but even the better ones are not that great. So it is maybe a more complicated answer than, they are great or, they are lousy.

Comparatively, there are some good examples but the best ones still are not that great.

Senator Coats. Well this recent announcement by the President that he is going to use the regulatory process to achieve what a lot of us think needed to be legislated is going to have enormous impact on energy costs in this country.

And so I think sound analysis, to the extent it can be provided for us as we examine how to go forward and address this, could be very helpful to us. I think the impact of this is going to transcend the impact of a lot of regulations that have come down, and it will particularly be relevant to different states depending on the source of energy that they supply to their people.

I think my time is about expired, and thank you, Mr. Chairman.

Chairman Brady. Thank you, Senator.

Representative Hanna.

Representative Hanna. In a recent transportation hearing, Administrator of the Federal Motor Carrier Safety Administration, Anne Ferro, someone who has worked well with my office, talked about hours of service for commercial trucks. This is sort of a real-life example of what we are talking about, and I want to ask you about the subjective nature, the culture of the bureaucrats and

workers behind these regulations, and the disincentives they may or may not have to not take risks but rather go through that regulation which offers the most safety for them and perhaps the most expensive for the public, not unlike Administrator Lisa Jackson's, to paraphrase, cost is not our problem; in certain regulation, we simply do—we are in the business of protecting the environment, which I respect.

The Federal Motor Carrier Safety Administration was working on a study. They didn't finish it. They did not include a study on regulation that impacts specific industries—for example, concrete, cellphone, trucks, asphalt, local deliveries of aggregates.

I simply asked the question, or it was asked at the committee hearing, how it made their new regulations credible when they had not even finished the study yet? And never really got an answer.

But I wondered, for example, Dr. Greenstone, you have great ideas in terms of follow-up and analysis of what the real-world impact is of some of these things, but do you believe there is a cultural bias of, for lack of a better way for me to explain it, of personal protection, and a disincentive to create regulation which is more relevant in the real world, as opposed to kind of subjective and value-based, which is more inclusive?

Dr. Greenstone. You know, I can't speak to the exact issue that you mentioned about the Department of Transportation, but what I do think is: There's not enough sunshine in the regulatory process.

And through this kind of look-back mechanism that I think would be a fantastic idea, and through having outside approvals, that would produce the sunshine that would allow for a healthier examination of some of the tradeoffs that you are talking about.

Representative Hanna. Dr. Dudley, do you believe that there is a bias towards more regulation inside of these organizations, as opposed to less, since the more regulation they create, the less risk comes to bear on their decision?

Professor Dudley. I think that is true, and I think it has been documented that the incentives are to err on the side of over-regulating. Because there are two types of errors a regulator could make.

If they make a mistake and allow action that later turns out not to have been safe, you all are going to haul them up before Congress and they will be berated. But if they take an action that maybe inhibits some innovation, that is less visible. That is certainly true in the medical area.

Representative Hanna. How do you address, in the medical area particularly with the FDA and the approval of drugs that can be life-saving but long in the tooth, people are dying while they are waiting for them, how do you change that culture for anybody out there who—any of you four gentlemen and lady—who might have an idea? How do you incentivize people to be creative in the process, as opposed to restrictive?

Professor Dudley. Let me concur with Professor Greenstone that the regulatory process is very insular, and there is not enough transparency and sunshine.

We need to bring in the wisdom of crowds, and there are a variety of ways of doing it. It is one of the things that we at GW are

thinking about. Getting a lot of different perspectives on a regulation, both after it is is in effect, but also before, I think could improve the regulatory process.

Dr. Ellig. I think one of the things Congress could do through oversight is continually asking agencies—and this is whether it is regulation, or spending programs, or whatever:

What is the result of what you did? And what is the evidence that you are actually solving problems, and that this is working?

I mean, a lot of times in this town we get caught up in the idea that, well, we've solved the problem because we passed a law. We solved the problem because we adopted a regulation. Sort of the government—the fact that the government engaged in activity is taken as proof that the problem is solved.

Representative Hanna. Check that box.

Dr. Ellig. Yes, check the box, and whatever. But, through vigorous oversight asking, all right, is the problem actually solved? Is the air cleaner? Is the water cleaner? Or whatever particular problem you are trying to deal with.

Dr. Kieval. As an industry right now our focus is not as much on wholesale reform of regulation, but it is on making sure that the regulations are applied in a transparent and consistent and a reasonable and predictable manner, and we think that MDFUA is going to help that.

You know, a simplistic comment that I could add is, the FDA is highly visible for all of the negative decisions that it makes, and they are highly criticized for all the decisions that people think are wrong. I think we could do a better job of celebrating the right decisions that they make, when they do make decisions to let new technologies out and to begin helping patients.

And I think they deserve as much visibility for those decisions as they do for what we think are the wrong ones.

Representative Hanna. Thank you. And my time has expired.

Chairman Brady. Thank you.

The former Chairman of JEC, Representative Maloney.

Representative Maloney. Thank you, Mr. Chairman, and Vice Chairwoman.

Mr. Greenstone, you testified that an equivalent of the Office of Information and Regulatory Affairs should be set up to provide Congress with regulatory impact evaluations. And why does a new office need to be created? And why can we not simply assign this task to an existing governmental body?

Senator Coats in his questioning pointed out that we already spend $1.7 trillion a year in regulatory oversight, and regulatory impact studies. So why do we need a new office? Why can't we just work through the $1.7 trillion that we are already spending?

Dr. Greenstone. Thank you for that question, Congresswoman Maloney.

I think actually currently we spend not very much on regulatory analysis. The regulations impose lots of costs and introduce lots of benefits on the overall economy, and I think that is what the $1.7 trillion refers to.

My view on why we need a new body—and I recognize that we are in tight budget times—is that currently the Regulatory Impact Analysis comes out of the very agencies that are implementing the

regulations, and it can be hard for people to be objective with themselves about what they are doing.

And so having an outside body like the CBO serves Congress in terms of providing independent information. I think it would be an effective way both to improve the analyses that are done inside the Administration, and also just to provide sunshine that would benefit everyone.

Representative Maloney. Also could you comment on the President's speech yesterday on carbon pollution? In his speech, the President pointed out that Americans are paying for inaction on carbon pollution through higher food costs, and higher taxes to pay for disaster relief and rebuilding. He also mentioned that certain states will need to budget for larger wildfire seasons. And how will the EPA take these costs into account in preparing their own cost/benefit analysis?

Dr. Greenstone. So I think the President's announcement yesterday is probably, to this Committee's point, one of the most consequential regulatory actions in many years. And with respect to your question, we are already experiencing costs of climate change. Hurricane Sandy is an excellent example. And some of the crop failures in the last two summers have been linked to climate change.

And I think what the President is saying is, we are already paying those costs. We are paying them in a very indirect way. Let's start to pay them up front, and maybe we will save on net through reduced damages in the future.

Representative Maloney. Well in creating this new body that you are advocating for, where does it end? There was a bill in one of my committees that I serve on to have more of a cost/benefit analysis on top of the cost/benefit analysis already in Dodd-Frank, and in the SEC.

So it seems like if you have all these analyses, it might get to the point where you can never do anything. Not only do you have the analysis of the committee, you then have the cost/benefit analysis; you then have Judicial review; now you're proposing another regulatory body to have yet another cost/benefit analysis. When does it end? And how much would it cost?

Would it not be more appropriate if you have a problem to ask GAO to do a specific analysis of that particular cost? And we're working within the regular framework that is already existing in government as opposed to going out and creating yet another layer?

I fail to understand what is the benefit. If we have a problem, look at it. Have the analysis done. Several Presidents—I'll cite the Grace Commission that President Reagan had—have come in and looked at particular areas, and particular areas and analyzed them. There is now a focus in energy where outside groups and governmental groups are doing more of an analysis of our cost/benefit in our energy strategies.

But to go in and create another complete bureaucratic overlay, what is the benefit? Why not focus on the problem and solve it, as opposed to creating yet another huge governmental employment bureau?

Dr. Greenstone. So I don't come here before you today lightly to suggest that there be another bureaucracy. I think the things to

keep in mind are that—I'm just citing the figure other people have used—but that the overall impact of regulations on the economy is numbered in the trillions of dollars annually.

And the problem is, although there are many people analyzing these regulations, as you point out, none of them, zero point zero, analyze them afterwards. And so all the analysis is done up front, and it is generally done with very good intentions, but the problem is people cannot predict the way things are going to turn out.

And so the reality often ends up being different than what people projected. And so what I am proposing is that this new institution is just a small increase in CBO and would provide the kind of information that currently does not exist.

Again, to put it in context, I believe that this could be funded for $15 to $20 million a year, probably less. And it is a small investment, in my view, relative to the trillions of dollars of impacts that the regulations have on the economy currently.

Representative Maloney. My time is expired.

Chairman Brady. Thank you.

Representative Delaney.

Representative Delaney. Thank you, Chairman Brady, and thank you for holding this important hearing. I want to thank all the the witnesses here today for their thoughtful comments.

I think this question about a prospective versus a retrospective analysis is really important. And I think, Dr. Greenstone, you made the point quite well, which is our ability to do prospective analysis on these questions is inherently limited unless we were to somehow adopt and embrace and really understand an incredibly dynamic model for understanding all the implications of these various regulations which, much to my dismay, it has been very hard for us to do that in the CBO on a prospective basis. And I think it might be even more complex here, because behavior does change.

I mean, the Clean Air Act I think—I don't have a terrific historical perspective, but that was done really for a quality of life perspective. I don't think people really understand that, depending upon the estimates, it has been an 8-to-1 to 25-to-1 savings from a pure economic standpoint.

So I think this notion of an incredibly vigorous, rigorous data-driven retroactive analysis, if you will, done by an independent agency is really, really important. My question for you, Dr. Greenstone—and then I have a question for Professor Dudley—is:

Do you anticipate that this entity would really be able to effectively analyze all of the various implications of regulations, including things that are not even anticipated based on the regulatory intent? Some of which may be quite positive under the category of unintended consequences. We could have really positive unintended consequences, or we could have really negative unintended consequences. Do you think that it can effectively do that?

Dr. Greenstone. You know, that is a very important question. Thank you. No analysis is perfect. I feel very confident that doing the first bit of ex post analysis has got to be an improvement over doing none.

I train graduate students. When Chairman Brady mentioned—and I wrote this down—that he was interested in doing a better job of quantifying the costs and benefits of regulations, you know, their

hearts were aflutter with the notion that people might be interested in that.

[Laughter.]

And I think having an agency, or a group of people devoted to that, who spend their lives on that—and they could be former graduate students of mine—would I think produce a lot of information that could help shape the regulatory process going forward in a way that better delivers benefits.

Representative Delaney. And I assume it could be very transparent. Again, unlike some of the things we sometimes see in CBO, which it's not quite clear how they came up with their answers, this, because it is a retrospective analysis, I would think we would be able to have detailed disclosure as to what inputs went in, and what analysis was done, which I think would also help inform new regulations even if we don't do as much prospective analysis—because I generally think all regulation should be held to a higher standard. But we have to recognize that prospectively it is hard to figure some of this stuff out, whereas on a retrospective basis we ought to have absolute answers as to whether these things are actually working.

And my question, maybe, for Professor Dudley in the same theme is: How do we think about overlapping regulations as it relates to this? Because my background is in the financial services industry, which prior to the crisis was subject to four banking regulators, and now has three banking regulators. And if you look at regulations, they put forth or promulgate individually, you'll do a certain cost/benefit analysis. But if you actually weave our somewhat byzantine overlapping, in my judgment, banking regulatory approach to the market, you would conclude that the effects of various regulations are producing a different cost/benefit analysis than they would individually.

How do you think about these decisions in that context? Because it is not just individual regulations; it is regulations working together towards the same goal. Do you think this capability could help us in some of that? Because that to me seems to be some of the low hanging fruit. Here we have multiple people trying to do the same thing. There's turf wars, et cetera. Whereas, if we could kind of level-set all of these things and look at them individually, look at their effect together, we could actually come up with a really good analysis of what we should be doing.

Professor Dudley. Well I agree. That is something that Presidents have assigned to the Office of Information and Regulatory Affairs. When they review agencies' regulations, part of that review is: Are they doing the analysis they should? But part of it is interagency review, OIRA shares draft regulations with other agencies to look for conflict, or overlap.

What is missing is your area, the financial regulations. The independent regulatory agencies don't have the value of OIRA's interagency review.

Representative Delaney. Right.

Professor Dudley. Which is another argument for the Congressional regulatory oversight. Because not only could that help you evaluate regulations, but as you develop legislation that office

would have that institutional knowledge to know what other agencies are doing similar things.

Representative Delaney. So it could look at individual regulations, and then it could look at a holistic regulatory approach to problems we want to regulate.

Like we clearly as a country want to regulate the banking industry. So we should look at not only individual banking regulations, but if the various banking—I use banking as an example; it applies to other areas, obviously, the economy, the quilt that we've weaved, if you will, for regulations, whether it's actually achieved so it could do both. I think it is a great idea, and it is something we should be advancing hard.

So thank you for your testimony.

Chairman Brady. I want to thank all of you. Regulation reminds me, when my first son was 5 years old, putting the group of five-year-olds on a soccer field. It doesn't actually mean you see a soccer game.

[Laughter.]

The way they run together in packs, and it doesn't even resemble it. Adding regulation upon regulation does not always mean you achieve a goal. And so having independent, objective, high-quality analysis up front, removing the bias, having standards we can comment on, a look-back that is reliable to improve the next round seems to me to be areas of common ground as we go forward.

I want to thank, on behalf of Vice Chair Klobuchar, each of the witnesses today. Very, very helpful, thoughtful, and insightful testimony and answers, as well. So thank you all very much for being here today.

The hearing is adjourned.

(Whereupon, at 11:15 a.m., Wednesday, June 26, 2013, the hearing was adjourned.)

SUBMISSIONS FOR THE RECORD

PREPARED STATEMENT OF HON. KEVIN BRADY, CHAIRMAN, JOINT ECONOMIC COMMITTEE

This month the current recovery celebrates its fourth anniversary. Now is a good time to assess how the U.S. economy is performing.

Unfortunately for American families, the current recovery remains the weakest since World War II. There is a troubling Growth Gap in economic performance between this recovery and the average of post-war recoveries, leaving our economy four million private sector jobs and $1.2 trillion short. While Wall Street is booming, every man, woman and child in America is missing nearly $3,000 in real disposable income due to the Growth Gap.

During this Congress, the Joint Economic Committee has been examining the causes of the Growth Gap and the types of alternative policies to close that gap. The JEC has studied how current fiscal and monetary policies have held back this recovery. Today, the JEC will explore regulatory policy.

From town hall meetings with my constituents in Texas to conversations with business leaders and economists across America, there is one consistent message: Uncertainty over the costs of new regulations in healthcare, the environment, labor issues and financial services is suppressing business investment and the creation of new jobs along Main Street.

The burden of federal regulations is large. At year-end 2012, the Code of Federal Regulations had 238 volumes and 174,545 pages.

That burden is growing. In 2012, the Federal Register—which publishes proposed new rules and regulations, final rules and changes to existing regulations—totaled 78,961 pages. Three of four highest page counts since the Federal Register began publication have occurred during the Obama presidency.

And that burden is costly. NERA Economic Consulting, in a study last year commissioned by Manufacturers Alliance for Productivity and Innovation (MAPI), estimates the current direct cost of compliance with "major" regulations—those with an estimated cost greater than $100 million per year—issued between 1993 and 2011 to be between $265 billion and $726 billion per year. Clyde Wayne Crews of the Competitive Enterprise Institute estimates the total cost of regulation in America approaches $1.8 trillion annually—or nearly 12% of GDP.

Given this historically weak recovery, the rise of technology to help us meet regulatory goals more cheaply and a shared belief that America should continue progress on a clean environment and safe workplace, when regulations are necessary doesn't the public deserve the most effective regulation at the least cost?

Smart regulations that improve the market process and its incentive structure to accelerate progress rather than dictate particular outcomes will prove superior to tens of thousands of pages of mandated rules and micro-managed instructions.

Devising process-enhancing rules that engage the private sector's versatility and creativity require objective upfront analysis and thoughtful design. Yet federal agencies often do things the other way around—deciding first what they want to do and then using whatever analysis is performed to justify their preconceived "solution." This abuse must stop.

In 1981, President Reagan issued an executive order requiring executive branch agencies to conduct Regulatory Impact Analysis, commonly known as cost-benefit analysis, before issuing major new regulations. This first step toward smarter regulation had its limitations.

An executive order affects only executive branch regulatory agencies and therefore does not affect independent regulatory agencies such as the Consumer Product Safety Commission, the Federal Trade Commission, the Federal Reserve, and the Consumer Financial Protection Board.

Over the years, Congress has exempted broad swaths of federal regulation from the scrutiny of cost-benefit analysis through provisions of the Clean Air Act, for example. While there are government-wide "best practice" standards on how agencies should conduct cost-benefit analysis, they are not uniformly applied and are not legally binding. The quality of agency cost-benefit analyses varies greatly.

Agency bureaucrats are naturally biased toward their proposed regulation and have learned how to manipulate cost-benefit analysis to justify whatever new regulations they wish to issue. For example, former Administrator of the Office of Information and Regulatory Affairs, professor John Graham, closely examined Corporate Average Fuel Economy (CAFE) standards for trucks in his testimony before the House Committee on Oversight and Government Reform in September 2011 and found that to inflate the benefits of their new rule, regulators had cut the discount rate and the so-called "rebound effect" of increased driving with better mileage to half or less. He also found that they failed to carefully consider the rule's effects on vehicle size, performance and safety.

In other words, today too few proposed rules are fully analyzed. There are too many loopholes, no uniform requirement across all agencies, a lack of standards with which to conduct the analysis, no check-and-balance against agency bias, no comparison of past analysis to real life impacts and little recognition of the total burdens on the economy of regulation.

We must do better. The purpose of this hearing is to discover ways in which Congress can make the regulatory process "smarter," more cost effective and better designed to accomplish the goals without damaging the economy.

In particular, the Committee hopes to hear from today's witnesses about the deficiencies in cost-benefit analysis as it is now practiced and how agencies can do a better job of quantifying and measuring the costs and benefits of both proposed and existing regulations. I look forward to the testimonies.

THE GEORGE WASHINGTON UNIVERSITY

WASHINGTON, DC

Prepared Statement of Susan E. Dudley

Director, GW Regulatory Studies Center
Research Professor,
Trachtenberg School of Public Policy and Public Administration

Hearing on

Reducing Unnecessary and Costly Red Tape through Smarter Regulations

Before the

Joint Economic Committee

June 26, 2013

Statement of Professor Susan E. Dudley

Chairman Brady, Vice-Chairman Klobuchar, and distinguished members of the Committee, thank you for inviting me to testify today on smarter regulations. I am Director of the George Washington University Regulatory Studies Center, and Research Professor in the Trachtenberg School of Public Policy and Public Administration.[1] From April 2007 to January 2009, I oversaw executive branch regulations of the federal government as Administrator of the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB). I have studied regulations and their effects for over three decades, from perspectives in government (as both a career civil servant and political appointee), the academy, non-profit organizations, and consulting.

In the 125 years since Congress created the first regulatory agency,[2] the number of regulatory agencies and the scope and reach of the regulations they issue has increased significantly. In 2013, there are over 70 federal agencies, employing over 300,000 people to write and implement regulation.[3] Every year, they issue thousands of new regulations, which now occupy over 168,000 pages of regulatory code. For over a century, concerns over the accountability of what some have called the "fourth branch" of government have led all three branches of government to take steps to exercise checks and balances on the development and enforcement of regulations.[4]

The Legislative Branch

Past congresses have passed several overarching laws governing regulatory practice, and establishing factors the executive branch must evaluate, information it must provide, and procedures for third-party review of regulations. Some of the most important regulatory review laws of the last few decades include:

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[1] The George Washington University Regulatory Studies Center aims to improve regulatory policy through research, education, and outreach. This statement reflects my views, and does not represent an official position of the GW Regulatory Studies Center or the George Washington University.

[2] The Interstate Commerce Act established the Interstate Commerce Commission in 1887 to regulate railroad rates http://www.ourdocuments.gov/doc.php?flash=true&doc=49&page=pdf

[3] Susan Dudley & Melinda Warren, FISCAL STALEMATE REFLECTED IN REGULATORS' BUDGET: AN ANALYSIS OF THE U.S. BUDGET FOR FISCAL YEARS 2012 AND 2013. The George Washington University Regulatory Studies Center and the Weidenbaum Center on the Economy, Government, and Public Policy. (2012) *available at* http://research.columbian.gwu.edu/regulatorystudies/sites/default/files/u41/Regulators_Budget_2012.pdf Note that "agencies that primarily perform taxation, entitlement, procurement, subsidy, and credit functions are excluded from this report," so these figures exclude staff developing and administering regulations in the Internal Revenue Service, the Centers for Medicaid and Medicare Services, etc.

[4] Elena Kagan, *Presidential Administration,* 114 HARV. L. REV. 2245 (2001).

- the Regulatory Flexibility Act (RFA) of 1980, which requires agencies to assess the impact of a regulation on small businesses and provides for review by the Small Business Office of Advocacy.[5]
- the Paperwork Reduction Act (PRA) of 1980 (amended in 1995), which established OIRA within the OMB to review the paperwork and information collection burdens imposed by the federal government.[6]
- the Unfunded Mandates Reform Act (UMRA) of 1995, which limits regulatory agencies' ability to place burdens on state, local, and tribal governments[7]
- the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, which enforces requirements for small business impact analyses under the RFA.[8]
- the Congressional Review Act (CRA) of 1996,[9] contained in the SBREFA, which requires rule-issuing agencies to send all mandated documentation that is submitted to the OMB to both houses of Congress as well. It also allows Congress to overturn regulations within a specified time with a congressional resolution of disapproval.
- the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (section 638(a)), which requires the OMB to report to Congress yearly on the costs and benefits of regulations and to provide recommendations for reform.[10]
- the Truth in Regulating Act of 2000, which gives Congress the authority to request that the GAO conduct an independent evaluation of economically significant rules at the proposed or final stages.[11]
- the Information Quality Act of 2000, which required the OMB to develop government-wide standards for ensuring and maximizing the quality of information disseminated by federal agencies. Under the guidelines, agencies must follow procedures for ensuring the utility, integrity, and objectivity of information used in rulemaking and elsewhere. They also must offer an administrative mechanism for responding to public requests to correct poor-quality information that has been or is being disseminated.[12]

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[5] Available at: http://www.sbaonline.sba.gov/advo/laws/law_lib.html
[6] Available at: http://www.archives.gov/federal-register/laws/paperwork-reduction/
[7] Available at: http://www.gsa.gov/portal/content/245277
[8] Available at: http://www.sba.gov/advocacy/825/12186
[9] Available at: http://www.archives.gov/federal-register/laws/congressional-review/
[10] OMB's annual reports are available at: http://www.whitehouse.gov/omb/inforeg_regpol_reports_congress/
[11] Available at: http://www.gpo.gov/fdsys/pkg/PLAW-106publ312/html/PLAW-106publ312.htm
[12] Available at: http://www.gpo.gov/fdsys/pkg/PLAW-106publ554/pdf/PLAW-106publ554.pdf

These efforts have had mixed results. Agencies generally meet UMRA requirements with reference to regulatory impact analyses prepared pursuant to Executive Order 12866, but rarely do more.[13] While pursuant to the RFA and SBREFA, courts have overturned regulations that fail to consider impacts on small business,[14] agencies have successfully defended regulations that ignore the RFA requirements if the regulation's effects on small entities are considered to be "indirect."[15,16] Congress has used the CRA to enact a resolution of disapproval only once, overturning an OSHA regulation addressing ergonomics in the workplace.[17]

OMB reports annually to Congress on the costs and benefits of major regulations, but a 2001 Congressional Research Service report observed that OMB's reports, "have been incomplete, and its benefits estimates have been questioned."[18] My own research corroborates those concerns, and shows that a large percentage of total reported benefit estimates are driven by a few questionable assumptions.[19] The General Accounting Office[20] and others[21] have noted that

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[13] See testimony of Susan Dudley and other witnesses before the House Subcommittee on Technology, Information Policy, Intergovernmental Relations and Procurement Reform, Committee on Oversight and Government Reform, February 15, 2011, *available at* http://oversight.house.gov/index.php?option=com_content&view=article&id=1129:qunfunded-mandates-and-regulatory-overreachq&catid=14:subcommittee-on-technology

[14] Northwest Mining Association v. Babbitt, 5 F.Supp. 2nd 9 (D.D.C. 1998), and Southern Fishing Association vs. Daley, 995 F.Supp. 1411 (M.D. Fla. 1998).

[15] American Trucking Assns v. EPA 175 F.3d 1027, 1043 (D.C. Cir 1999)

[16] Jeffrey J. Polich, *Judicial Review and the Small Business Regulatory Enforcement Fairness Act: An Early Examination of When and Where Judges Are Using Their Newly Granted Power over Federal Regulatory Agencies*, 41 Wm. & Mary L. Rev. 1425 (2000).

[17] While several resolutions of disapproval have passed one house of Congress, only one joint resolution of disapproval has passed both. It overturned an OSHA regulation addressing ergonomics in the workplace. Though resolutions of disapproval require only a simple majority in Congress, they face the threat of presidential veto, which would require a two-thirds majority to override. The conditions surrounding the ergonomics regulation were likely key to its disapproval. It was a "midnight regulation" issued amid much controversy at the end of the Clinton administration. The resolution disapproving the rule came at the beginning of the Bush administration (which did not support the rule), eliminating the veto threat. Richard S. Beth, Disapproval of Regulations by Congress, Congressional Research Service (2011). Available at http://www.senate.gov/CRSReports/crs-publish.cfm?pid=%270E%2C*P_%3D%22P%20%20%0A. Susan E. Dudley testimony http://judiciary.house.gov/hearings/pdf/Dudley02282011.pdf

[18] Rogelio Garcia, Cong. Research Serv., IB95035, Federal Regulatory Reform: An Overview (2001), *available at* http://www.thecre.com/pdf/2002-crs.pdf.

[19] Susan E. Dudley, "OMB's Reported Benefits of Regulation: Too Good to be True?" *Regulation*. Vol. 36 No. 2 (2013) available at: http://www.cato.org/sites/cato.org/files/serials/files/regulation/2013/6/regulation-v36n2-4.pdf

[20] U.S. Gen. Accounting Office, GAO/GGD-99-59, Analysis of OMB's Reports on the Costs and Benefits of Federal Regulation (1999), *available at* http://www.gao.gov/archive/1999/gg99059.pdf.

[21] Susan E. Dudley, Perpetuating Puffery: An Analysis of the Composition of OMB's Reported Benefits of Regulation, Business Economics (2012) 47, 165–176. doi:10.1057/be.2012.14.

it is difficult for OMB to report objectively on estimates of regulatory benefits and costs. As discussed under Recommendations below, additional efforts are needed to ensure meaningful analysis of regulatory consequences.

The Executive Branch

The executive branch has also made efforts to improve regulatory analysis, accountability, and outcomes. President Carter built on initiatives of Presidents Nixon and Ford to create procedures for analyzing the impact of new regulations and minimizing their burdens,[22] and every subsequent president has expanded executive oversight of regulatory agency activities. (See table below.)

Executive Order 12866,[23] issued by President Clinton in 1993, continues to guide the development and review of regulations today. E.O. 12866, like its predecessor E.O. 12291 (issued by President Reagan), expresses the philosophy that regulations should (1) address a "compelling public need, such as material failures of private markets"; (2) be based on an assessment of "all costs and benefits of available regulatory alternatives, including the alternative of not regulating"; and (3) "maximize net benefits" to society unless otherwise constrained by law.

E.O. 12866 requires, among other things, that a regulatory analysis be performed on all rules deemed to be of significant economic impact (i.e., that have an effect of $100 million or more in a year). The regulatory analysis must include a statement of need for the regulation, an assessment of alternative regulatory approaches, and a benefit- cost analysis.

Like presidents before him, President Obama has reinforced and expanded the principles and practices of regulatory analysis and executive oversight. He retained OIRA, and its staff of under fifty career civil servants who operate within the Executive Office of the President, reviewing regulations to ensure they are consistent with the President's priorities, and coordinating interagency review to avoid redundancy and conflict. With its mission to ensure regulations' benefits justify their costs, OIRA plays an important role. It is institutionally more interested in impacts on society broadly and less susceptible to special interest pressures than line

[22] President Carter's E.O. 12044 required agency heads to determine the need for a regulation, evaluate the direct and indirect effects of alternatives, and choose the least burdensome. Exec. Order No. 12044, 43 Fed. Reg. 12661 (Mar. 24, 1978).

[23] Available at: http://www.whitehouse.gov/sites/default/files/omb/inforeg/eo12866/eo12866_10041993.pdf

agencies,[24] and provides what President Obama has called "a dispassionate and analytical 'second opinion' on agency actions."[25]

Executive Order 13563,[26] issued in January 2011, reaffirmed the regulatory principles and practices that have been in effect since 1981.[27] It reinforced E.O. 12866 and stressed the importance of conducting sound analysis of likely regulatory impacts, of providing public opportunities to engage in the process of developing new regulations, and of designing less-burdensome, more flexible approaches to achieve regulatory goals. It also required agencies to develop plans for periodically reviewing regulations already on the books, with an eye toward streamlining, repealing, or expanding them to make them more effective and less burdensome.

E.O. 13579, issued in July 2011, encouraged independent regulatory agencies to comply with E.O. 13563 requirements "concerning public participation, integration and innovation, flexible approaches, and science," to the extent permitted by law. E.O. 13579 also said that these agencies "should consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned," and make such information public.[28]

While these executive branch efforts have done little to slow the growth in new regulation, they have focused attention on understanding the effects of regulations, and some argue they have resulted in "smarter regulation" that produces more benefits than costs.[29] Ultimately, however, statements of principles from the President are not enforceable in court, and will accomplish little unless the President is willing and able to enforce them in practice.

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[24] Susan E. Dudley, "Regulatory Reform: Lessons Learned, Challenges Ahead," *Regulation*, Vol. 32, Number 2, Summer 2009, available at http://www.cato.org/pubs/regulation/regv32n2/v32n2-1.pdf

[25] Memorandum of January 30, 2009—Regulatory Review, 74 Fed. Reg. 5977 (Jan. 30, 2009), *available at* http://www.reginfo.gov/public/jsp/EO/fedRegReview/POTUS_Memo_on_Regulatory_Review.pdf.

[26] Exec. Order No. 13563, 76 Fed. Reg. 3821 (Jan. 21, 2011).

[27] Press Release, The White House, Fact Sheet: The President's Regulatory Strategy (Jan. 18, 2011), *available at* http://www.whitehouse.gov/the-press-office/2011/01/18/fact-sheet-presidents-regulatory-strategy.

[28] http://www.whitehouse.gov/the-press-office/2011/07/11/executive-order-regulation-and-independent-regulatory-agencies

[29] See, for example, John D. Graham, Paul R. Noe, and Elizabeth L. Branch, Managing the Regulatory State: The Experience of the Bush Administration, Fordham L. Rev 33(2005), and Cass Sunstein, Smarter Regulation: Remarks from Cass Sunstein, AdLawRev 63 (2011)

Executive Orders on Regulatory Analysis and Oversight[30]

Executive Order	Title	President	Date Signed
EO 12044	"Improving Government Regulations" (revoked by EO 12291)	Carter	March 1978
EO 12174	"Paperwork" (revoked by EO 12291)	Carter	November 1979
EO 12291	"Federal Regulation" (revoked by EO 12866)	Reagan	February 1981
EO 12498	"Regulatory Planning Process" (revoked by EO 12866)	Reagan	January 1985
EO 12866	"Regulatory Planning and Review" (amended by EO 13258)	Clinton	September 1993
EO 13258	"Amending Executive Order 12866 on Regulatory Planning and Review" (revoked by EO 13497)	G. W. Bush	February 2002
EO 13422	"Further Amendment to Executive Order 12866 on Regulatory Planning and Review" (revoked by EO 13497)	G. W. Bush	January 2007
EO 13497	"Revocation of Certain Executive Orders Concerning Regulatory Planning and Review"	Obama	January 2009
EO 13563	"Improving Regulation and Regulatory Review"	Obama	January 2011
EO 13579	"Regulation and Independent Regulatory Agencies"	Obama	July 2011
EO 13609	"Promoting International Regulatory Cooperation"	Obama	May 2012
EO 13610	"Identifying and Reducing Regulatory Burdens"	Obama	May 2012

Recommendations for Improving Regulatory Policy

Recent Congresses have considered legislation to improve the quality of regulations, and make them more accountable to the American people. I have evaluated the possible consequences of different legislative initiatives elsewhere.[31] This section discusses several categories of reform that may prove useful.

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[30] www.RegulatoryStudies.gwu.edu

[31] Susan Dudley, "Prospects for Regulatory Reform," *Engage* Vol 12, Issue 1 (2011), available at: http://www.fed-soc.org/doclib/20110603_DudleyEngage12.1.pdf, and prepared statement before the Senate Homeland Security and Government Affairs Committee, July 2011, available at: http://www.tspppa.gwu.edu/docs/20110720_testimony_dudley.pdf

Improving Regulatory Impact Analysis

One focus of regulatory reform legislation has been on improving the quality of the analysis agencies conduct before issuing regulation. Given that presidents of both parties for over 30 years have supported ex ante impact analysis of regulations, the creation of a statutory obligation for doing so is probably not necessary to ensure continued analysis, however, codifying the requirements could have several advantages.

- First, such legislation would lend Congressional support to these nonpartisan principles and the philosophy that before issuing regulations agencies should identify a compelling public need, evaluate the likely effects of alternative regulatory approaches, and select the alternative that provides the greatest net benefit to Americans.[32]

- Second, legislation could apply these requirements to independent agencies (which Administrations have been reluctant to do through executive order for fear of stirring up debate over the relationship between independent agencies and the President). Senators Portman, Warner and Collins have recently introduced the Independent Agency Regulatory Analysis Act of 2013, which has received bipartisan support from former OIRA administrators, former heads of independent regulatory agencies, and legal academics.[33]

- Third, Congress could make compliance with them judicially reviewable. Judicial review could be valuable, not because the courts have a particular expertise in regulatory analysis, but because agencies tend to take more seriously aspects of their mission that are subject to litigation. Like executive and Congressional oversight, judicial oversight would likely make regulatory agencies more accountable for better decisions based on better analysis. (Judicial review is discussed further below.)

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[32] Section 1(a) of Executive Order 12866 states the regulatory philosophy as follows: "Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach."

[33] The legislation and letters of support are available at: http://www.portman.senate.gov/public/index.cfm/press-releases?ID=dd889275-da52-4764-b2c9-f02ab26fc881

Requiring better regulatory impact analysis before regulations are issued is important, but will not guarantee "smarter regulation" for several reasons.

- First, unless the cross-cutting analytical requirements supersede the decision criteria expressed in individual authorizing statutes, such as Section 109 of the Clean Air Act,[34] many regulations will continue to be based on limited information. Statutes that ignore or explicitly prohibit analysis of tradeoffs lead to regulations with questionable benefits that divert scarce resources from more pressing issues.[35]

- Second, ex ante regulatory impact analysis necessarily rests on hypotheses of how the regulatory action will alter outcomes and what they will cost. It is easy for regulators to fall prey to the "planner's paradox"[36] without appreciating that efforts to address perceived problems often have unintended consequences. Planned solutions always look better on paper than unplanned solutions, because the planner sees only his "data, assumptions, biases, and understandings of the way the world works.... All of the unseen difficulties with the planned solution — the data, assumptions, biases, and understandings of the world that turn out to be wrong — are invisible to the analyst because the data he considers are his own." Even the most carefully analyzed regulations may result in unanticipated changes in behavior that undermine the desired effects of the regulation.

- Third, agencies have strong incentives to demonstrate through analysis that their desired regulations will result in benefits that exceed costs. Regulatory impact analyses are often developed after decisions are made and used to justify, rather than inform, them. In principle, a benefit-cost analysis should be "complete." It should include all the significant consequences of a policy decision: direct and indirect, intended and unintended, beneficial and harmful. In practice, all such analyses must to some degree fall short of completeness. My review of agencies' analyses as reported through OMB's annual reports suggests that regulatory agencies are not approaching the problem objectively. On the benefit side of the equation, they quantify or list every conceivable good thing that they can attribute to a decision to issue new regulations, while on the cost side they only consider the most

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[34] The Administrative Conference of the United States has conducted studies and provided recommendations on applications of these decision criteria that the Committee may find useful, including: 79-4 Cost-Benefit Analysis in Regulatory Decision-Making; 85-2 Regulatory Analysis of Agency Rules; 88-9 Presidential Review of Agency Rulemaking [60 Fed. Reg. 56312 (Nov 8, 1995)]; and Paul Verkuil, *A Critical Guide to the Regulatory Flexibility Act,* Duke L.J. 213 (1982).

[35] See Susan Dudley and George Gray, "Improving the Use of Science to Inform Environmental Regulation," in *Institutions and Incentives in Regulatory Science,* Lexington Books, Jason Johnston ed. (2012)

[36] Brian Mannix, "The Planners' Paradox," *Regulation,* Summer 2013, available at: http://www.cato.org/sites/cato.org/files/serials/files/regulation/2003/7/mannix.pdf

obvious direct and intended costs of complying with the regulation.[37] (This is a problem of "confirmation bias," discussed further below.)

Only Congress can address the first problem by amending language in existing legislation that precludes reliance on sound decision criteria or hinders APA procedures (such as requirements that agencies issue interim final regulations that limit public comment).[38] New statutes that authorize executive agencies to issue regulations should require them to conduct careful analysis of likely effects, both intended and unintended, and provide them adequate time to research, deliberate, and consult with the public before issuing new rules.

A minimum step toward addressing the second problem would be to require agencies to present evidence that the identified problem requires a federal regulatory solution, as well as an objective evaluation of alternative solutions. To this end, it is essential that analytical requirements not be limited to conducting benefit-cost analysis, but rather capture the broader philosophy and principles articulated in E.O. 12866. Legislation should require that regulatory decisions be based on the identification of a compelling public need (a material failure of private markets), an objective review of alternatives (including the alternative of not regulating), and an understanding of the distributional impacts of different approaches.

To truly address the latter two problems, however, institutional changes are needed to alter incentives for conducting analysis and making decisions. Despite requirements for public comment and practices for executive oversight, regulatory decision-making is often insulated from different perspectives. Regulatory agency staff are smart and motivated, but, like everyone else, they are susceptible to what behavioral psychologists call "confirmation bias,"[39] and their single-mission focus leads them to discount data, research, values and perspectives that do not corroborate their preferred regulatory action. As a result, as Justice Stephen Breyer observed in his 1993 book *Breaking the Vicious Circle,* "well-meaning, intelligent regulators, trying to carry out their regulatory tasks sensibly, can nonetheless bring about counterproductive results."[40] Breyer referred to this institutional phenomenon as "tunnel vision," where agencies single-

[37] See Susan Dudley, "Perpetuating Puffery: An Analysis of the Composition of OMB's Reported Benefits of Regulation," *Business Economics* Vol. 47, No. 3, August 2012.

[38] See Susan Dudley, "GAO Report: Agencies Circumvent Public Comment on Major Rules," available at: http://research.columbian.gwu.edu/regulatorystudies/sites/default/files/u41/GAO%20report%20Dudley.pdf and Sofie Miller, "What the Unified Agenda Tells Us About Notice and Comment Rulemaking," available at: http://research.columbian.gwu.edu/regulatorystudies/sites/default/files/2012agenda_Miller.pdf

[39] For a short description of confirmation bias, see http://skepdic.com/confirmbias.html.

[40] Stephen Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation*, Harvard University Press, 1993.

mindedly pursue a particular goal to a point that "the regulatory action imposes high costs without achieving significant additional safety benefits."[41]

Institutional changes that provide for more checks and balances, and harness the "wisdom of crowds"[42] are needed to counter these natural incentives. As discussed below, congressional oversight, judicial oversight, and opportunities for public involvement could provide greater accountability and improve the reasoning underlying regulatory decisions as well as the decisions themselves.

Enhanced Congressional Oversight

Executive branch oversight of regulatory actions has proven valuable, but it is not sufficient.[43] Congress may also want to consider legislation that would strengthen its own ability to control regulation. One approach would require a Congressional vote before major new regulations can become effective, and another would establish a Congressional office to review and evaluate regulations.

Congressional Approval of New Rules

The Regulations from the Executive In Need of Scrutiny (REINS) Act[44] would provide a tool for Congress to "increase accountability for and transparency in the federal regulatory process."[45] It is patterned after the 1996 CRA, providing expedited procedures for evaluating and voting on major regulations, but it changes the default outcome. Rather than requiring Congress to enact a "joint resolution of disapproval" to prevent a rule from going into effect, no major rule could go into effect until Congress enacted an affirmative "joint resolution of approval."[46]

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[41] Susan E. Dudley, "Regulatory Reform: Lessons Learned, Challenges Ahead," *Regulation*, Vol. 32, Number 2, Summer 2009, available at http://www.cato.org/pubs/regulation/regv32n2/v32n2-1.pdf

[42] James Surowiecki, *The Wisdom of Crowds*. Anchor Books, 2005.

[43] Susan Dudley, "Congress Needs its own Regulatory Oversight Office," Penn RegBlog, http://www.law.upenn.edu/blogs/regblog/2011/08/congress-needs-its-own-regulatory-review-office.html (2011)

[44] S. 15 available at: http://beta.congress.gov/bill/113th-congress/senate-bill/15

[45] Regulations from the Executive in Need of Scrutiny Act, H.R. 10, 112th Cong. § 2 (2011).

[46] See my analysis of the advantages and disadvantages of REINS in a GW Regulatory Studies Center working paper available at: http://research.columbian.gwu.edu/regulatorystudies/sites/default/files/u38/regreform_dudley_workingpaper_20110405.pdf

Congressional Regulatory Oversight Office

A Congressional office responsible for reviewing regulations would have several benefits.[47] Most importantly, it would serve as an independent check on the analysis and decisions of regulatory agencies and OIRA.[48] While a Congressional office would not have the same authority OIRA exercises to affect agency draft regulations, it would be able to devote resources to areas OIRA does not, such as examining the effects of regulations issued by independent regulatory agencies. Just as the CBO provides independent estimates of the on-budget costs of legislation and federal programs, a Congressional regulatory office could provide Congress and the public independent analysis regarding the likely off-budget effects of legislation and regulation.[49]

Judicial Branch Oversight of Regulation

Under the APA, after a regulatory agency issues a final rule, an affected party may challenge it in court. Reviewing courts may reverse or remand the rule to the agency for reconsideration on constitutional grounds, on procedural grounds (whether the agency followed the procedures specified in the APA), or on the basis of the agency's interpretation of the authorizing statute.

Recent courts have overturned several regulations of the Securities and Exchange Commission as being arbitrary and capricious and in violation of the APA, finding that compliance with the Commission's statutory criteria demanded a more rigorous analysis of benefits and costs to evaluate the rule's effects on efficiency, competition, and capital formation.[50]

Courts defer to agency expertise when evaluating regulatory records,[51] however, and presidential executive orders governing regulatory impact analysis have stated that their requirements are not

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[47] See Testimony of Robert W. Hahn and Robert E. Litan before the House Government Reform Committee, Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs, March 2003, *available at:* http://www.brookings.edu/testimony/1999/04_righttoknow_litan.aspx

[48] GAO noted "It is politically difficult for OMB to provide an independent assessment and analysis of the administration's own estimates in a public report to Congress. If Congress wants an independent assessment of executive agencies' regulatory costs and benefits, it may have to look outside of the executive branch or outside of the federal government." U.S. Gen. Accounting Office, GAO/GGD-99-59, Analysis of OMB's Reports on the Costs and Benefits of Federal Regulation (1999), *available at* http://www.gao.gov/archive/1999/gg99059.pdf.

[49] Susan Dudley, "Congress Needs its own Regulatory Oversight Office," Penn RegBlog, http://www.law.upenn.edu/blogs/regblog/2011/08/congress-needs-its-own-regulatory-review-office.html (2011)

[50] For a discussion of recent cases, see Jane Luxton, *An Uncomfortable Wake-Up Call For Dodd-Frank Regulators*, Futures & Derivatives Law Report (Vol. 32, Issue 1) available at: http://www.pepperlaw.com/publications_update.aspx?ArticleKey=2296

[51] In *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, the Supreme Court established a two-step test for determining whether to grant deference to a government agency's interpretation of a statute. Under the second

enforceable by law.[52] The Regulatory Accountability Act attempts to alter the deference to agencies by subjecting regulations issued under APA notice-and-comment rulemaking procedures to a "substantial evidence" standard of judicial review, which directs a reviewing court to set aside an agency action unless the record provides "such relevant evidence as a reasonable person would accept as adequate to support a conclusion."[53] This is arguably a more exacting standard than "arbitrary and capricious" standard of review.[54]

The small business community has been frustrated that courts have interpreted the Regulatory Flexibility Act's requirements to assess economic impact as applying only to direct compliance costs. They argue that agencies should consider reasonably foreseeable indirect economic impacts on small entities, such as increases in input prices (e.g., electricity, natural gas, or transportation) or state-level regulations issued pursuant to federal rules. This latter issue is particularly important for environmental regulations, where the "duty of regulating is passed on to the states without any corresponding analysis or requirements for states to consider less burdensome alternatives for small business."[55]

Enhanced Public Input

It is popular to talk about the possibility of using modern technology to improve regulatory policy by engaging the wisdom of crowds. While there are some promising ideas on this front, it is important to keep in mind that the most powerful technology for effectively using the decentralized wisdom of crowds is a very old one: the market.[56] There are countless opportunities to improve regulatory policy by giving greater deference to the wisdom of the market. Regulatory agencies continue to issue energy efficiency standards for appliances,

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step, if Congressional intent is not clear, "the issue for the court is whether the agency's answer is based on a permissible construction of the statute." *Chevron U.S.A. v. NRDC*, 467 U.S. 837 (1984).

[52] See EO 12866 Sec. 11. "*Judicial Review.* Nothing in this Executive order shall affect any otherwise available judicial review of agency action. This Executive order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person."

[53] Mareno v. Apfel, 1999 U.S. Dist. LEXIS 8575 (S.D. Ala. Apr. 8, 1999) ("more than a scintilla but less than preponderance").

[54] 5 U.S.C. § 706(2)(A).

[55] *Hearing on Legislation to Improve the Regulatory Flexibility Act Before the H. Comm. on Small Business*, 110th Cong. (2007) (testimony of Thomas Sullivan, Chief Counsel for Advocacy, Small Business Administration), *available at* http://archive.sba.gov/advo/laws/test07_1206.html.

[56] See John O. McGinnis, *Accelerating Democracy: Transforming Governance through Technology.* Princeton University Press, 2013.

vehicles, and businesses, all of which depend on a falsehood: the theory that regulators know more than consumers about consumers' own welfare.[57]

Apart from greater reliance on the market, engaging the wisdom of crowds to improve regulatory outcomes could take several forms. Requiring pre-rulemaking disclosure of key information related to problem formulation, risk assessment, and impact analysis, would engage broad public comment on the proper choice of studies, models, assumptions, etc. long before any policy decisions are framed, and positions established.[58] The bicameral Regulatory Accountability Act (RAA)[59] would further these objectives by amending the Administrative Procedure Act to codify and extend some of the analytical requirements in presidential executive orders and also provide for more extensive opportunities for public involvement, particularly for rules designated as "high impact." Depending on their expected impacts, rules and guidance documents would be subject to procedures beyond the notice and comment procedures currently embodied in the APA, and could bring greater transparency to the basis for regulatory decisions, and engage broader public input earlier in the regulatory process.

Incentives to Reexamine Existing Regulations

Most legislative and executive branch reforms have focused on analyzing and improving new regulations, and agencies seldom look back to evaluate whether existing regulations are having their intended effects. Initiatives to require ex post evaluation of regulations that are in effect have met with limited success[60] largely because they did not change the underlying incentives.

Several initiatives would seek to alter those incentives. Senator Angus King is seriously considering a proposal by the Progressive Policy Institute for a Regulatory Improvement Commission, patterned after the Base Realignment and Closing Commission, that would review public recommendations for removing existing regulations and present a package recommendation to Congress for an up or down vote.[61]

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[57] Susan E. Dudley, Perpetuating Puffery: An Analysis of the Composition of OMB's Reported Benefits of Regulation, Business Economics (2012) 47, 165–176. doi:10.1057/be.2012.14.

[58] See Dudley and Gray 2012 for more ideas related to engaging a wide range of resources to expand regulatory information.

[59] S. 1029 (available at: http://www.govtrack.us/congress/bills/113/s1029/text) and H.R. 2122 (available at: http://www.govtrack.us/congress/bills/113/hr2122)

[60] Susan E. Dudley prepared statement before the Senate Homeland Security and Government Affairs Committee, July 2011, available at: http://www.tspppa.gwu.edu/docs/20110720_testimony_dudley.pdf

[61] Based on discussion with Sen. King's staff. The Progressive Policy Institute's analysis of the problem of accumulating regulation and its proposal is available at: http://www.progressivepolicy.org/2013/05/regulatory-improvement-commission-a-politically-viable-approach-to-u-s-regulatory-reform/

Congress is considering using budgeting concepts to alter regulatory agencies' incentives to issue new regulations and examine the effectiveness of existing regulations.[62] The United Kingdom's "one-in-one-out" approach to regulation forces agencies to make tradeoffs when issuing new regulation,[63] and members of the U.S. Senate are considering similar legislation.[64] Under a strict "regulatory paygo" or "one-in-one-out" approach, regulatory agencies would be required to eliminate an outdated or duplicative regulation before issuing a new regulation of the same approximate economic impact. While subject to analytical challenges, this has the potential to impose some needed discipline on regulatory agencies, and to generate a constructive debate on the real impacts of regulations.[65]

The Regulatory Accountability Act would require all final rules to include a plan for review at least every 10 years, to "determine whether, based upon evidence, there remains a need for the rule, whether the rule is in fact achieving statutory objectives, whether the rule's benefits continue to justify its costs, and whether the rule can be modified or rescinded to reduce costs while continuing to achieve statutory objectives."[66]

Conclusion

Regulatory impact analysis is a longstanding and important element of US regulatory policy, but a variety of institutional obstacles prevent regulatory impact analysis from being a silver bullet for producing smarter regulation. As long as agencies themselves conduct the analysis, selected actions will suffer from confirmation bias. Analyses are often used to justify, rather than inform, decisions, and intentionally or unintentionally become tools for advocacy (by agencies and others). Current procedures do not provide other participants incentives to invest in careful, objective analysis, nor to conduct ex-post evaluation of regulatory outcomes (or empirical verification of ex ante estimates of impacts).

Institutional changes that provide for more effective checks and balances, and engage the wisdom of crowds are needed to counter these incentives. Greater congressional oversight, judicial oversight, and opportunities for public involvement could provide greater accountability and improve the reasoning underlying regulatory decisions as well as the decisions themselves.

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[62] See statement of Senator Portman before Homeland Security and Government Affairs Committee, June 23, 2011, *available at http://www.hsgac.senate.gov/hearings/federal-regulation-a-review-of-legislative-proposals-part-i.*

[63] http://www.bis.gov.uk/policies/bre/one-in-one-out

[64] See statement of Senator Mark Warner before Homeland Security and Government Affairs Committee, June 23, 2011, *available at* http://www.hsgac.senate.gov/hearings/federal-regulation-a-review-of-legislative-proposals-part-i.

[65] Susan E. Dudley prepared statement before the Senate Homeland Security and Government Affairs Committee, July 2011, available at: http://www.tspppa.gwu.edu/docs/20110720_testimony_dudley.pdf

[66] Regulatory Accountability Act Sec. 3((f)(4)(G)

PREPARED STATEMENT OF MICHAEL GREENSTONE, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, THE HAMILTON PROJECT, THE BROOKINGS INSTITUTION

Thank you Chairman Brady, Vice Chair Klobuchar, and members of the Joint Economic Committee for inviting me to speak today.

My name is Michael Greenstone, and I am the 3M Professor of Environmental Economics at the Massachusetts Institute of Technology, the Director of the Hamilton Project, and a Senior Fellow at the Brookings Institution. My research focuses on estimating the costs and benefits of environmental quality, with a particular emphasis on the impacts of government regulations.

I appreciate the opportunity to speak with you today about opportunities to improve the government's regulatory system. Under all economic circumstances, regulatory efficiency and clarity are crucial objectives for the credibility and predictability of the government's role in the marketplace. However, given the continuing weak economic environment, it is absolutely essential to design a regulatory structure that protects the wellbeing of our citizens without imposing unnecessary costs on American businesses and society as a whole.

We can achieve these objectives without compromising our values in key areas ranging from the protection of public health to the supervision of financial markets by ensuring that the Executive and Legislative branches have the tools of analysis and measurement they need to review current and proposed regulations. The purpose of my testimony is to describe in concrete terms how this can be accomplished.

INTRODUCTION

American government, at every level, regulates a broad array of social and economic life. Regulatory policy determines the air we breathe, the quality of the water we drink, the materials we use to construct our homes, the cars we buy, the safety of our workplaces, the investments we make, and much more. Government regulates these activities because in cases of market failures, for example, our free market system does not create the necessary incentives for businesses and individuals to protect the public good.

But, in making decisions about regulations, public officials must choose which areas of our lives merit government rules, as well as how stringent those rules should be.

The Clean Air Act is a classic example of a regulation with significant benefits and costs. Before its passage in 1970, there were few constraints on businesses that emitted pollution as a byproduct of their operations. The result was poor air quality. As one small example, white collar workers in Gary, Indiana, often brought an extra shirt to work because the first would be dirty from the air and unfit to wear by midday. Even more importantly, some of my research, as well as research by others, has found that the polluted air led to elevated mortality rates that reduced the lifespans of the American people.[1] Obviously, no business sets out to cause these impacts; but, in trying to maximize their profits, it was not in their interests to install expensive pollution abatement equipment when their competitors did not. As a result, they did not act to adequately reduce emissions.

At the same time, the Clean Air Act's regulations require firms to alter their production processes in ways that raise their costs. Indeed, some of my recent research finds that an important set of Clean Air Act rules has raised polluting industries' costs of production by roughly 2.6%. This has reduced firms' profits and led to higher prices for consumers. Further, it has caused regulated firms to scale back their operations, which led to employment losses at those firms.[2] Although the ultimate effect on the level of jobs in the economy is likely minimal in normal economic times, recent research indicates that workers who lose their jobs due to regulations often face prolonged periods of unemployment and become reemployed at lower wages.[3]

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[1] Kenneth Chay and Michael Greenstone, "The Impact of Air Pollution on Infant Mortality: Evidence from Geographic Variation in Pollution Shocks Induced by a Recession," Quarterly Journal of Economics, 2003, 118(3); Olivier Deschenes, Michael Greenstone and Joseph Shapiro, "Defending Against Environmental Insults: Drugs, Emergencies, Mortality and the NOx Budget Program Emissions Market," Department of Economics, MIT (2011).

[2] Michael Greenstone, "The Impacts of Environmental Regulations on Industrial Activity: Evidence from the 1970 and 1977 Clean Air Act Amendments and the Census of Manufacturers." Journal of Political Economy, 2002, 110(6); Michael Greenstone, John A. List and Chad Syverson, "The Effects of Environmental Regulation on the Competitiveness of U.S. Manufacturing," Department of Economics, MIT (2011).

[3] Reed Walker, "The Transitional Costs of Sectoral Reallocation: Evidence From the Clean Air Act and the Workforce," Department of Economics, Columbia University (2011).

The challenge then for regulators is to consistently set rules with benefits that exceed their costs.

In a pair of Executive Orders, President Obama has created a framework that has the potential to be the most fundamental shift in regulatory policy in more than three decades. The Executive Orders require that federal agencies routinely review existing significant regulations in order to "determine whether any such regulations should be modified, streamlined, expanded, or repealed" with the purpose of making the "regulatory program more effective or less burdensome in achieving the regulatory objectives." These reforms offer the promise of finding a better balance between our health and safety and our economic growth.

To understand why the president's efforts are so critical, imagine if the Food and Drug Administration approved new drugs without ever having tested them on people—that it approved drugs knowing only in theory how they were likely to affect the human body. Further imagine if such drugs remained on the market for years, or even decades, without their effects ever being subject to evaluation. This path is simply inconceivable, but until recently was how the vast majority of government regulations were treated.

Make no mistake—inadequate regulatory policy can be, as with drug approvals, a life-or-death issue because of the significant role regulations play in every aspect of our daily lives.

A bit of history: U.S. regulations used to be designed essentially in the dark. Then, in 1981, President Ronald Reagan issued an executive order institutionalizing the idea that regulatory action should be implemented only in cases when, among other provisions, "the potential benefits to society for the regulation outweigh the potential costs to society." It sounds obvious. But this idea of applying cost-benefit analysis in the regulatory arena fundamentally altered the way in which regulations were considered.

In 1993, President Bill Clinton outlined more specific guidelines for prospective analysis of cost-benefit trade-offs. And yet, the regulatory review process was still operating with one hand tied behind its back. As a general matter, a regulation's likely benefits and costs were considered only before the proposal was enacted—the point when we know the least precisely because the regulations are untested. Consequently, prospective estimates of the costs and benefits must rest on many unverifiable and potentially controversial assumptions.

And, once a regulation passed through a prospective analysis and went on the books, it could remain there for decades without any further evaluation.

Some regulations work out exactly as intended. But some, of course, do not. For example, an air pollutant may prove to be more harmful than was originally understood. Or innovation may lead to new and less expensive pollution-abatement technology. In our rapidly changing world, regulations can and should adapt to change.

President Obama's Executive Orders take a critical step forward by looking backward. They require that agencies routinely reevaluate the costs and benefits of existing regulations and identify whether the goals of a regulation could be achieved through less expensive means. This revolutionary process of retrospective analysis offers the promise of finding a better balance between our health and safety and our economic growth

In the remainder of my testimony, I will identify two further changes that would increase the chances that our regulatory system consistently produces rules with benefits that exceed costs.

I. EXTENDING EXECUTIVE ORDERS 13563 AND 13610

The first change is to make three reforms that build on Executive Orders 13563 and 13610.

First, I recommend institutionalizing the retrospective review of economically significant rules in a public way so that these reviews are automatic in nature. In the case of rules that are currently in force, this would mean publicly committing to a retrospective analysis of each existing rule within a pre-specified period. This might be 5 or 10 years, with the length of time depending on the particulars of the rule and the results of any previous reviews.

In the case of new rules, the implementing agency would be required to announce a timetable for review with a maximum allowable amount of time, perhaps 5 or 10 years, with shorter time periods being preferable. In addition, the agency would be required to pre-specify the expected benefits (e.g., reduced child mortality rates) and costs (e.g., reduced business profits) so that the terms of the subsequent review would be known in advance. The agency would also be required to identify how these benefits and costs would be measured, such as the types of data and other information that it anticipates being necessary for review.

Second, the relevant agency should commit to undertaking a new rulemaking when the results from the retrospective analysis differ from the benefits and costs that were expected prior to the rule's implementation. As with the retrospective analysis, there should be a time limit for conducting the new rulemaking. In cases where the realized benefits exceed the costs by a wider margin than expected, there may be further opportunities to maximize net benefits. In cases where the rules are found to be ineffective or unjustified, agencies should identify ways to modify the rules or abandon them. Finally, if the retrospective analysis confirms the original expectation of benefits and costs, then there would not be a need for a new rulemaking.

Third, these efforts would be strengthened if they were accompanied by a triggering mechanism to ensure that retrospective evaluations occur and, when appropriate, for new rulemakings to be undertaken within the prescribed time periods. One approach would be for agencies to announce publicly and post on their website the deadline for a rule's review and reconsideration. A stronger approach would be for judicial action to compel reviews and rulemaking in the cases where an agency has failed to comply with a review timeline or to act upon its results.

II. A CBO FOR REGULATIONS

The second change is to ensure that the quality of the reviews is commensurate with the stakes of getting regulatory policy right. In this spirit, there are some difficulties with the approach I just outlined. Many agencies do not have the staff, expertise, or resources necessary to undertake these reviews. Further, the process of self-evaluation is challenging for all organizations, as it requires complete objectivity. Indeed, history is unkind to organizations that fail to get outside reviews of their work.

My recommendation is to establish a new, independent body for regulatory review. This body could be housed within the Legislative Branch, and it could be modeled after the Congressional Budget Office (CBO) or even become a division within the existing CBO.

As you know, before the CBO was established, only the President had a ready source of budgetary and economic data and analysis. Congress was forced to largely rely on the Office of Management and Budget (OMB) for this sort of information. The CBO was invented to level the playing field. Its analyses allow Congress to consider the economic and budgetary implications of new policy ideas. Crucially, the CBO also helps Congress evaluate the information that it receives from the Executive Branch.[4]

The entire budget process has benefited from CBO's existence. This is a direct result of its independence. The budgetary analyses and proposals of all legislators and Executive agencies are now created to a higher standard, knowing that they must ultimately stand up to scrutiny by the non-partisan CBO.

This system of budgetary review and economic analysis could be a model for a reorganized regulatory review process. Like the CBO, this new organization would reside in the Legislative Branch, and it would be non-partisan. The organization would be charged with conducting independent regulatory impact evaluations. Some of the organization's activities would be statutory in nature—for example, automatic reviews of economically significant regulations—while other evaluations could be performed at the request of Congressional committees and members.

Such an organization would directly strengthen our regulatory system. Agency analyses would benefit from the scrutiny that they would ultimately receive from this new, independent organization. Further, the results of the retrospective reviews would become part of the agencies' automatic assessments of their regulations that I described above. I believe that providing this type of rigorous, independent review would build confidence within the business community and a better sense of transparency.

Finally, this new organization could help to increase the credibility of the regulatory evaluations by developing an explicit checklist to determine the rigor of regulatory analyses. The checklist should favor randomized control trials, the gold standard in terms of evidence, and natural experiments over models and observational studies. A 2011 Hamilton Project paper provides some other ideas for a check list.[5]

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[4] Congressional Budget Office, "CBO Testimony: Statement of Robert D. Reischauer, Director, Congressional Budget Office, before the Joint Committee on the Organization of Congress" (1993). *http://www.cbo.gov/ftpdocs/105xx/doc10580/1993_06_10_mission.pdf*

[5] Ted Gayer, "A Better Approach to Environmental Regulation: Getting the Costs and Benefits Right," Discussion Paper 2011–06, The Hamilton Project, Brookings Institution (2011).

Such a checklist could also be issued as guidance by the Administration to its agencies.

Of course, the creation of such a body would require resources, which are difficult to come by in our current fiscal environment. However, I think it is extraordinarily likely that such an office would pay for itself many times over. To put this in context, the current CBO budget is less than $50 million annually. My best estimate is that the new budget for such an organization would be less, perhaps substantially so.

This is a very small amount of money when compared to the potential costs and benefits that regulations impose on our economy. Although it is difficult to determine the total number of economically significant regulations that are on the books, the Office of Management and Budget reviewed 540 major regulations between 2001 and 2010,[6] which are defined as having an effect of more than $100 million on the economy annually—either in costs or benefits. Consequently, it seems safe to conclude that the total costs and benefits of regulations can be measured in the hundreds of billions of dollars annually. It is apparent that we have a lot at stake economically with regard to our regulatory system and the cost of finding out which parts are working is almost trivially quite small in comparison.

By creating a body that can undertake rigorous analysis of the costs and benefits of regulation—both ex-ante and ex-post—policymakers will have better tools for protecting those regulations with great benefits for our society, reforming those regulations that impose unnecessary costs, and potentially culling those that no longer serve their purpose.

IV. CONCLUSIONS

In conclusion, our regulatory system is a linchpin of our well-being. It allows us to live longer and healthier lives, among many other important impacts. However, these important benefits come with direct economic costs. The purpose of my testimony has been to identify some reforms that will help to ensure that our regulatory system does its job in the most cost-effective way possible—in which the benefits to society exceed the costs.

To quickly summarize, I propose two key reforms:

1. Institutionalize a process by which agencies automatically undertake retrospective reviews of regulations and initiate a new rulemaking when the results from the retrospective analysis differ from the expected benefits and costs.
2. Create a new, independent body for rigorous, objective regulatory review that is modeled on the Congressional Budget Office.

We live in a rapidly changing economy and need a regulatory review structure that evolves to meet the new and different needs of our society. The reforms that I have outlined here will allow our regulatory system to consistently produce rules with benefits that exceed costs. That would be good for our well-being, and good for the American economy.

Thank you once again for inviting me to participate in this discussion. I will gladly respond to any questions.

[6] Office of Information and Regulatory Affairs, Office of Management and Budget, "2011 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities" (2011).

Bridging the gap between academic ideas and real-world problems

TESTIMONY

IMPROVING REGULATORY IMPACT ANALYSIS THROUGH PROCESS REFORM

BY JERRY ELLIG

Joint Economic Committee
United States Congress

Hearing on "Reducing Unnecessary and Costly Red Tape through Smarter Regulations"

June 26, 2013

Good morning Chairman Brady, Vice Chairman Klobuchar, and members of the committee. Thank you for inviting me to testify today.

I am an economist and research fellow at the Mercatus Center, a 501(c)(3) research, educational, and outreach organization affiliated with George Mason University in Arlington, Virginia. I've previously served as a senior economist for this committee and as deputy director of the Office of Policy Planning at the Federal Trade Commission. My principal research for the last 25 years has focused on the regulatory process, government performance, and the effects of government regulation. For these reasons, I'm delighted to testify on today's topic.

For more than three decades, presidents of both political parties have instructed executive branch agencies to conduct Regulatory Impact Analysis when issuing significant regulations. Some independent agencies, such as the Securities and Exchange Commission, are required by law to assess the economic effects of their regulations. Executive orders and laws requiring economic analysis of regulations reflect a bipartisan consensus that economic analysis should inform, but not dictate, regulatory decisions.

Unfortunately, agencies' Regulatory Impact Analyses are not nearly as informative as they ought to be, and there is often scant evidence that agencies utilized the analysis in decision making. These problems have persisted through multiple administrations of both political parties. The problem is institutional, not partisan or personal. Further improvement in the quality and use of Regulatory Impact Analysis will likely occur only as a result of legislative reform of the regulatory process. To achieve improvement, all agencies should be required to conduct thorough and objective Regulatory Impact Analysis for major regulations and to explain how the results of the analysis informed their decisions.

Let me elaborate on each of these points.

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The ideas presented in this document do not represent official positions of the Mercatus Center or George Mason University.

WHY REGULATORY IMPACT ANALYSIS IS NECESSARY

We expect federal regulation to accomplish a lot of important things, such as protecting us from financial fraudsters, preventing workplace injuries, preserving clean air, and deterring terrorist attacks. And regulation also requires sacrifices; there is no free lunch. Depending on the regulation, consumers may pay more, workers may receive less, our retirement savings may grow more slowly due to reduced corporate profits, and we may have less privacy or less personal freedom. Regulatory Impact Analysis is the key tool that makes these tradeoffs more transparent to decision makers. Understanding the effects of regulation has to start with sound Regulatory Impact Analysis.

A thorough Regulatory Impact Analysis should do four things:

1. assess the nature and significance of the problem the agency is trying to solve, so the agency knows whether there is a problem that could be solved through regulation and, if so, the agency can tailor a solution that will effectively solve the problem;

2. identify a wide variety of alternative solutions;

3. define the benefits the agency seeks to achieve in terms of ultimate outcomes that affect citizens' quality of life and assess each alternative's ability to achieve those outcomes;

4. identify the good things that regulated entities, consumers, and other stakeholders must sacrifice in order to achieve the desired outcomes under each alternative. In economics jargon, these sacrifices are known as "costs," but just like benefits, costs may involve far more than monetary expenditures.

Without all of this information, regulation becomes a faith-based initiative. That is, where regulators have discretion under the law, they would be making choices based merely on the hope that good intentions will produce good results. Given the enormous influence regulation has on our day-to-day lives, decision makers have a responsibility to act based on knowledge of regulation's likely effects, not just good intentions.

SHORTCOMINGS IN THE QUALITY AND USE OF REGULATORY IMPACT ANALYSIS

Scholarly research demonstrates that Regulatory Impact Analysis often falls short of the standards articulated in executive orders and Office of Management and Budget guidance. More often than not, agencies do not appear to use Regulatory Impact Analysis to inform major decisions. Regulatory Impact Analyses often seem to be advocacy documents written to justify decisions that were already made, rather than information that helped regulators figure out what to do.[1]

The Mercatus Center's Regulatory Report Card provides some of the most recent evidence on the quality and use of Regulatory Impact Analysis.[2] The Regulatory Report Card is a qualitative evaluation of both the quality and use of regulatory analysis in federal agencies. The scoring process uses 12 criteria grouped into three categories:

1. **Openness:** how easily can a reasonably informed, interested citizen find the analysis, understand it, and verify the underlying assumptions and data?

2. **Analysis:** how well does the analysis define and measure the outcomes or benefits the regulation seeks to accomplish, define the systemic problem the regulation seeks to solve, identify and assess alternatives, and evaluate costs and benefits?

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1. Richard Williams. "The Influence of Regulatory Economists in Federal Health and Safety Agencies." Mercatus Working Paper. Arlington, VA: Mercatus Center at George Mason University, July 2008, http://mercatus.org/sites/default/files/publication/WP0815_Regulatory%20Economists.pdf; Wendy E. Wagner, "The CAIR RIA: Advocacy Dressed up as Policy Analysis," in Reforming Regulatory Impact Analysis, ed. Winston Harrington et al. (Washington, DC: Resources for the Future, 2009), 57.
2. The Report Card methodology and 2008 scoring results are in Jerry Ellig and Patrick McLaughlin, "The Quality and Use of Regulatory Analysis in 2008," Risk Analysis 32, no. 5 (May 2012): 855–80. Scores for all regulations evaluated in 2008 and subsequent years are available at www.mercatus.org/reportcard.

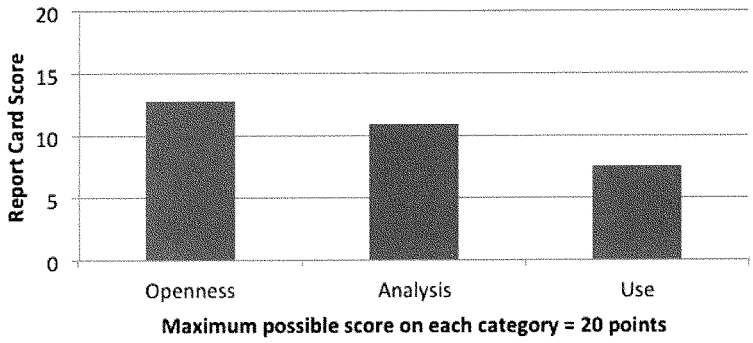
3. **Use:** how much did the analysis affect decisions in the proposed rule, and what provisions did the agency make for tracking the rule's effectiveness in the future?

For each criterion, trained evaluators assigned a score ranging from 0 (no useful content) to 5 (comprehensive analysis with potential best practices).[3] Thus, each analysis has the opportunity to earn between 0 and 60 points.

The Report Card assesses how well a Notice of Proposed Rulemaking and the accompanying Regulatory Impact Analysis complies with key principles in Executive Order 12866, which governs regulatory analysis and review.[4] The scores do not assess whether the evaluators agree with the results of the analysis or believe the regulation is a good idea.

The online Report Card database now includes evaluations of every economically significant, prescriptive regulation proposed between 2008 and 2012—a total of 108 regulations.[5] Figure 1 shows average scores for each of the three categories of criteria. In each category, the average falls far short of the maximum possible score of 20 points.

Figure 1: Regulatory Report Card scores for 108 economically significant regulations, 2008–2012



Source: Author's calculations, based on data available at www.mercatus.org/reportcard.

Table 1 shows the average scores on each of the 12 criteria, plus the average total score. The average total score was just 31.2 out of 60 possible points—barely 50 percent. The highest total score ever achieved was 48 out of 60 possible points (80 percent), equivalent to a B-. This was the joint Environmental Protection Agency/National

3. For the first several years, the evaluators were senior Mercatus Center regulatory scholars and graduate students trained in Regulatory Impact Analysis. Since 2010, we have developed a nationwide team of economics professors who serve as evaluators in conjunction with senior Mercatus Center regulatory scholars. Biographical information on current evaluators is available at www.mercatus.org/reportcard.

4. Exec. Order No. 12866, 50 Fed. Reg. 190 (Sept. 30, 1993), 51735–44, http://www.whitehouse.gov/sites/default/files/omb/inforeg/eo12866/eo12866_10041993.pdf. President Obama reaffirmed Exec. Order No. 12866 in Exec. Order No. 13563, "Improving Regulation and Regulatory Review," 76 Fed. Reg. 14 (Jan. 21, 2011), 3821–23, http://www.whitehouse.gov/sites/default/files/omb/inforeg/eo12866/eo13563_01182011.pdf.

5. "Prescriptive" regulations are what most people think of when they think of regulations: they mandate or prohibit certain activities. This is distinct from budget regulations, which implement federal spending programs or revenue collection measures. The Report Card evaluated budget regulations in 2008 and 2009, then discontinued evaluating budget regulations in subsequent years because it was clear the budget regulations have much lower-quality analysis. See Patrick A. McLaughlin and Jerry Ellig, "Does OIRA Review Improve the Quality of Regulatory Impact Analysis? Evidence from the Bush II Administration," *Administrative Law Review* 63 (2011): 179–202; Jerry Ellig and John Morrall., "Assessing the Quality of Regulatory Analysis." (Working Paper No. 10-75, Mercatus Center at George Mason University, Arlington, VA, December 2010).

Highway Traffic Safety Administration regulation revising Corporate Average Fuel Economy standards proposed in 2009.

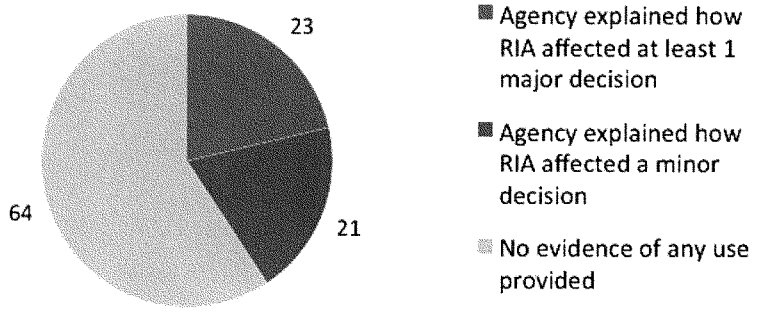
Table 1: Regulatory Report Card scores on individual criteria for 108 economically significant regulations, 2008–2012

Criterion	2008–2012 Average Score
Openness	
1. Accessibility	3.7
2. Data documentation	2.9
3. Model documentation	2.9
4. Clarity	3.2
Analysis	
5. Outcome definition	3.2
6. Systemic problem	2.2
7. Alternatives	2.8
8. Benefit-cost analysis	2.6
Use	
9. Any use of analysis	2.2
10. Cognizance of net benefits	2.5
11. Measures and goals	1.3
12. Retrospective data	1.6
Total	31.2

Source: Author's calculations, based on data available at www.mercatus.org/reportcard.

Table 1 shows that most of the lowest scores are for criteria measuring the use of analysis. The broadest Report Card criterion measuring use of analysis (Criterion 9) asks whether the agency claimed or appeared to use any part of the analysis to guide any decisions. As Figure 2 demonstrates, agencies often fail to provide any significant evidence that any part of the Regulatory Impact Analysis helped inform their decisions. Perhaps the analysis affects decisions more frequently than these statistics suggest, but agencies fail to document this in the Notice of Proposed Rulemaking or the Regulatory Impact Analysis. If so, then at a minimum there is a significant transparency problem.

Figure 2: Use of RIAs in 108 economically significant regulations, 2008–12



Source: Author's calculations, based on data available at www.mercatus.org/reportcard.

For each Report Card criterion, we have found a few examples of reasonably good quality or use of analysis. These are documented in past testimony and in a series of short Mercatus on Policy publications.[6] But best practices are not widespread.

Unfortunately, these less-than-stellar Report Card results are consistent with prior published research on Regulatory Impact Analysis. Case studies document instances in which Regulatory Impact Analysis helped improve regulatory decisions by providing additional options regulators could consider or unearthing new information about benefits or costs of particular modifications to the regulation.[7] But Government Accountability Office studies and scholarly research reveal that in many cases, Regulatory Impact Analyses are not sufficiently complete to serve as a guide to agency decisions. The quality of analysis varies widely, and even the most elaborate analyses still have problems.[8] Surveying the scholarly evidence as of 2008, Robert Hahn and Paul Tetlock concluded that

6. Jerry Ellig, "Look Before You Leap: Improving Pre-Proposal Regulatory Analysis," Congressional testimony, March 29, 2011, before the Committee on the Judiciary, Subcommittee on the Courts, Commercial, and Administrative Law, US House of Representatives; Jerry Ellig and James Broughel, "Regulation: What's the Problem?," Mercatus on Policy no. 100 (Nov. 2011); Jerry Ellig and James Broughel, "Regulatory Alternatives: Best and Worst Practices," (Mercatus on Policy, Mercatus Center at George Mason University, Arlington, VA, Feb. 2012); Jerry Ellig and James Broughel, "Baselines: A Fundamental Element of Regulatory Impact Analysis," (Mercatus on Policy, Mercatus Center at George Mason University, Arlington, VA, June 2012).

7. Winston Harrington, Lisa Heinzerling, and Richard D. Morgenstern, eds., *Reforming Regulatory Impact Analysis* (Washington, DC: Resources for the Future, 2009); Richard D. Morgenstern, *Economic Analyses at EPA: Assessing Regulatory Impact* (Washington, DC: Resources for the Future, 1997); Thomas O. McGarity, *Reinventing Rationality: The Role of Regulatory Analysis in the Federal Bureaucracy* (New York: Cambridge University Press, 1991).

8. See Art Fraas and Randall Lutter, "The Challenges of Improving the Economic Analysis of Pending Regulations: The Experience of OMB Circular A-4," *Annual Review of Resource Economics* 3 no. 1 (2011): 71–85; Jamie Belcore and Jerry Ellig, "Homeland Security and Regulatory Analysis: Are We Safe Yet?," *Rutgers Law Journal* 40, no. 1 (2008): 1–96; Robert W. Hahn, Jason Burnett, Yee-Ho I. Chan, Elizabeth Mader, and Petrea Moyle, "Assessing Regulatory Impact Analyses: The Failure of Agencies to Comply with Executive Order 12,866." *Harvard Journal of Law and Public Policy* 23, no. 3 (2001): 859–71; Robert W. Hahn, and Patrick Dudley, "How Well Does the Government Do Cost–Benefit Analysis?" *Review of Environmental Economics and Policy* 1, no. 2 (2007): 192–211; Robert W. Hahn, and Robert Litan, "Counting Regulatory Benefits and Costs: Lessons for the U.S. and Europe," *Journal of International Economic Law* 8, no. 2 (2005): 473–508; Robert W. Hahn, Randall W. Lutter, and W. Kip Viscusi. *Do Federal Regulations Reduce Mortality?* Washington, DC: AEI-Brookings Joint Center for Regulatory Studies (2000);

economic analysis has not had much impact, and the general quality of Regulatory Impact Analysis is low.[9] The Mercatus Center's Regulatory Report Card suggests that matters have not improved since then.

IMPROVEMENT IN THE QUALITY AND USE OF REGULATORY IMPACT ANALYSIS REQUIRES REFORM OF THE REGULATORY PROCESS

The problems identified by the Report Card occurred under both President Bush and President Obama. An econometric analysis that controls for other factors affecting the quality and use of analysis finds that there is no statistically significant difference in Report Card scores between the Bush and Obama administrations, although Bush administration regulations that cleared OIRA review after June 1, 2008 tended to have lower Report Card scores.[10] Previous research by other scholars also finds little variation in the quality of Regulatory Impact Analysis across administrations of different parties.[11] Another consistent—but disturbing—pattern is that administrations of both parties appear to require less thorough analysis from agencies that are more central to the administration's policy priorities. The Bush administration, for example, permitted the Department of Homeland Security to proceed with a number of regulations that were accompanied by very incomplete Regulatory Impact Analysis; the Obama administration did likewise with the first major regulations implementing the Patient Protection and Affordable Care Act.[12] This same pattern appears to occur with other agencies.[13]

The persistence of mediocre Regulatory Impact Analysis across administrations is an institutional problem, not a personal or partisan problem. Deficiencies in the quality and use of Regulatory Impact Analysis transcend individuals and administrations. Substantial impetus for improvement in the quality and use of Regulatory Impact Analysis will require changes in the regulatory process.

Because current law rarely requires comprehensive economic analysis to inform regulatory decisions, agencies often treat Regulatory Impact Analysis as a paperwork exercise necessary to clear a regulation through OIRA, rather than a tool to aid decision making. Instead, they focus on other factors that are viewed as more central to ensuring that a regulation gets upheld in court. In the absence of a requirement for Regulatory Impact Analysis, these factors may actually hamper agencies from considering the pros and cons of a wide variety of alternatives. For example, agencies may tend to follow past precedent in designing new regulations because current regulatory approaches have already been defended and upheld in court. As a result, one agency economist noted, "We do what we always do, just trotting out the same old thing. That's why we don't come up with better regulations; we just come up with the same regulations in different areas."[14]

When evaluating regulations for the Regulatory Report Card, we have found that when Congress requires agencies to consider specific factors such as costs or efficiency, they usually do so. Agencies pay attention to what the law says they should do, because otherwise a court might vacate the regulation. To improve the quality and use

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Government Accountability Office, *Regulatory Reform: Agencies Could Improve Development, Documentation, and Clarity of Regulatory Economic Analyses*, Report GAO/RCED-98-142 (May 1998); Government Accountability Office, *Air Pollution: Information Contained in EPA's Regulatory Impact Analyses Can Be Made Clearer*, Report GAO/RCED 97-38 (April 1997).

9. Robert W. Hahn and Paul C. Tetlock, "Has Economic Analysis Improved Regulatory Decisions?," *Journal of Economic Perspectives* 22, no. 1 (2008): 67–84.

10. See Jerry Ellig, Patrick A. McLaughlin, and John F. Morrall III. "Continuity, Change, and Priorities: The Quality and Use of Regulatory Analysis Across U.S. Administrations," *Regulation & Governance* 7 (2013): 153–73; Jerry Ellig, "Midnight Regulation: Decisions in the Dark?," (Mercatus on Policy, Mercatus Center at George Mason University, Arlington, VA, Aug. 2012).

11. Hahn and Dudley, "How Well Does the Government Do Cost-Benefit Analysis?"

12. Belcore and Ellig, "Homeland Security and Regulatory Analysis;" Christopher J. Conover and Jerry Ellig, "Beware the Rush to Presumption, Part C: A Public Choice Analysis of the Affordable Care Act's Interim Final Rules" (Working Paper No. 12-03, Mercatus Center at George Mason University, Arlington, VA, Jan. 2012); Christopher J. Conover and Jerry Ellig, "Rushed Regulation Reform," (Mercatus on Policy, Mercatus Center at George Mason University, Arlington, VA, Jan. 2012).

13. Ellig, McLaughlin, and Morrall, "Continuity, Change, and Priorities."

14. Williams, "The Influence of Regulatory Economists," 5.

of Regulatory Impact Analysis, therefore, Congress could require federal agencies to conduct thorough Regulatory Impact Analysis before they write and propose significant regulations. The most obvious method would be a legislative requirement for Regulatory Impact Analysis coupled with judicial review. To enforce the law, judges need not engage in benefit-cost balancing or second-guess agency expertise. They would merely need to check that the agency's analysis covered the topics specified in the law (such as analysis of the systemic problem, development of alternatives, and assessment of benefits and costs of alternatives), ensure that the analysis included the quality of evidence required by the legislation, and ensure that the agency explained how the results of the analysis affected its decisions.

Independent agencies are not currently subject to the executive orders on regulatory analysis and review. Some, such as the Securities and Exchange Commission, are required by law to conduct economic analysis when determining whether their regulations are in the public interest. Others have no such requirement. Scholarly research has found that many independent agencies conduct even less thorough economic analysis than executive branch agencies.[15] Requiring independent agencies to conduct Regulatory Impact Analysis and explain how they used it in decisions would likely improve their quality and use of analysis. Many of the independent agencies, such as the Consumer Product Safety Commission, Federal Trade Commission, Federal Communications Commission, and Consumer Financial Protection Board, deal with similar kinds of financial risk, physical risk, and consumer protection questions that executive branch agencies address in their assigned spheres of competence, so I see no reason a Regulatory Impact Analysis requirement could not apply to them as well.

Thank you for your time, and I look forward to your questions.

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15. Arthur Fraas and Randall L. Lutter, "On the Economic Analysis of Regulations at Independent Regulatory Commissions," *Administrative Law Review* 63 (2011): 213–41.

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The Quality and Use of Regulatory Analysis in 2008

Jerry Ellig[1,*] and Patrick A. McLaughlin[2,3]

This article assesses the quality and apparent use of regulatory analysis for economically significant regulations proposed by federal agencies in 2008. A nine-member research team used a six-point (0–5) scale to evaluate regulatory analyses according to criteria drawn from Executive Order 12866 and Office of Management and Budget Circular A-4. Principal findings include: (1) the average quality of regulatory analysis, though not high, is somewhat better than previous regulatory scorecards have shown; (2) quality varies widely; (3) biggest strengths are accessibility and clarity; (4) biggest weaknesses are analysis of the systemic problem and retrospective analysis; (5) budget or "transfer" regulations usually receive low-quality analysis; (6) a minority of the regulations contain evidence that the agency used the analysis in significant decisions; (7) quality of analysis is positively correlated with the apparent use of the analysis in regulatory decisions; and (8) greater diffusion of best practices could significantly improve the overall quality of regulatory analysis.

KEY WORDS: Benefit-cost; cost-benefit analysis; regulation; regulatory impact analysis; regulatory process; regulatory reform

1. INTRODUCTION

Since 1974, all presidents have issued executive orders requiring regulatory agencies to analyze the anticipated effects of proposed regulations. President Obama's Executive Order 13563 reaffirms the principles and review processes in Executive Order 12866, which has guided regulatory analysis since 1993.[1,2]

Scholars, decisionmakers, interest groups, and advocates spill much ink debating whether and how agencies should do regulatory analysis. Some view regulatory analysis as an imperfect but necessary tool for understanding regulation's effects.[3] Others see regulatory analysis as an attempt to "stack the deck" against new regulations, arguing that costs are easier to measure than benefits (pp. 35–36).[4,5] Yet others regard regulatory analysis as a tool for crafting "smart" regulations that do more good than harm.[6,7] Some view the whole enterprise as a fundamentally immoral attempt to put prices on public values that cannot be assigned monetary worth (pp. 61–62).[4]

Nonetheless, many scholars agree that regulatory analysis is here to stay.[3,6,8–12] Executive Order 13563 provides further evidence of this. Yet as former Office of Information and Regulatory Affairs (OIRA) Administrator Sally Katzen noted, "we still do not know whether the agencies are implementing CBA [cost-benefit analysis] appropriately and whether the way the agencies use CBA produces better regulatory decisions" (pp. 1314–1315).[11]

This article takes up that challenge. We apply a 12-point qualitative framework to evaluate regulatory analyses of "economically significant" rules that were reviewed by OIRA in 2008 and proposed

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in the *Federal Register*.[4] The evaluation criteria are drawn from Executive Order 12866 and Office of Management and Budget (OMB) Circular A-4, the 2003 guidance document on best practices in regulatory analysis.[13]

Our evaluation yields numerous insights into the quality and use of regulatory analysis. Principal findings include: (1) the average quality of regulatory analysis is not high; (2) quality varies widely; (3) the biggest strengths in the analyses are accessibility and clarity; (4) the biggest weaknesses are analysis of the systemic problem and retrospective analysis; (5) budget or "transfer" regulations receive much lower quality analysis than other regulations; (6) the agency claimed to use the analysis in significant decisions for a minority of the regulations; (7) quality of analysis is positively correlated with the apparent use of the analysis in regulatory decisions; and (8) greater diffusion of best practices could significantly improve the overall quality of regulatory analysis.

2. EXISTING LITERATURE AND OUR APPROACH

Several strands of scholarly literature assess the quality of federal regulatory analysis. Some assessments are in-depth case studies, whereas others apply quantitative scoring methods to numerous regulatory analyses.

2.1. Case Studies

Case studies suggest that even extensive economic analyses of regulations can have significant flaws. They also find that regulatory impact analysis has had marginal effects on some regulations, but rarely if ever drives major decisions.

McGarity presents five case studies from the Reagan administration.[14] Some are success stories, but they also reveal shortcomings in monetizing benefits, gathering reliable cost data, explaining large uncertainties in estimates, or identifying a wide range of regulatory options. Similarly, Fraas credits good Regulatory Impact Analyses (RIAs) with improvements in the Environmental Protection Agency's (EPA) rules removing lead from gasoline and banning asbestos, but he also finds analytical shortcomings and notes that they did not serve as "blueprints" for the entire EPA decision.[15] Case studies of 12 EPA rules issued between 1985 and 1995 in Morgenstern (p. 458) reveal that economic analysis always helped reduce costs, and it increased the benefits of five rules.[16] Nevertheless, economics had little effect on decisions. The analyses exhibited a "considerable range" in quality (p. 456).[16] Posner performed the only published study we have seen that assesses the quality of regulatory analysis for budget or "transfer" regulations that define how the federal government will spend or collect money.[17] He concludes that agencies rarely perform analysis for these regulations and presents several cases of inadequate analysis.

Several validation studies judge the quality of RIAs by comparing their predictions to the actual results of the regulation revealed by retrospective analysis. Validation studies find that agencies tend to overstate benefits and costs more frequently than they understate them. OMB concludes that agencies tend to overstate benefit-cost ratios, whereas independent scholars conclude there is no systematic bias in the ratios. All of these studies find that benefits, costs, and benefit-cost ratios are inaccurate (over- or underestimated) more frequently than they are accurate.[18–20]

Harrington *et al.* present the most recent collection of case studies.[10] They assembled multiple studies of three "relatively sophisticated" RIAs issued during the G. W. Bush administration. Despite their sophistication, the analyses had significant flaws. The authors' recommendations for improvement are: consider meaningful alternative policy options, use baselines that reveal choices and tradeoffs, include a checklist of practices that should be in an analysis, and explain deviations from this list. Noting that some regulatory analyses are prepared after key decisions have been made, they also call on EPA to prepare a preliminary regulatory impact analysis six months before the agency's final review of proposed and final regulations.

2.2. Quantitative Scoring

Quantitative approaches usually employ a "yes/no" checklist to assess whether RIAs include certain elements. Early Government Accountability

[4]"Economically significant" regulations are defined as regulations that have an economic impact exceeding $100 million or that adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (Sec. 3[f][1]). Economically significant regulations require an extensive Regulatory Impact Analysis that assesses the need, effectiveness, benefits, costs, and alternatives for the proposed regulation (Sec. 6[a][3][C]).

Office evaluations of health, safety, and environmental regulations found that RIAs frequently failed to include key elements recommended in OMB's guidance.[21,22] Robert Hahn co-authored a series of papers that evaluate the quality of analysis for health, safety, and environmental regulations across three administrations—Ronald Reagan, G. H. W. Bush, and Bill Clinton—using a "yes/no" checklist based on OMB guidance.[23–26] The regulatory analyses of a large sample of environmental regulations covered an average of approximately 30 of 76 items on Hahn's scorecard, or 40% (p. 74).[27]

Belcore and Ellig score the quality of analysis for all economically significant regulations issued by the Department of Homeland Security between 2003 and 2007.[28] They found that the quality of analysis is generally low but improved over time. They also found that quality tends to be lower for rules issued subject to tight legislative deadlines, or where Congress gave the department little discretion.

Fraas and Lutter assess 13 of the most important rules issued by EPA between 2005 and 2009, after OMB issued new and more detailed guidance in the form of Circular A-4.[29] Scores ranged from three points to a maximum possible nine, with an average of 5.25 (58%). Fraas and Lutter maintain that the quality of analysis is generally higher for rules issued under legislation that requires agencies to consider costs or net benefits.

Shapiro and Morrall examine 100 economically significant regulations adopted between 2002 and 2010.[30] They assign each analysis a score of between zero and six points based on six OMB criteria. Scores ranged from zero to six, with an average of 3.85 (64%). They find that the quality of analysis is unrelated to the size of the rule's net benefits, but rules with lower political salience have higher net benefits.

Both the qualitative and quantitative literature reveal some general patterns. Some RIAs are relatively high quality, but many lack key information, and even the best ones could be improved. Analysis has never dictated decisions but has sometimes influenced decisions on the margin, and occasionally these margins involve large benefits or costs.

2.3. Our Approach

We develop a scoring system to evaluate the quality and use of regulatory analysis for a relatively large number of regulations. Our approach differs from most previous evaluations in several ways.

1. It is the first project that evaluates the regulatory analyses accompanying all economically significant regulations proposed in a given year. Most previous evaluations focus on health, safety, and environmental regulations.
2. We focus on proposed regulations, rather than final regulations. We seek to gauge the quality of analysis at the earliest possible point, when it arguably has the best chance of affecting decisions. Of course, many decisions have already been made by the time a rule is proposed,[31] but we remain optimistic that better analysis may sometimes lead to better decisions (pp. 18–19).[32] In any case, the analysis accompanying the proposed rule is usually the first comprehensive regulatory analysis available to evaluate.
3. We opt for a qualitative evaluation of how well the analysis was performed, rather than an objective "yes/no" checklist of analytical issues and approaches covered.
4. Our approach assesses whether the agency actually claims to use regulatory analysis to guide decisions. We also evaluate whether the agency makes a commitment to conducting retrospective analysis to assess the actual outcomes of the rule in the future.

Although we seek to evaluate the quality and use of regulatory analysis, one might also interpret this study as an evaluation of the quality of regulations themselves, for a couple of reasons. First, regulatory analysis and regulations are often jointly produced, with lawyers and economists working together on every step of a rulemaking, possibly making the quality of the analysis correlated with quality of the regulation. Second, the quality of regulatory analysis is likely correlated with the quality of regulations because the outputs of the regulatory analysis should serve as inputs to regulatory decisions. For example, one important component of regulatory analysis is the consideration of alternative approaches to achieve the desired outcomes. If a low-quality analysis fails to consider alternatives, how can an agency be confident that its regulatory approach represents the best one, however "best" may be defined?

Although our results may provide a perspective on the quality of regulations, we caution against interpreting our study as a comprehensive evaluation of regulatory quality. We can rate the quality of regulatory analysis because a number of components

are required by executive order or statute. These components are familiar to most economists and can easily be assessed by any economist with the right training. Conversely, we have not attempted to define a method of rating the quality of regulations themselves. Although such an endeavor may be worthwhile, it is beyond the scope of this article.

3. EVALUATION PROTOCOL

3.1. What Was Evaluated?

Evaluations were performed for 45 economically significant proposed regulations whose OIRA reviews were completed in 2008.[5] The research team read the preamble to each proposed rule and the accompanying RIA. In some cases, agencies produced a risk assessment or additional analysis in technical support documents that we also considered. We included the Regulatory Flexibility Analysis, which assesses the effects on small entities, to the extent that this analysis had content relevant to our evaluation criteria.

This approach is broader than just reading the RIA document or section of the *Federal Register* notice explicitly labeled "Regulatory Impact Analysis." It is necessary because agencies organize the content differently in different rules. Sometimes the RIA is a separate document only referenced or summarized in the *Federal Register* preamble.[33] Alternatively, the entire RIA may constitute a separate section of the preamble.[34] In one case, the RIA for a proposal was in the preamble of the Notice of Proposed Rulemaking (NPRM) for a related regulation published the same day.[35] Some parts may be in a separate regulatory analysis section of the preamble, and other parts, such as environmental impact analysis or risk assessment, may be in other sections of the preamble that discuss justifications for the regulation.[36–38] Reading all of this material allowed us to give the agency credit when due, regardless of where the analysis appears.

3.2. Scoring System

We evaluate regulatory analysis on the basis of 12 criteria, grouped into three categories:

1. Openness: How easily can a reasonably informed, interested citizen locate the analysis, understand it, and verify the underlying assumptions and data?
2. Analysis: How well does the analysis define and measure the outcomes or benefits the regulation seeks to accomplish, define the systemic problem the regulation seeks to solve, identify and assess alternatives, and evaluate costs and benefits?
3. Use: How much did the analysis appear to affect decisions in the proposed rule, and what provisions did the agency make for tracking the rule's effects in the future?

Fig. 1 lists the 12 criteria. Appendix A lists detailed questions considered under each criterion. Appendix B presents a cross-walk chart that maps OMB's November 2010 "Regulatory Impact Analysis Checklist" into our scoring criteria. The Openness and Analysis criteria, numbered 1–8, are straightforward interpretations of provisions in Executive Order 12866 and Circular A-4.

The Use criteria deserve further explanation. The first Use criterion asks whether the analysis seemed to affect decisions. To score this criterion, we assess whether the agency claimed to use information about the regulation's expected outcomes, the systemic problem, or benefits or costs of alternatives to make decisions. The second Use criterion asks whether the agency made its decisions fully cognizant of the net benefits of alternatives. We do not expect the analysis to dictate the decision via a rigid rule, such as "regulate only when monetized benefits exceed monetized costs." Section 1 of Executive Order 12866 explicitly instructs agencies to regulate only when the benefits "justify" the costs, unless the law requires another approach. Thus, we look to see whether the agency either selected the alternative that maximized net benefits or clearly explained why some other alternative was preferable to the one that maximized net benefits.

Searching the *Federal Register* notice for documentation of use will not identify any undocumented, "behind the scenes" influence of the analysis. We may also overestimate the effects of analysis in situations where the agency reached decisions, then crafted or cited the analysis to support those decisions.[31] The actual influence of economists and economic analysis in rulemaking (as opposed to the influence documented in the *Federal Register* notice) likely differs across agencies and even across rules

[5]Reginfo.gov lists 48 proposed, economically significant regulations whose OIRA reviews were concluded in 2008. Three RIAs could not be found at the time these evaluations were performed, leaving us with 45 regulations to evaluate.

Openness

1. **Accessibility:** How easily were the RIA, the proposed rule, and any supplementary materials found online?
2. **Data Documentation:** How verifiable are the data used in the analysis?
3. **Model Documentation:** How verifiable are the models and assumptions used in the analysis?
4. **Clarity:** Was the analysis comprehensible to an informed layperson?

Analysis

5. **Outcomes:** How well does the analysis identify the desired benefits or other outcomes and demonstrate that the regulation will achieve them?
6. **Systemic Problem:** How well does the analysis identify and demonstrate the existence of a market failure or other systemic problem the regulation is supposed to solve?
7. **Alternatives:** How well does the analysis assess the effectiveness of alternative approaches?
8. **Benefit-Cost Analysis:** How well does the analysis assess costs and benefits?

Use

9. **Use of Analysis:** Does the proposed rule or the RIA present evidence that the agency used the Regulatory Impact Analysis?
10. **Net Benefits:** Did the agency maximize net benefits or explain why it chose another option?
11. **Measures and Goals:** Does the proposed rule establish measures and goals that can be used to track the regulation's results in the future?
12. **Retrospective Data:** Did the agency indicate what data it will use to assess the regulation's performance in the future and establish provisions for doing so?

Fig. 1. Regulatory analysis assessment criteria.

within agencies. At one extreme, economists can have a lot of influence when a regulation is drafted, although it may not be documented in the proposed regulation or preamble (pp. 6–7).[32] At the other extreme, economists and their analyses may be ignored entirely. Two points in between are: (1) the economic analysis has no effect, but the agency writes it to support the rule, or (2) the economic analysis has some effect that is documented in the notice. Our evaluation method identifies these latter kinds of cases. Because we cannot easily distinguish between the two on the basis of claims in the NPRM or RIA, our method only assesses whether the agency seemed to use the analysis. By examining the documentation of use, we at least identify where analysis is likely to have influenced rulemaking and offer a starting point for future research into the matter.

Criteria 11 and 12 assess the extent to which the RIA or preamble to the regulation make provisions for retrospective analysis. The executive orders governing regulation offer scant guidance on this, but Executive Order 13563 reiterates the requirement in Executive Order 12866 that each agency have a plan for retrospective review of regulations. A recent edition of OMB's annual report on the benefits and costs of federal regulation declared, "we recommend that serious consideration be given to finding ways to employ retrospective analysis more regularly, in order to ensure that rules are appropriate, and to expand, reduce, or repeal them in accordance with what has been learned" (p. 43).[39] The Government Performance and Results Act (GPRA) Modernization Act of 2010 requires the federal government and agencies to identify high-priority goals; specify the programs, activities, tax expenditures, and regulations that contribute to each goal; and regularly evaluate the contributions.[40] An agency can lay the groundwork for compliance with the law by establishing goals and measures, identifying data, and committing to retrospective analysis in the preamble to the regulation. Agencies have in fact done these things for some regulations.[6][41–44]

[6]For readers who are still skeptical about the value of including the two retrospective analysis criteria, we calculated Spearman's rho and Kendall's tau-b to assess whether inclusion of these criteria substantially alters the ranking of the regulations. The rankings with and without the Use criteria are highly correlated—rho = 0.981 and tau-b = 0.920—with p values of 0.000.

Table I. What Do the Scores Mean?

5	Complete analysis of all or almost all aspects, with one or more "best practices."
4	Reasonably thorough analysis of most aspects and/or shows at least one "best practice."
3	Reasonably thorough analysis of some aspects.
2	Some relevant discussion with some documentation of analysis.
1	Perfunctory statement with little explanation or documentation.
0	Little or no relevant content.

For each criterion, evaluators assigned a score ranging from 0 (no useful content) to 5 (comprehensive analysis with potential best practices). Thus, each analysis has the opportunity to earn between 0 and 60 points. In general, the research team used the guidelines in Table I for scoring. Because the Analysis criteria involve many discrete issues, we developed a series of subquestions for each of the four Analysis criteria (listed in Appendix A), and awarded a 0–5 score for each subquestion. These scores were then averaged to calculate the score for the individual criterion.

Compared to an objective checklist, our qualitative approach provides a richer and potentially more accurate evaluation of the actual quality of the analysis. As OIRA notes: "Objective metrics can measure whether an agency performed a particular type of analysis, but may not indicate how well the agency performed this analysis" (p. 19).[45] For example, rather than just asking whether the analysis considered alternatives or counting the number of alternatives considered, we give an analysis a higher score if it considered a wider range of alternatives. Instead of just asking whether the agency named a market failure, we assess whether the agency provides a coherent theory and plausible evidence that the market failure exists, awarding a higher score on the basis of how convincing the evidence is. The qualitative approach also encourages agencies to find the best way to do analysis that can inform decisions, instead of treating regulatory analysis as a "check the box" compliance exercise.

A qualitative evaluation can be more subjective, less transparent, and harder to replicate. Several aspects of our research design seek to minimize these drawbacks. We designed the evaluation process to achieve a common, intersubjective understanding of which practices deserve which kind of score, and evaluators took notes justifying each score.[7] The entire nine-member research team underwent extensive training in which we evaluated several of the same proposed regulations and accompanying RIAs, compared scores, and discussed major differences until we achieved a consensus on scoring standards. For questions that were particularly difficult to evaluate, we developed written guidelines describing practices that would justify various scores in most cases. Each analysis was scored by one of the authors of this article and another team member, with discussion to achieve consensus when scores differed significantly. Each author also reviewed the other's scores and notes, and then discussed and resolved differences to ensure that all documents were evaluated as consistently as possible on all questions.

In addition, we subjected the scores to *ex post* statistical analyses to test whether our research design produced a high degree of interrater reliability. Interrater reliability is the degree to which raters agree with each other about their subjective evaluations of a given object. The Cohen kappa index is the most commonly used statistical measure of interrater reliability in social sciences.[48,49] Other typical tests include Spearman's rho and Pearson's chi-squared, both of which test the independence of the ratings.

The goal of our interrater reliability testing was to ascertain whether our evaluation system yields consistent agreement among raters trained in the system. First, we created agreement matrices using the prediscussion scores for all questions together and for each individual question. These scores reflected each rater's evaluation before any discussion and deliberation about differences in ratings. Appendix C reports these agreement matrices. The first matrix, in Table A.I, uses score data for all criteria. Each subsequent table shows the agreement matrix for a specific scoring criterion. The first scorer's rating dictates vertical location whereas the second scorer's rating controls the horizontal location. Thus, each matrix that corresponds to a particular criterion—Tables A.II through A.XIII—has 45 observations of score pairs.

[7]The term "intersubjective" refers to subjective interpretations that different individuals can share because they have commonly understood meanings. Social scientists most commonly use the term to denote economic agents' ability to understand the interpretations and meanings of other economic agents, or the social scientist's ability to understand the interpretations and meanings of the economic agents who are the subject of study.[46,47] We think it applies equally well here, when colleagues share similar subjective understandings of what constitutes better and worse analyses.

Table II. Analysis of Interrater Reliability

Criterion	Spearman's rho	p-Value
All	0.621	0.000
1	0.414	0.005
2	0.675	0.000
3	0.713	0.000
4	0.504	0.000
5	0.447	0.002
6	0.586	0.000
7	0.646	0.000
8	0.591	0.000
9	0.639	0.000
10	0.504	0.000
11	0.421	0.004
12	0.465	0.001

A well-designed system would show substantial agreement between scorers, regardless of whom the scorers were or which regulation was scored. Such agreement would produce density along the diagonal in the agreement matrices, and that is precisely what we observe. At the bottom of each agreement matrix, we list the count and percentage of score pairs that are in perfect agreement or disagreement by different numbers of points. Table A.I reveals considerable agreement between raters: 42.4% of all ratings (229 of 540) were in perfect agreement, and another 36.7% (198 of 540) exhibited a difference of only one point. About 15% (79 of 540) showed a difference of two points, and only 6.3% (34 of 540) had a difference of more than two points. Tables A.II–A.XIII show similar results for the agreement distributions for each individual question. No particular question stands out as an egregious generator of disagreement among the raters.

Cohen's kappa for the entire sample is 0.4784, which, according to the rules of thumb put forth by Landis and Koch, indicates moderate agreement.[50] Of course, this kappa is calculated using prediscussion ratings. After discussions, there was 100% agreement, and Cohen's kappa equaled 1. Table II shows the results of Spearman's rho tests for the entire sample and for each individual question. The values of rho range from 0.414 to 0.713, and the null hypothesis that the two ratings are independent is strongly rejected for each question. We also tested independence by calculating Pearson's chi-squared (not reported), finding similar results.

The tests indicate that our rating system would likely produce statistical agreement for any set of raters, assuming they underwent the same training. Scores for each regulation on each criterion, as well as notes justifying the scores, are available at www.mercatus.org/reportcard.

3.3. An Example

To illustrate how the evaluation protocol works, Table III reproduces scores and notes for a regulation that received a middling score on criterion 5, outcomes. "Outcomes are not what the program itself did but the consequences of what the program did" (p. 15).[51] We intentionally employ the broader term "outcomes" rather than "benefits" because some regulations seek to achieve goals that do not necessarily meet the economist's definition of a social benefit. We ask merely whether the regulatory analysis articulates, measures, and justifies an outcome that affects citizens' quality of life, regardless of whether the goal increases net social benefits.

The regulation in Table III is an Occupational Safety and Health Administration (OSHA) regulation intended to improve safety around cranes and derricks at construction sites. The analysis identified workplace safety outcomes and explained how to measure them, earning a five on each of these questions. However, the analysis does not provide much documented theory or evidence that the regulations would reduce fatalities and accidents; the reader is simply assured that "OSHA analysis" proves this is so. An explicit theory, rather than just an assertion, and documentation of evidence supporting the theory would have earned this analysis a higher score on these two questions. Although the RIA acknowledges uncertainty about benefits, it provides little analysis showing how the uncertainties would affect estimates of injuries and fatalities.

3.4. Caveats

Three significant caveats accompany our findings. First, we evaluate the quality of regulatory analysis and its apparent use in decisions, but we do not evaluate whether the proposed rule is economically efficient, fair, or otherwise good public policy. This article is an assessment of how agencies conduct and claim to use regulatory analysis, not a policy analysis of the regulations themselves.

Second, we evaluated whether the RIA and preamble to the proposed rule make a reasonable effort at covering the major elements of regulatory analysis. We did not seek to replicate the results, produce our own analysis, or verify the underlying

Table III. Outcome Discussion in Labor Department's Cranes and Derricks Proposed Rule

Criterion	Score	Comment
How well does the analysis identify the desired outcomes and demonstrate that the regulation will achieve them?	3	–
Does the analysis clearly identify ultimate outcomes that affect citizens' quality of life?	5	Workplace safety—reduced fatalities and accidents.
Does the analysis identify how these outcomes are to be measured?	5	Number of fatalities and accidents avoided.
Does the analysis provide a coherent and testable theory showing how the regulation will produce the desired outcomes?	1	Asserts only that "OSHA analysis" shows that an indicated number of fatalities would be eliminated. The text of the rule does a better job explaining several published articles that identify major causes of crane accidents.
Does the analysis present credible empirical support for the theory?	2	Some examples of recent accidents are presented, and the preamble to the rule explains how the proposed rules would have prevented those accidents. It is not clear if these are typical or generalized examples.
Does the analysis adequately assess uncertainty about the outcomes?	2	Uncertainty is acknowledged, and several benefit estimates are offered. However, the sensitivity discussion is cursory and does not provide much in-depth analysis on how injuries and fatalities would likely be affected.

data and studies. Commenters on this article who have in-depth experience with particular regulations have usually told us that we have been too lenient. For example, an EPA air pollution regulation proposed in 2008 scores fairly high for its analysis of uncertainty regarding the size of benefits, but Fraas documents significant shortcomings in the EPA's uncertainty analysis of benefits of air quality regulations.[52] A high-scoring analysis may thus still have flaws and inaccuracies because of poor underlying data or theories that turn out to be wrong. Authors of previous regulatory scorecards have also noted this drawback (p. 196, p. 3).[24,29] Nevertheless, as Dudley (p. 8) notes: "Benefit-cost analysis isn't perfect, but it's the best we have."[3] The strength of a scorecard approach is its ability to rank numerous regulatory analyses according to consistent criteria. As we shall see, the approach identifies significant differences in the quality of analysis across different regulations.

Third, we give each criterion the same weight. Of course, some criteria, such as whether the agency identified a systemic problem or whether it analyzed a broad array of alternatives, may have more policy impact than whether the RIA is clearly written for the average citizen. The results below often break out score data by our three categories of criteria or by individual criteria, so that readers who want to focus on particular criteria or groups of criteria can do so. For example, readers who are concerned solely about the quality of regulatory analysis can ignore our evaluations of Use and focus on criteria 1–8, which assess Openness and Analysis. We calculated Spearman's rho and Kendall's tau-b to assess whether inclusion of the Use criteria substantially alters the ranking of the regulations. The rankings with and without the Use criteria are highly correlated—$\rho = 0.959$ and $\tau_b = 0.861$—with p-values of 0.000. Readers who believe some individual criteria should be omitted or weighted more heavily are welcome to download our Excel spreadsheet with a full set of score results for every regulation, and conduct similar tests.[8]

4. SCORES AND RANKINGS

4.1. Summary Statistics

Both the average and median score were 27 of 60 possible points, or 45%. The best analysis received 43 points (72%), and the worst received only seven points (12%). Fig. 2 shows the distribution of scores.

In general, the documents score higher on Openness than on the other two categories. The average score on the Openness criteria was 11 of 20 possible points, compared to 8.5 points for Analysis, and 7.7 points for Use.

4.2. Best and Worst Analyses

Table IV lists scores for all 45 regulations, along with their Regulation Identifier Numbers and

[8]The spreadsheet is available at www.mercatus.org/reportcard.

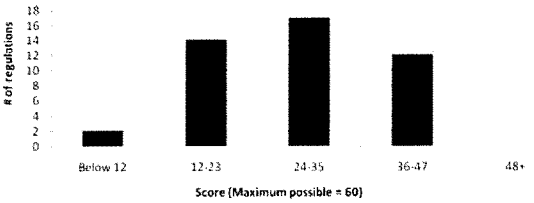

Fig. 2. Distribution of analysis scores.

the name of the issuing department. The best initial analysis in 2008 was for the Department of Transportation's (DOT) proposed Corporate Average Fuel Economy regulation, followed by the EPA's National Ambient Air Quality Standards (NAAQS) for Lead, and Housing and Urban Development's (HUD) proposed revisions to the Real Estate Settlement Procedures Act. The three worst analyses come from the Social Security Administration, Department of Veterans' Affairs, and Department of Defense.

4.3. Average Scores by Regulation Type

The 15 regulations in italics in Table IV are budget or "transfer" regulations. These regulations outline how the federal government will spend money, set fees, or administer spending programs. Most of these regulations score poorly. Calculating average scores by type of regulation reveals a big discontinuity, as Table V shows. Average scores for most types of regulations range between 30 and 35 points. Transfer regulations, however, average just 17 points. Transfer regulations score lower on all the three categories of criteria, but the biggest difference is in the Analysis category, where transfer regulations score only about one-third the points of other types of regulations.

This finding is consistent with OMB's observation that agencies do not usually estimate the social benefits and costs of transfer regulations (p. 19).[39] Posner documents the same phenomenon.[17] It is not obvious why transfer regulations should receive different analytical treatment, for as OMB notes (p. 19), transfer regulations generate substantial social costs via mandates, prohibitions, and price distortions.[39] Our results on transfer regulations illustrate a more general point: the data from this project can provide a starting point for analyzing a variety of factors that might influence the quality of regulatory analysis, such as the nature of the regulation, politics, legislative mandates, or deadlines. (See Shapiro and Morrall and Belcore and Ellig (pp. 38–41) for similar examples.)[30,28]

4.4. Agency Average Scores

Table VI lists average scores for each agency. HUD's one regulation earned it the highest agency average. EPA placed second, and Homeland Security placed third. Scores decline relatively smoothly as one moves down the list, except for the 7.7-point gap that separates Health and Human Services (HHS), ranked 13th, from State, ranked 14th.

Most of the agencies in the top half of the list produced more than one economically significant regulation in 2008. All of the agencies in the bottom half produced just one, except for HHS (11 regulations) and Education (two regulations). Whether this pattern reflects economies of scale or mere coincidence remains to be seen.

We caution the reader against drawing strong inferences about agencies' analytical abilities on the basis of these scores for one year. Most departments produced small numbers of regulations, and many consist of diverse agencies that may not all produce the same quality of analysis. Generalizations about different agencies' abilities would require either a larger data set spanning more years or in-depth case studies.

4.5. Average Scores by Criterion

Average scores on individual criteria reveal where regulatory analysis in practice is generally strongest and weakest. The criterion with the highest average score in Table VII is criterion 1, Accessibility. This is not surprising, as making documents accessible to the public via the Internet is relatively easy to do regardless of the quality of the analysis itself. The two lowest scoring criteria are both related to retrospective analysis: establishing measures and

Table IV. Scores for 45 Economically Significant Regulations from 2008

Proposed Rule	RIN	Department	Total	Openness	Analysis	Use
Car and Light Truck Corporate Average Fuel Economy 2011–2015	2127-AK29	DOT	43	15	16	12
National Ambient Air Quality Standards for Lead	2060-AN83	EPA	42	14	16	12
Real Estate Settlement Procedures Act	2502-AI61	HUD	41	15	16	10
Class Exemption for Provision of Investment Advice, Proposed Rule	1210-AB13	Labor	40	15	15	10
Congestion Management Rule for LaGuardia Airport	2120-AI70	DOT	39	13	13	13
Large Aircraft Security Program	1652-AA53	DHS	38	15	13	10
US VISIT Biometric Exit System	1601-AA34	DHS	38	9	15	14
Fiduciary Requirements for Disclosure in Participant-Directed Plans	1210-AB07	Labor	37	15	11	11
Notice of Class Exemption for Provision of Investment Advice	1210-ZA14	Labor	37	12	14	11
Effluent Limitations Guidelines and Standards for Construction	2040-AE91	EPA	37	14	14	9
Electronic Prescriptions for Controlled Substances	1117-AA61	DOJ	36	14	12	10
Migratory Bird Hunting	1018-AV62	Interior	35	14	12	9
Nondiscrimination in State/Local Government Services	1190-AA46	DOJ	35	14	9	12
Nondiscrimination by Public/Commercial Facilities	1190-AA44	DOJ	34	14	9	11
Railroad Tank Car Transportation of Hazardous Materials	2130-AB69	DOT	33	10	13	10
HIPAA Code Sets	0958-AN25	HHS	33	15	10	8
Family and Medical Leave Act of 1993	1215-AB35	Labor	33	18	10	5
Congestion Mgt. for John F. Kennedy Airport and Newark Airport	2120-AJ28	DOT	30	10	8	12
Cranes and Derricks in Construction	1218-AC01	Labor	30	14	9	7
Refuge Alternatives for Underground Coal Mines	1219-AB58	Labor	28	12	8	8
Integrity Management Program for Gas Distribution Pipelines	2137-AE15	DOT	28	7	11	10
State-Specific Inventoried Roadless Area Management	0596-AC74	USDA	28	11	12	5
Energy Conservation Standards for Fluorescent Lamps	1904-AA92	Energy	27	6	11	10
Alternative Energy Production on the OCS	1010-AD30	Interior	27	8	10	9
Standardized Risk-Based Capital Rules (Basel II)	1557-AD07	Treasury	27	9	9	9
Changes to the Outpatient Prospective Payment System	*0938-AP17*	*HHS*	*27*	*13*	*7*	*7*
Hospital Inpatient Prospective Payment Systems	*0938-AP15*	*HHS*	*27*	*14*	*6*	*7*
Oil Shale Management–General	1004-AD90	Interior	26	9	9	8
HIPAA Electronic Transaction Standards	0938-AM50	HHS	25	12	8	5
Employment Eligibility Verification	9000-AK91	FAR	24	13	7	4
Teacher Education Assistance Grant Program	*1840-AC93*	*ED*	*23*	*10*	*4*	*9*
Abandoned Mine Land Program	1029-AC56	Interior	21	10	4	7
Maximum Operating Pressure for Gas Transmission Pipelines	2137-AE25	DOT	21	11	7	3
Federal Perkins Loan Program	*1840-AC94*	*ED*	*21*	*10*	*2*	*9*
Revisions to Medicare Advantage and Prescription Drug Benefits	*0938-AP24*	*HHS*	*19*	*8*	*6*	*5*
Prospective Payment System for Long-Term Care Hospitals	*0983-AO94*	*HHS*	*17*	*9*	*2*	*6*
Medicare Program: Revisions to Physician Fee Schedules	*0938-AP18*	*HHS*	*17*	*6*	*4*	*7*
Medicaid Program Premiums and Cost Sharing	*0938-AO47*	*HHS*	*17*	*10*	*3*	*4*
State Flexibility for Medicaid Benefit Packages	*0938-AO48*	*HHS*	*16*	*9*	*4*	*3*
Proposed Hospice Wage Index for Fiscal Year 2009	*0938-AP14*	*HHS*	*16*	*9*	*3*	*4*
Prospective Payment System for Skilled Nursing Facilities	*0938-AP11*	*HHS*	*14*	*7*	*2*	*5*
Schedule of Fees for Consular Services	*1400-AC41*	*State*	*13*	*7*	*4*	*2*
CHAMPUS/TRICARE	*0720-AB22*	*Defense*	*12*	*7*	*4*	*1*
Post-9/11 GI Bill	*2900-AN10*	*VA*	*10*	*6*	*2*	*2*
Time and Place for a Hearing Before an Administrative Law Judge	*0960-AG61*	*SSA*	*7*	*4*	*0*	*3*
Average			27.3	11.04	8.5	7.7

Note: Regulations in italics are budget or "transfer" regulations.

goals to track the regulation's effects in the future (criterion 11) and gathering data for such assessment (criterion 12).

The other low-scoring criterion is identification of the market failure or other systemic problem the regulation is supposed to solve. This low score is puzzling because Section 1 of Executive Order 12866 leads off by stating that each regulation must identify the problem it seeks to address and assess the significance of that problem. The analyses that score low on this criterion either simply assert a reason for the regulation, with no accompanying theory or evidence, or mention no explicit rationale at all beyond implementing a statute. Such weaknesses are

Table V. Average Scores by Regulation Type

Type	Number of Regulations	Average Score	Openness	Analysis	Use
Civil rights	2	34.5	14.0	9.0	11.5
Economic	10	34.2	13.4	11.4	9.4
Security	3	33.3	12.3	11.7	9.3
Environment	9	31.8	11.2	11.6	9.0
Safety	6	29.3	11.3	10.0	8.0
Transfer	15	17.1	8.6	3.5	4.9

Table VI. Agency Average Scores

Agency	Number of Regulations	Average Score	Openness	Analysis	Use
1. HUD	1	41.0	15.0	16.0	10.0
2. EPA	2	39.5	14.0	15.0	10.5
3. DHS	2	38.0	12.0	14.0	12.0
4. DOJ	3	35.0	14.0	10.0	11.0
5. Labor	6	34.2	14.3	11.2	8.7
6. DOT	6	32.3	11.0	11.3	10.0
7. USDA	1	28.0	11.0	12.0	5.0
8. Interior	4	27.3	10.3	8.9	8.3
9. Treasury	1	27.0	9.0	9.0	9.0
10. Energy	1	27.0	6.0	11.0	10.0
11. Federal acquisition	1	24.0	13.0	7.0	4.0
12. Education	2	22.0	10.0	3.0	9.0
13. HHS	11	20.7	10.2	5.0	5.5
14. State	1	13.0	7.0	4.0	2.0
15. Defense	1	12.0	7.0	4.0	1.0
16. Veterans affairs	1	10.0	6.0	2.0	2.0
17. Social security	1	7.0	4.0	0	3.0

Table VII. Ranking of Scores on Individual Criteria

Criterion	Including Transfer Regulations	Excluding Transfer Regulations
Accessibility	3.53	3.30
Clarity	2.93	3.50
Some use of analysis	2.44	2.63
Outcome definition	2.36	3.10
Model documentation	2.33	2.83
Alternatives	2.29	2.93
Data documentation	2.24	2.63
Net benefits	2.20	2.93
Benefit-cost analysis	2.09	2.60
Systemic problem	1.80	2.40
Retrospective data	1.73	2.03
Measures and goals	1.36	1.53
Overall average score	27.31	32.43

disturbing. It is hard to have confidence that a regulation really will solve a problem, or that the agency has selected the best option for solving a problem, if the agency cannot articulate the problem, cite convincing evidence that the problem exists, and explain its root cause.

Given the lower average scores of transfer regulations, it is no surprise that average scores on individual criteria are generally higher when transfer regulations are excluded. But even excluding transfer regulations, the average score on this criterion is only 2.4 points. We can identify more than a few examples of prescriptive regulations that scored a 1 or 2 on identification of the systemic problem. These include Treasury's risk-based capital rules for banks, Interior's abandoned mine land program and oil shale management rules, DOT's maximum operating pressure for gas transmission pipelines, and Federal Acquisition's employment eligibility verification rules.

5. USE OF REGULATORY ANALYSIS

Different scholars offer different conclusions about whether economic analysis actually has much influence on regulatory decisions. Hahn and Tetlock conclude that few RIAs have much effect.[27] Officials interviewed by West claim that decisionmakers often make up their minds before the analysis is done.[31] Williams, on the other hand, suggests that regulatory analysis can affect decisions behind the scenes, even if the agency does not explicitly explain in its *Federal Register* notice (pp. 6–7).[32] Our scoring on the Use criteria offers another perspective on this question.

5.1. Do Agencies Claim to Use Regulatory Analysis?

Table VI shows that criterion 9, Use of Analysis, has the third highest average score. An agency can earn points on this criterion even if statutorily prohibited from considering some factors, such as costs or net benefits. For example, when setting NAAQS, "[a]ccording to the Clean Air Act, EPA must use health-based criteria in setting the NAAQS and cannot consider estimates of compliance cost."[42] However because health is one of the key benefits of air quality standards, the EPA received two points on criterion 9 for using the health analysis to inform its decision.

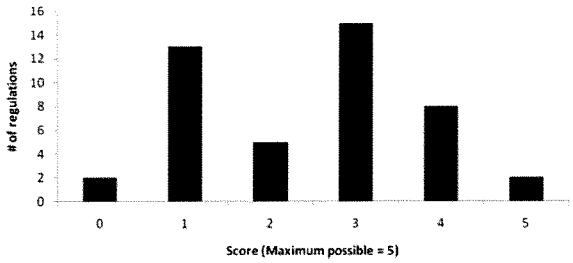

Fig. 3. Breakdown of criterion 9.

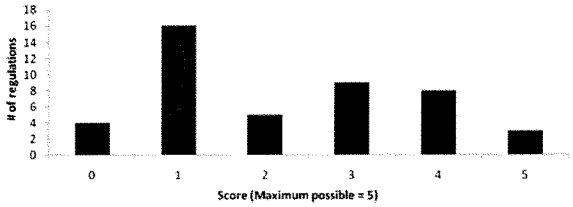

Fig. 4. Breakdown of criterion 10.

Criterion 10, Net Benefits, receives a lower average score when transfer regulations are included (2.20 points) than when they are excluded (2.93 points). One might argue that net benefits are irrelevant when a regulation "merely" transfers money, but surely most federal expenditures are supposed to achieve some type of public benefit that could often be measurable. To achieve a good score on this criterion, the agency does not have to select the alternative that maximizes net benefits. Rather, the agency must demonstrate that it was cognizant of net benefits and weighed them against other factors when making its decision. If the RIA calculates net benefits of multiple alternatives but the preamble to the proposed rule clearly states the justification for choosing an alternative that did not maximize net benefits, the agency can still score well on this criterion. We score the Net Benefits criterion this way to avoid imposing the value judgment that agencies "ought" to choose the alternative that maximizes net benefits. Instead, we evaluate whether decisionmakers considered net benefits and then determined what weight net benefits should have in the decision.

Figs. 3 and 4 show that the scores on these two criteria have a somewhat bimodal distribution. About 10 regulations earned a score of 4 or 5. For more than 20 regulations, the agency seems to have used little or nothing of the analysis. The remaining regulations show some apparent use of the analysis, but not substantial use. We infer from this that agencies sometimes claim regulatory analysis had a significant effect on the regulation, but more often they claim a marginal effect or make no claim at all.

The really low scores in the Use category are on the two retrospective analysis criteria. Only four regulations earned a 3 or better on criterion 11, Measures and Goals, and only 10 regulations earned a 3 or better on criterion 12, Retrospective Data. Few economically significant regulations include any substantial plans for retrospective analysis of either costs or benefits. Seventeen years after passage of the GPRA required agencies to develop goals and measures for their major programs, this is disappointing news indeed. Because economically significant regulations are the ones with the largest impact, surely most of them are related to an agency's fundamental mission and strategic goals.

5.2. Correlation of Quality and Use

Because we evaluated both the quality and the apparent use of regulatory analysis, we can test to see whether there is any correlation between the two. Table VIII shows regression results using all 45 regulations; Table IX excludes transfer regulations. Both tables reveal that there is a tighter and more

Table VIII. Use of Analysis Versus Quality, 45 Regulations (Tobit Regressions)

Dependent Variable	Constant	Quality Score (Criteria 1–8)	Analysis Score (Criteria 5–8)	Chi-Squared	Pseudo R-Squared
Criteria 9–12 (All Four Use Criteria)	1.48	0.32	–	27.27**	0.12
	[1.36]	[6.12]***	–	–	–
Criteria 9–12 (All Four Use Criteria)	3.20	–	0.54	34.77***	0.15
	[4.49]***	–	[7.24]***	–	–
Criteria 9 and 10 (Some Use and Net Benefits)	1.69	–	0.35	22.37***	0.11
	[2.69]***	–	[5.35]***	–	–
Criteria 11 and 12 (Measures and Goals and Retrospective Data)	1.28	–	0.21	10.99***	0.06
	[2.24]**	–	[3.51]***	–	–
Criterion 9 (Some Use of Analysis)	1.43	–	0.12	6.88***	0.04
	[3.36]***	–	[2.71]***	–	–
Criterion 10 (Net Benefits)	−0.02	–	0.26	29.46***	0.18
	[−0.05]	–	[6.26]***	–	–
Criterion 11 (Measures and Goals)	0.36	–	0.11	7.70***	0.06
	[0.97]	–	[2.85]***	–	–
Criterion 12 (Retrospective Data)	0.68	–	0.12	9.37***	0.07
	[1.91]*	–	[3.22]***	–	–

t-statistics in brackets.
***Significant at the 1% level.
**Significant at the 5% level.
*Significant at the 10% level.

Table IX. Use of Analysis Versus Quality, 30 Nontransfer Regs (Tobit Regressions)

Dependent Variable	Constant	Quality Score (Criteria 1–8)	Analysis Score (Criteria 5–8)	Chi-Squared	Pseudo-R^2
Criteria 9–12 (All Four Use Criteria)	4.35	0.209	–	5.14**	0.04
	[2.09]**	[2.37]***	–	–	–
Criteria 9–12 (All Four Use Criteria)	3.58	–	0.51	13.73***	0.10
	[2.57]**	–	[4.17]***	–	–
Criteria 9 and 10 (Some Use and Net Benefits)	2.31	–	0.30	5.47**	0.04
	[1.63]	–	[2.44]**	–	–
Criteria 11 and 12 (Measures and Goals and Retrospective Data)	0.90	–	0.24	4.58**	0.04
	[0.72]	–	[2.21]**	–	–
Criterion 9 (Some Use of Analysis)	0.67	–	0.18	4.56**	0.04
	[0.71]	–	[2.19]**	–	–
Criterion 10 (Net Benefits)	1.44	–	0.14	3.73*	0.04
	[1.75]*	–	[1.98]*	–	–
Criterion 11 (Measures and Goals)	0.15	–	0.12	3.69*	0.04
	[0.72]	–	[1.98]*	–	–
Criterion 12 (Retrospective Data)	0.63	–	0.12	3.28*	0.03
	[0.77]	–	[1.85]*	–	–

t-statistics in brackets.
***Significant at the 1% level.
**Significant at the 5% level.
*Significant at the 10% level.

significant correlation between Use (criteria 9–12) and the Analysis score (criteria 5–8) than between Use and the total Quality score (criteria 1–8). In other words, agencies are likely to claim they used the analysis if it is more thorough, even if it is more difficult to find, less thoroughly documented, or harder to read.

Table VIII shows that there is a positive and statistically significant correlation between the quality of the analysis and every subcomponent of the Use score. When the sample is confined to nontransfer regulations, however, the relationship is somewhat less extensive, as Table IX shows. Taken together, the Use criteria are still highly correlated with

quality of the analysis. Quality of analysis is also correlated with the sum of criteria 9 and 10 (Some Use of Analysis and Net Benefits), and with the sum of criteria 11 and 12 (Measures and Goals and Retrospective Data). But when the regressions are run using individual criteria, the quality of analysis is only marginally significant for criteria 10–12. For nontransfer regulations, it seems that the principal source of correlation between quality and apparent use is criterion 9, which measures whether the agency claimed the RIA affected decisions in the regulation. For nontransfer regulations, good analysis might not be correlated with consideration of net benefits, nor does it necessarily imply that the agency will provide for retrospective analysis.

Nevertheless, there is some evidence that agencies claim they used the analysis in regulatory decisions when the analysis is better. Perhaps improving the quality of analysis improves the odds that decisionmakers will find it useful. Or perhaps when decisionmakers are willing to use regulatory analysis, better regulatory analysis gets produced. It is also possible that, by the time a proposed rule and the accompanying analysis emerge from several iterations of revision within the agency and the OIRA review process, quality and use are mutually interdependent. Finally, the correlation may be driven by other factors, such as statutory requirements that agencies either must or must not consider various aspects of regulatory analysis when making decisions.

Even if most agencies treat RIAs as a mere compliance exercise, it is interesting to note that agencies are more likely to claim that their analysis influenced their decisions when the analysis is better. Clearly, the relationship between quality of analysis and agencies' claimed use of analysis is an area ripe for further research.

6. BEST PRACTICES

Our qualitative evaluation method identifies which analyses have done a particularly good job according to the various criteria. Table X compares the average score on each criterion with the highest score any analysis achieved on that criterion. On most criteria, only a handful of analyses earned the highest score of 5. No analysis earned a score of 5 for criterion 8, Benefit-Cost Analysis, but at least one earned a 5 on each subquestion under Benefit-Cost Analysis. Clearly, more widespread adoption of existing best practices could substantially improve the quality of most regulatory analyses.

Table X. Best Practices Not Widely Shared

Criterion	Average Score	Highest Score Achieved	No. Earning Highest Score
1. Accessibility	3.53	5	12
2. Data documentation	2.24	5	1
3. Model documentation	2.33	5	3
4. Clarity	2.93	5	3
5. Outcome definition	2.36	5	2
6. Systemic problem	1.80	5	1
7. Alternatives	2.29	5	1
8. Benefit-cost analysis	2.09	4	3
9. Some use of analysis	2.44	5	2
10. Considered net benefits	2.20	5	2
11. Measures and goals	1.36	5	1
12. Retrospective data	1.73	5	1

7. CONCLUSIONS

Regulatory analysis is supposed to inform regulatory decisions, not simply justify them after the fact or merely fulfill a requirement to clear a rule through OIRA. Because proposed regulations usually reflect a great deal of up-front work and are supposed to represent the agency's preferred approach to problem solving, we evaluated the quality of regulatory analyses accompanying proposed regulations. This allows us to assess whether the analysis publicly disclosed closest to the time when initial decisions are made is comprehensive and reliable enough to inform those decisions. In addition, we evaluated whether the agency claims to use regulatory analysis to inform its decisions, now and in the future. This allows us to assess whether the quality of regulatory analysis is correlated with its apparent use.

Our findings on quality are generally consistent with prior literature. Previous regulatory scorecard literature finds that analyses earn an average of 40–64% of the total possible points, with higher scores for more recent years.[27,29,30] The average for all regulations we assessed was 27.3 of 60 possible points, or 46%. Excluding transfer regulations, the average was 32.4 points, or 54%. Along with Shapiro and Morrall and Fraas and Lutter, our figures may suggest that the quality of regulatory analysis has improved somewhat since Hahn's seminal scorecards.[30,29]

Qualitative scoring allows us to distinguish between better and worse implementation of economic analysis. The scores clearly indicate that every aspect of regulatory analysis is done at least somewhat well by someone in some agency on some regulation, but no single analysis comes close to doing everything

well. Substantial improvements in regulatory analysis could occur across the board if federal agencies had the incentives to mobilize and spread know-how that already exists.

Our results also suggest that regulatory analysis is perhaps more widely used than previous research has shown. Agencies claimed that some aspect of the analysis affected some major aspect of the regulatory decision in about 10 rules, or 22% of the total. Moreover, the apparent use of analysis is positively correlated with quality of analysis. Agencies are more likely to claim they used the RIA when the RIA is better—though which way the causation runs remains to be seen.

This article reports just the first steps in a multifaceted, ongoing research project. One extension would be to evaluate regulations issued in 2009, to assess whether there was much difference in the quality of regulatory analysis during the last year of the Bush administration and the first year of the Obama administration. Evaluations similar to ours could also be used to assess whether President Obama's Executive Order 13563 has any effect on the quality of regulatory analysis.

Finally, the data can be used to analyze other factors that might affect the quality of regulatory analysis, such as deadlines, politics, statutory requirements, court decisions, or institutional factors unique to particular agencies. Some of the literature cited in Section 1 found that these types of factors affected the quality of regulatory analysis.[30,28] Other research is also suggestive. McLaughlin, for example, finds that "midnight" regulations issued late in an outgoing administration's term receive shorter review at OIRA.[53] McLaughlin and Ellig report that midnight regulations, transfer regulations, and regulations with statutory deadlines all have lower quality analysis, and the latter two types of regulations also receive shorter review times at OIRA.[54] This suggests that the quality of analysis varies systematically with institutional factors. The evaluations reported in this article are the first step in testing these types of hypotheses.

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APPENDIX A: MAJOR FACTORS CONSIDERED WHEN EVALUATING EACH CRITERION

Note: Regardless of how they are worded, all questions involve qualitative analysis of how well the RIA addresses the issue, rather than "yes/no" answers.

Openness

1. *How easily were the RIA, the proposed rule, and any supplementary materials found online?*
   How easily can the proposed rule and RIA be found on the agency's website?
   How easily can the proposed rule and RIA be found on Regulations.gov?
   Can the proposed rule and RIA be found without contacting the agency for assistance?

2. *How verifiable are the data used in the analysis?*
   Is there evidence that the RIA used data?
   Does the RIA provide sufficient information for the reader to verify the data?
   How much of the data are sourced?
   Does the RIA provide direct access to the data via links, URLs, or provision of data in appendices?
   If data are confidential, how well does the RIA assure the reader that the data are valid?

3. *How verifiable are the models and assumptions used in the analysis?*
   Are models and assumptions stated clearly?
   How well does the RIA justify any models or assumptions used?
   How easily can the reader verify the accuracy of models and assumptions?
   Does the RIA provide citations to sources that justify the models or assumptions?
   Does the RIA demonstrate that its models and assumptions are widely accepted by relevant experts?
   How reliable are the sources? Are the sources peer-reviewed?

4. *Was the Regulatory Impact Analysis comprehensible to an informed layperson?*
   How well can a nonspecialist reader understand the results or conclusions?
   How well can a nonspecialist reader understand how the RIA reached the results?
   How well can a specialist reader understand how the RIA reached the results?
   Is the RIA written in "plain English"? (Light on technical jargon and acronyms, well organized, grammatically correct, and direct language used.)

Analysis

5. *How well does the analysis identify the desired outcomes and demonstrate that the regulation will achieve them?*
   How well does the RIA identify ultimate outcomes that affect citizens' quality of life?
   How well does the RIA identify how these outcomes are to be measured?
   Does the RIA provide a coherent and testable theory showing how the regulation will produce the desired outcomes?
   Does the analysis present credible empirical support for the theory?
   Does the analysis adequately assess uncertainty about the outcomes?

6. *How well does the analysis identify and demonstrate the existence of a market failure or other systemic problem the regulation is supposed to solve?*
   Does the analysis identify a market failure or other systemic problem?
   Does the analysis outline a coherent and testable theory that explains why the problem (associated with the outcome above) is systemic rather than anecdotal?
   Does the analysis present credible empirical support for the theory?
   Does the analysis adequately assess uncertainty about the existence and size of the problem?

7. *How well does the analysis assess the effectiveness of alternative approaches?*
   Does the analysis enumerate other alternatives to address the problem?
   Is the range of alternatives considered narrow or broad?
   Does the analysis evaluate how alternative approaches would affect the amount of the outcome achieved?
   Does the analysis adequately address the baseline—what the state of the world is likely to be in the absence of further federal action?

8. *How well does the analysis assess costs and benefits?*
   Does the analysis identify and quantify incremental costs of all alternatives considered?
   Does the analysis identify all expenditures likely to arise as a result of the regulation?
   Does the analysis identify how the regulation would likely affect the prices of goods and services?
   Does the analysis examine costs that stem from changes in human behavior as consumers and producers respond to the regulation?
   Does the analysis adequately address uncertainty about costs?
   Does the analysis identify the approach that maximizes net benefits?
   Does the analysis identify the cost-effectiveness of each alternative considered?
   Does the analysis identify all parties who would bear costs and assess the incidence of costs?
   Does the analysis identify all parties who would receive benefits and assess the incidence of benefits?

Use

9. *Does the proposed rule or the RIA present evidence that the agency used the Regulatory Impact Analysis?*
   Does the proposed rule or the RIA assert that the RIA's results affected any decisions?

How many aspects of the proposed rule did the RIA affect?
How significant are the decisions the RIA affected?

10. *Did the agency maximize net benefits or explain why it chose another option?*
Did the RIA calculate net benefits of one or more options so that they could be compared?
Did the RIA calculate net benefits of all options considered?
Did the agency either choose the option that maximized net benefits or explain why it chose another option?
How broad a range of alternatives did the agency consider?

11. *Does the proposed rule establish measures and goals that can be used to track the regulation's results in the future?*
Does the RIA contain analysis or results that could be used to establish goals and measures to assess the results of the regulation in the future?
In the RIA or the proposed rule, does the agency commit to performing some type of retrospective analysis of the regulation's effects?
Does the agency explicitly articulate goals for major outcomes the rule is supposed to affect?
Does the agency establish measures for major outcomes the rule is supposed to affect?
Does the agency set targets for measures of major outcomes the rule is supposed to affect?

12. *Did the agency indicate what data it will use to assess the regulation's performance in the future and establish provisions for doing so?*
Does the RIA or proposed rule demonstrate that the agency has access to data that could be used to assess some aspects of the regulation's performance in the future?
Would comparing actual outcomes to outcomes predicted in the RIA generate a reasonably complete understanding of the regulation's effects?
Does the agency suggest it will evaluate future effects of the regulation using data it has access to or commits to gathering?
Does the agency explicitly enumerate data it will use to evaluate major outcomes the regulation is supposed to accomplish in the future?
Does the RIA demonstrate that the agency understands how to control for other factors that may affect outcomes in the future?

APPENDIX B: CROSS-WALK OF 2010 OMB REGULATORY IMPACT ANALYSIS CHECKLIST WITH OUR EVALUATION CRITERIA

OMB Checklist	Our Evaluation Criteria
Does the RIA include a reasonably detailed description of the need for the regulatory action?	Criterion 6: How well does the analysis demonstrate the existence of a market failure or other systemic problem the regulation is supposed to solve?
Does the RIA include an explanation of how the regulatory action will meet that need?	Criterion 5: How well does the analysis identify the desired outcomes and demonstrate that the regulation will achieve them?
Does the RIA use an appropriate baseline (i.e., best assessment of how the world would look in the absence of the proposed action)?	Criterion 7, question D: Does the analysis adequately assess the baseline—what the state of the world is likely to be in the absence of further federal action?
Is the information in the RIA based on the best reasonably obtainable scientific, technical, and economic information and is it presented in an accurate, clear, complete, and unbiased manner?	Criterion 2: How verifiable are the data used in the analysis Criterion 3: How verifiable are the models or assumptions used in the analysis? Criterion 4: Was the analysis comprehensible to an informed layperson? *Criterion 3 includes an assessment of whether the models and assumptions are based on peer-reviewed or otherwise reliable publications. However, the evaluation does not assess the quality of the underlying science.*
Are the data, sources, and methods used in the RIA provided to the public on the Internet so that a qualified person can reproduce the analysis?	Criterion 1 takes the first step by assessing how easily the RIA itself can be found on the Internet. Criteria 3 and 4 include an assessment of how easily the reader could find the underlying data, sources, and methods from information or links provided in the RIA or the *Federal Register* notice.

To the extent feasible, does the RIA quantify and monetize the anticipated benefits from the regulatory action?	Criterion 5, question 2: How well does the analysis identify how the outcomes are to be measured?
To the extent feasible, does the RIA quantify and monetize the anticipated costs?	Multiple questions under Criterion 8 (Benefits and Costs) assess how well the analysis identifies, quantifies, and monetizes costs.
Does the RIA explain and support a reasoned determination that the benefits of the intended regulation justify its costs (recognizing that some benefits and costs are difficult to quantify)?	Criterion 8, question F: Does the analysis identify the approach that maximizes net benefits? Criterion 8, question G: Does the analysis identify the cost-effectiveness of each alternative considered?
Does the RIA assess the potentially effective and reasonably feasible alternatives?	Criterion 7: How well does the analysis assess the effectiveness of alternative approaches?
Does the preferred option have the highest net benefits (including potential economic, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires a different approach?	Criterion 10: Did the agency maximize net benefits or explain why it chose another option?
Does the RIA include an explanation of why the planned regulatory action is preferable to the identified potential alternatives?	Criterion 9: Does the proposed rule or RIA present evidence that the agency used the regulatory analysis? Criterion 10: Did the agency maximize net benefits or explain why it chose another option?
Does the RIA use appropriate discount rates for the benefits and costs that are expected to occur in the future?	Considered under Criterion 5, question 2: How well does the analysis identify how the outcomes are to be measured?, as well as several questions about measurement and comparison of benefits and costs under Criterion 8 (Benefits and Costs).
Does the RIA include, if and where relevant, an appropriate uncertainty analysis?	Criterion 5, question E: Does the analysis adequately assess uncertainty about the outcomes? Criterion 6, question D: Does the analysis adequately assess uncertainty about the existence and size of the problem? Criterion 8, question E: Does the analysis adequately address uncertainty about costs?
Does the RIA include, if and where relevant, a separate description of the distributive impacts and equity (including transfer payments and effects on disadvantages or vulnerable populations)?	Criterion 8, question H: Does the analysis identify all parties who would bear costs and assess the incidence of costs? Criterion 8, question I: Does the analysis identify all parties who would receive benefits and assess the incidence of benefits?
Does the analysis include a clear, plain-language executive summary, including an accounting statement that summarizes the benefit and cost estimates for the regulatory action under consideration, including the qualitative and nonmonetized benefits and costs?	Criterion 4: Was the analysis comprehensible to an informed layperson?
Does the analysis include a clear and transparent table presenting (to the extent feasible) anticipated benefits and costs (qualitative and quantitative)?	Criterion 4: Was the analysis comprehensible to an informed layperson?
Goals and measures to assess results of the regulation in the future—No content.	Criterion 11: Does the proposed rule establish measures and goals that can be used to track the regulation's results in the future?
Provisions for gathering data to assess results of the regulation in the future—No content.	Criterion 12: Did the agency indicate what data it will use to assess the regulation's performance in the future and establish provisions for doing so?

APPENDIX C: EVALUATION OF INTERRATER RELIABILITY

Table A.I. All Questions

	Score 2						
Score 1	0	1	2	3	4	5	Total
0	54	21	8	4	3	2	92
1	24	45	17	5	5	1	97
2	14	29	32	32	10	5	122
3	5	22	18	60	20	9	134
4	1	4	8	22	26	7	68
5	0	3	1	3	8	12	27
Total	98	124	84	126	72	36	540

Distance from diagonal	Observations	Percentage
0	229	0.424
1	198	0.367
2	79	0.146
>2	34	0.063

Table A.II. Question 1

	score2						
Score	0	1	2	3	4	5	Total
0	2	0	0	0	1	0	3
1	0	0	0	0	0	0	0
2	1	0	2	0	1	2	6
3	2	0	1	6	5	5	19
4	0	0	0	2	7	1	10
5	0	0	0	0	2	5	7
Total	5	0	3	8	16	13	45

Distance from diagonal	Observations	Percentage
0	22	0.489
1	11	0.244
2	7	0.156
>2	5	0.111

Table A.III. Question 2

	score2						
Score	0	1	2	3	4	5	Total
0	2	0	0	0	0	0	2
1	0	9	2	1	0	0	12
2	1	3	4	3	0	0	11
3	0	2	2	8	2	1	15
4	0	0	2	0	3	0	5
5	0	0	0	0	0	0	0
Total	3	14	10	12	5	1	45

Distance from diagonal	Observations	Percentage
0	26	0.578
1	12	0.267
2	7	0.156
>2	0	0

Table A.IV. Question 3

	score2						
Score	0	1	2	3	4	5	Total
0	3	0	0	0	0	0	3
1	0	6	3	1	0	0	10
2	0	1	4	5	1	0	11
3	0	2	3	6	2	0	13
4	0	0	0	2	2	0	4
5	0	0	0	1	2	1	4
Total	3	9	10	15	7	1	45

Distance from diagonal	Observations	Percentage
0	22	0.489
1	18	0.400
2	5	0.111
>2	0	0

Table A.V. Question 4

	score2						
Score	0	1	2	3	4	5	Total
0	1	0	1	0	0	0	2
1	0	2	0	0	0	0	2
2	0	2	3	1	0	0	6
3	0	1	0	6	2	0	9
4	0	1	3	6	8	1	19
5	0	1	1	1	3	1	7
Total	1	7	8	14	13	2	45

Distance from diagonal	Observations	Percentage
0	21	0.467
1	15	0.333
2	6	0.133
>2	3	0.067

Table A.VI. Question 5

	score2						
Score	0	1	2	3	4	5	Total
0	2	1	4	0	1	0	8
1	3	1	2	2	1	0	9
2	2	1	2	0	5	0	10
3	0	1	1	5	3	1	11
4	0	0	0	3	2	0	5
5	0	1	0	0	0	1	2
Total	7	5	9	10	12	2	45

Distance from diagonal	Observations	Percentage
0	13	0.289
1	14	0.311
2	15	0.333
>2	3	0.067

Table A.VII. Question 6

	score2						
Score	0	1	2	3	4	5	Total
0	8	6	0	2	0	0	16
1	3	2	0	0	2	0	7
2	1	2	3	2	2	0	10
3	0	3	0	1	1	0	5
4	0	1	0	3	1	1	6
5	0	0	0	0	0	1	1
Total	12	14	3	8	6	2	45

Distance from diagonal	Observations	Percentage
0	16	0.356
1	18	0.400
2	6	0.133
>2	5	0.111

Table A.VIII. Question 7

	score2						
Score	0	1	2	3	4	5	Total
0	3	3	0	0	0	0	6
1	1	5	6	0	0	0	12
2	2	4	5	4	0	0	15
3	0	1	1	8	0	0	10
4	0	0	1	1	0	0	2
5	0	0	0	0	0	0	0
Total	6	13	13	13	0	0	45

Distance from diagonal	Observations	Percentage
0	21	0.467
1	20	0.444
2	4	0.089
>2	0	0.000

Table A.IX. Question 8

Score	0	1	2	3	4	5	Total
0	0	2	0	0	0	0	2
1	0	7	1	0	0	0	8
2	0	7	2	9	0	0	18
3	0	2	3	8	0	1	14
4	0	0	1	0	2	0	3
5	0	0	0	0	0	0	0
Total	0	18	7	17	2	1	45

Distance from diagonal	Observations	Percentage
0	19	0.422
1	22	0.489
2	4	0.089
>2	0	0.000

Table A.X. Question 9

	score2						
Score	0	1	2	3	4	5	Total
0	1	1	0	0	0	0	2
1	6	6	0	0	1	0	13
2	2	4	1	0	1	1	9
3	0	3	2	5	2	1	13
4	0	1	0	1	0	1	3
5	0	1	0	1	1	2	5
Total	9	16	3	7	5	5	45

Distance from diagonal	Observations	Percentage
0	15	0.333
1	18	0.400
2	8	0.178
>2	4	0.089

Table A.XI. Question 10

Score	0	1	2	3	4	5	Total
0	4	1	1	1	1	0	8
1	2	4	1	0	1	0	8
2	0	3	2	4	0	2	11
3	0	4	1	2	2	0	9
4	0	1	1	2	1	3	8
5	0	0	0	0	0	1	1
Total	6	13	6	9	5	6	45

Distance from diagonal	Observations	Percentage
0	14	0.311
1	19	0.422
2	6	0.133
>2	6	0.133

Table A.XII. Question 11

	score2						
Score	0	1	2	3	4	5	Total
0	12	1	1	1	0	1	16
1	7	2	1	0	0	0	10
2	2	1	2	3	0	0	8
3	3	1	3	3	1	0	11
4	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0
Total	24	5	7	7	1	1	45

Distance from diagonal	Observations	Percentage
0	19	0.422
1	17	0.378
2	4	0.089
>2	5	0.111

Table A.XIII. Question 12

	score2						
Score	0	1	2	3	4	5	Total
0	16	6	1	0	0	1	24
1	2	1	1	1	0	1	6
2	3	1	2	1	0	0	7
3	0	2	1	2	0	0	5
4	1	0	0	2	0	0	3
5	0	0	0	0	0	0	0
Total	22	10	5	6	0	2	45

Distance from diagonal	Observations	Percentage
0	21	0.467
1	14	0.311
2	7	0.156
>2	3	0.067

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PREPARED STATEMENT OF ROBERT S. KIEVAL

Good morning. Congressman Brady, Senator Klobuchar, members of the Joint Economic Committee, it is an honor to have this opportunity to address you today and to endeavor to answer your questions. I have a deep respect for the work of this Committee, and for all of the policy makers striving to preserve and foster innovation in the United States. My name is Robert Kieval, and I am the Founder and Chief Technology Officer of CVRx, a Minneapolis-based medical device company. I have worked in the medical technology industry for over 20 years, with experience in both a large medical device company and in the entrepreneurial, start-up environment. In addition to my work at CVRx, I serve on the Board of Directors of two industry advocacy organizations, the Medical Device Manufacturers Association (MDMA) here in Washington, DC, and LifeScience Alley (LSA) in Minneapolis.

In our 11 year history, CVRx has developed an implantable medical device that is intended to treat two prevalent cardiovascular diseases: hypertension, or high blood pressure, and chronic heart failure. Together, these diseases afflict over 80 million Americans. They are a primary cause of more than 128,000 deaths each year in the United States, and represent an annual economic burden of over $100B to CMS and private insurers in health care costs and lost productivity. They are diseases for which effective new treatments are desperately needed. Our product was approved in Europe in 2011 for the treatment of hypertension, and it is under clinical evaluation here in the U.S.

The medical technology industry accounts for at least 400,000 jobs in the U.S., supports nearly 2 million additional jobs in adjacent industries, and remains one of the few American industries that is a net exporter of goods and services. Small businesses like CVRx, often with fewer than 50 employees, are a vital source of innovation and comprise approximately 80% of the industry.

Companies like ours, with a single product focus and no alternative revenue streams, depend on outside investment for our existence. Investors require assurance of a reasonable and predictable path to product approval. Ambiguous or overly burdensome approval thresholds can fatally inhibit investment and prevent development of a potentially important new therapy. This is especially critical for patients suffering from diseases that have few treatment options.

Since 2005, the time and capital required for a company to get a clear definition of its required regulatory pathway, to negotiate product testing and clinical trial requirements, and to obtain an approval or clearance decision once a completed application has been submitted have risen dramatically. Small, venture capital-backed companies typically spend $500,000 to $2 million per month to operate. A six to twelve month delay, for example, in reaching agreement with the FDA about a clinical trial design issue, or in the time required to complete an overly burdensome clinical trial, could result in the loss of precious time to deliver a potentially life-saving new treatment to patients, and require a company to raise millions of dollars of additional capital in order to get through the approval process.

The regulatory approval process itself has become increasingly inefficient, inconsistent and unpredictable, and the level of clinical evidence required to obtain product approval has also continued to rise. This has led to a situation in which patients outside of the U.S. frequently gain access to American innovation and technology an average of two years before American patients do. In many cases it has also led to jobs and Research & Development moving overseas, weakening the competitiveness of our medical technology industry. Such are also the cases for CVRx. While we work through the regulatory approval process here at home, our product is being used to treat patients in Germany, Italy, the Netherlands, Hungary and Turkey. I just returned from a trip to Europe where I heard firsthand from doctors how patients there are benefiting from our technology. As a result, the jobs that we are adding are also largely overseas. Finally, the recently enacted Medical Device Tax, a 2.3% excise tax on revenues irrespective of a company's earnings, has put additional financial pressure on companies and has compounded these difficulties. For large companies, these often represent issues of profitability. For small companies, they may be issues of survivability.

A 2011 study by the National Venture Capital Association (NVCA) found that U.S. venture capital firms have and will continue to decrease their investment in biotechnology and medical device start-ups and shift focus away from the United States toward Europe and emerging markets. In that study, FDA regulatory challenges were identified as having the highest impact on these investment decisions. The first quarter 2013 MoneyTree report released by PriceWaterhouse Coopers and NVCA reflects a continued decline in medical technology investment. In fact, the Life Science sector experienced a dramatic drop to $98 million, the lowest quarterly amount since the third quarter of 1996. To put this in perspective, in 2007 alone,

116 early stage medical device companies raised approximately $720 million in initial venture capital. These early stage investments are the single largest indicator of future innovations and breakthroughs, and thus the current environment does not bode well for patients.

To be sure, federal regulators and policy makers have acknowledged and have been working to address these issues. Our industry appreciates the overwhelming bipartisan support for The Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA). This legislation reauthorized the medical device user fee program for five years and includes many reforms that, if implemented as intended, will be a real benefit for patients, innovation and our economy.

These reforms include earlier substantive interactions between FDA and industry, better manager-to-reviewer ratios to deal with capacity issues and shared outcome goals that will track performance based on calendar days.

While it is too soon to evaluate the ultimate impact of these measures, the industry is beginning to see early evidence of improvements, and CVRx has also had positive experience in this regard. In addition, the Medical Device Innovation Consortium, a public-private partnership that had its roots with LSA in Minnesota but has now become a national program, is a promising example of government and industry working collaboratively to identify and improve regulatory inefficiencies. While industry, including MDMA, AdvaMed and LSA, endeavor to work with all stakeholders to improve the regulatory environment, we will also be relying on the FDA to utilize its user fees and appropriations efficiently and effectively.

Looking forward, opportunities remain for further improvements, and we need to continue to work together so that the United States doesn't lose its leadership position in healthcare innovation. The FDA has a crucial mission to protect the public health. Clearly this means providing reasonable assurance that products are safe before they're made available to patients. However, I believe it also means that patients in need of effective treatments should not be unduly deprived of new innovations because of an inefficient or overly burdensome approval process. Successfully implementing this aspect of its mission will depend on a cultural change at the FDA as much as it will rely on processes and procedures.

As mentioned above, increasing numbers of medical technology companies are developing and evaluating their products in clinical trials outside the United States. Given the millions of dollars of investment that this entails, we look forward to working with FDA on ways to better leverage these data domestically in a meaningful manner.

I am also encouraged by reports that the FDA is currently focusing on three highly practical priorities of 1) improving efficiency in clinical trials, 2) balancing the premarket and postmarket process, and 3) identifying ways to shorten the lag between product approval by the FDA and reimbursement approval by CMS and/or private payers.

Capitalizing on many of these opportunities will require close collaboration between patients, industry and the FDA. However, Congress can play an important role as well, by ensuring that all parties continue to work in a highly constructive and productive manner.

Thank you for your attention, and I look forward to your questions.

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