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THE FIRST STEP TO CUTTING RED TAPE: BETTER ANALYSIS

HEARING

BEFORE THE

JOINT ECONOMIC COMMITTEE
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THE FIRST STEP TO CUTTING RED TAPE: BETTER ANALYSIS

WEDNESDAY, APRIL 30, 2014

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

The committee met, pursuant to call, at 9:32 a.m. in Room 301 of the Russell Senate Office Building, the Honorable Kevin Brady, Chairman, presiding.

Representatives present: Brady of Texas, Paulsen, and Carolyn B. Maloney.

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

Staff present: Corey Astill, Ted Boll, Gail Cohen, Jon Foltz, and Connie Foster, Niles Godes, Colleen Healy, Patrick Miller, and Robert O'Quinn.

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

Chairman Brady. Good morning, everyone. Welcome to the Joint Economic Committee hearing entitled The First Step Toward Reducing Red Tape: Better Analysis.

Too often Congressional hearings are given titles that merely attract attention. But I believe the title for today's Joint Economic Committee hearing accurately describes what our witnesses are here to talk about, and what we should take to heart—namely, that the first step toward reducing red tape and achieving our regulatory goals is better analysis.

Every Member of Congress recognizes the economic justification and the Constitutional authority under the Commerce Clause in Article I, Section 8 of the U.S. Constitution for balanced Federal regulation to protect public health and safety, preserve our environment, and prevent fraud of all kinds.

At the same time, many Members of Congress also recognize that Federal regulation has become overly burdensome and costly to job creators and the economy alike. Some regulations, regrettably, are even counterproductive.

As the volume of Federal regulation has grown, regulation has done less to advance its stated goals and imposed ever more costs. These costs include slower economic growth, higher uncertainty that inhibits business investment and job creation, foregone product and process innovation, a lessening in the international competitiveness of American businesses, and stagnant incomes for hardworking American families. Unnecessarily burdensome regulation also aggravates our country's long-term fiscal imbalance by in-

hibiting the natural growth of Federal revenues under existing tax law.

Consider the following facts:

In 2013, the federal government issued 3,659 final rules contained on 26,417 pages, a record number in the Federal Register. Including proposed rules, the Federal Register finished last year with over 79,000 pages.

Four of the five highest regulatory page counts have occurred during President Obama's Administration, the all-time record being over 81,000 in 2010.

Mr. Wayne Crews, the author of TEN THOUSAND COMMANDMENTS: AN ANNUAL SNAPSHOT OF THE FEDERAL REGULATORY STATE, estimates the overall annual cost of regulatory compliance to be $1.9 trillion, about equal to the economy of Australia, Canada, or Italy.

Mr. Crews estimates that U.S. households face an annual hidden regulatory "tax" of nearly $15,000.

In last year's draft report to Congress on the benefits and the costs of Federal regulation, the Office of Management and Budget stated that Executive agencies and independent regulatory agencies promulgated a combined total of 68 major rules during 2012—each of which, as you know, have an impact of $100 million or more. Alarmingly, OMB presented a cost-benefit analysis for only 14 of those 68 major rules.

Looking longer term, during the decade ending in 2012, Federal agencies published over 37,000 final regulatory rules—with OMB presenting cost-benefit analysis for only 115 of them. That is 3/10ths of 1 percent, meaning only 3 in every 1,000 regulations were subject to a complete analysis of their effects on the U.S. economy, job creators, and families. For a Nation seeking a smarter, more efficient government, that is just shameful.

America's regulatory system should be designed to achieve the greatest good at the least cost. Both Republicans and Democrats should be able to agree on that principle.

Smart, effective regulations should seek to reduce rates of illness, mortality, and pollution—but not by reducing economic growth, job creation, and the incomes of hardworking Americans out of neglect or disregard.

Safety and security must not come at the cost of stagnation, unemployment, and lower incomes that rob from the middle class. Yes, there will be tradeoffs, but too often our Federal regulatory system pursues singular objectives blind to the unintended consequences of its methods, and indeed often does not even focus on realizing the intended results.

We need a better way, a 21st Century way to sift through regulations, both proposed and existing; transparently identify their true costs; and find the least costly, the least intrusive way to achieve the goals on which we all agree.

We cannot do that without better analysis.

My colleague, Senator Dan Coats, and I have introduced the Sound Regulation Act to improve the regulatory process through better analysis. The Sound Regulation Act would:

First, expand accurate cost-benefit analysis to all Federal regulatory agencies—beyond the Executive Branch agencies to the inde-

pendent ones as well—and close loopholes that allow some Federal agencies to skirt the requirement for objective economic analysis.

It would end agency bias and establish more public transparency by requiring agencies to clearly identify the nature and significance of the market failure or other problem that necessitates regulatory action; establish an achievable objective for the regulatory action; and publish for public comment in advance the method and process for objectively weighing the costs and benefits of the proposed regulation.

It would encourage more innovative solutions by requiring the development and evaluation of the costs and benefits of at least three regulatory options ranked by cost from lowest to highest.

And, justify the—require justifying the choice of any option that is not the least cost method of achieving the objective.

Finally, it would require reviewing existing regulations on a timely basis to determine the success and costs of the regulation in the real world.

The Sound Regulation Act would not dictate solutions or how to achieve them. Instead, it would provide a better framework for rulemaking by Federal regulators so that regulations work more effectively and at least cost to the American economy. I believe that all Members of Congress in both chambers and both parties can ascribe to this goal.

We have many ideas on how best to move forward on smart regulations. Senator Coats and I have one. There are others. That is the topic of the discussion today, and with that I look forward to the testimony of today's witnesses.

I would yield to the Vice Chair, Senator Klobuchar, for her opening remarks.

[The prepared statement of Chairman Brady appears in the Submissions for the Record on page 28.]

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

Vice Chair Klobuchar. Well thank you very much, Mr. Chairman. I am pleased that the Committee is again looking at regulatory issues, and thank you for holding this hearing.

Improving regulation is a big issue in our country. It is important to business. It is also important to consumers.

I would like to thank the witnesses on our panel. Some of you are making return visits. Mr. Mandle, of course, is just going to become the new President and Chief Executive Officer of LifeScience Alley, which specializes in medical device and technology.

I knew, Mr. Chairman, you would like to see from Representative Paulsen and myself another medical device witness.

[Laughter.]

We also have with us Dr. Graham. Thank you, Dr. Greenstone, thank you, and also a special note to Jay Timmons, the head of the National Association of Manufacturers. Thank you so much for your leadership. I truly enjoyed recently addressing the Women in Manufacturing, which are growing daily, and thank you for your work.

Dr. Greenstone, last summer you pointed out in a hearing that cost-benefit analysis of proposed regulations are done only before

the regulations are enacted, when we least know what their impact will be. And I took your words to action, and Senator Susan Collins, Republican of Maine, and I introduced bipartisan legislation requiring a look-back to assess whether the regulation is actually meeting its goals. And I want to thank you for your testimony. We actually came out with that idea. And I also thank NAM and others for endorsing our bill.

Our legislation requires the Congressional Budget Office to conduct a cost-benefit analysis of an economically significant Federal rule or regulation after it has been in effect. This would provide important information on which regulations are working, and I think would be a good step toward reducing red tape.

Of course there's more to be done. This is especially important to me. As I pointed out in our last hearing, I spent 13 years representing companies in regulatory areas. Americans expect a common sense approach to regulation. They want to have their water, and air, and their safety protected, but they also do not want to stifle innovation and economic growth. And we need to protect consumers with clarity and consistency, and not endless red tape.

Medical devices are of course one example. Our State has a long history of leadership in this area of manufacturing and, Mr. Mandle, I am eager to hear your views on the opportunities and challenges facing the medical device industry.

As head of LifeScience Alley, you represent hundreds of organizations that employ nearly a quarter of a million people in my State alone. The U.S. is the largest net exporter of medical devices in the world, enjoying a trade surplus of $6 billion a year. Yet we have seen a decline in venture capital funding, partially due to delays in the approval process.

According to one study, venture capital investment in the medical device industry fell 17 percent in 2013. It is critical we prevent regulatory burdens from interfering with the delivery of life-saving products.

That is why in 2012 we passed the FDA Safety and Innovation Act. There are some very good ideas that many of us, including Senator Coats and Representative Paulsen, worked on, the least-burdensome principles, which has been ignored by FDA reviewers. It improved conflict-of-interest provisions, making it easier for the FDA to recruit top-line experts. And, from what we have heard, there has been some improvement.

I know, hearing from the companies in our State, that while there are still issues that the FDA has made some significant improvements in getting these approvals done. And I am hoping the future looks bright for medical devices.

Tourism is another example. Senator Blunt and I have taken on this issue and done a lot without legislation. We have worked with the State Department to reduce wait lines, making it easier for tourists to visit the U.S.

When they come here, they spend an average of $4,000. The Visa process itself is a profit-making center for our government because when they apply for a Visa, just doing that, we make money. But imagine how much money we make when they actually come to visit our country.

Yet, in some countries they were waiting, like in Brazil, 100 days, and we were losing business to other countries. If they could go to Great Britain in 3 days, that is where they would go. And so we have greatly improved that, and we were able to get an increase in tourism-related goods and services of 9 percent over 2012, and reduced wait lines significantly in Brazil and in China.

We also, along with Representative Joe Walsh, streamlined the process for crossing the U.S.-Canada Border, something we care a lot about in our State.

Exports is another great example, trying to reform the Export Control List. As we look at some decreased defense spending, looking at how we keep these companies strong by not just relying on old lists that, you know, basically make it hard to literally export nuts and bolts. And we have to do everything we can to make that easier.

And the last thing I would mention is just one example of this regulatory reform is agriculture. We have seen a number of rules from the EPA that have come out and then been rejected, whether it's protecting farmers from regulations that require milk spills to be treated like oil spills, or burdensome dust regulations. We can be smarter about how we regulate farming in rural America.

I was pleased that the recent farm bill included something that Senator Lugar, when he was still with us, he and I had introduced a bill on the EPA to make sure that people with rural backgrounds were on the rulemaking authority that would suggest that they can bring a little of their expertise and farm backgrounds into the EPA.

Mr. Chairman, thank you again for holding this important hearing. We have good attendance. As you know, I have two other hearings this morning, including one involving an important bill that I passed with Senator Cornyn where we have waited—are you ready for this, guys?—four years for the rules to come out involving allowing people to take back their prescription drugs. And I want to be at the hearing to ask the DEA why it is taking so long, and that is my good purpose for leaving early. And I appreciate your leadership in holding this hearing, and I will be turning this over to Representative Maloney.

Chairman Brady. Thank you, Vice Chair, and good luck getting an answer.

[Laughter.]

I would like to—and I appreciate each of the Members being here today on this important topic.

I would like to welcome our four witnesses this morning. I will be introducing three of them, and I will let my colleague, Senator Coats, introduce our witness from Indiana.

Jay Timmons is President and CEO of the National Association of Manufacturers. Prior to his appointment as NAM president, Mr. Timmons was Executive Vice President and Senior Vice President of Policy and Government Relations at NAM. His previous experience includes serving as Chief of Staff to Congressman, Governor, and Senator George Allen of Virginia from 1991 to 2002. He is a Buckeye, Ohio State University.

Dr. Michael Greenstone is a 3M Professor of Environmental Economics in the Department of Economics at the Massachusetts Institute of Technology. He is a nonresident Senior Fellow at the Brook-

ings Institution, a Research Associate at the National Bureau of Economic Research, and is on the MIT Energy Initiatives Energy Council. Dr. Greenstone previously served as the Chief Economist for President Obama's Council of Economic Advisers, and as the Director of the Hamilton Project at the Brookings Institution. Dr. Greenstone received a Ph.D. in Economics from Princeton, and a B.A. in Economics with High Honors from Swarthmore College.

Shaye Mandle serves as Executive Vice President and COO for LifeScience Alley. Previously Mr. Mandle served as Executive Director of the FedEx Institute of Technology at the University of Memphis. Mr. Mandle has served as chief executive to industry and economic development organizations, the East-West Corporate Corridor Association, and the Illinois Coalition; and he previously served on the policy staff of former U.S. House Speaker Dennis Hastert, and former Illinois Governor Jim Edgar. Mr. Mandle has a J.D. from Duquesne University Law School, and a B.A. from Illinois Wesleyan University.

And I would turn to Senator Coats for the final introduction.

Senator Coats. Well, Mr. Chairman, thank you very much, and Vice Chair Klobuchar, also. It has been a pleasure for me to work with both of you. Vice president—Vice—Chair—I've got you moved up to Vice President already.

[Laughter.]

Chairman Brady. Is there an announcement here?

Senator Coats. This could make some news this morning, if you want to respond to that——

Vice Chair Klobuchar. We have had a number of them from our State.

[Laughter.]

Senator Coats. The Vice Chair and I have worked together on the medical device issues in the FDA, and am very pleased to work with Chairman Brady on the Sound Regulation Act, which as you said will require every Federal agency to engage in extensive cost-benefit analysis to determine the actual cost in dollars of regulations under each agency's jurisdiction.

The negative effects of over-regulation are felt in industries throughout my home State, and I'm sure throughout the states being represented here by the panel. While many regulations of course are of worthy purpose, there are many that I think unnecessarily increase costs and slow productivity.

The statistics are pretty compelling, particularly as it impacts on small business. The Small Business Administration found that complying with Federal regulations cost small businesses 36 percent more per employee than larger firms. In many cases, this cost amounts to the difference between a small business hiring or not hiring additional employees.

And further, new financial regulations have imposed what Indiana bankers are telling me is an avalanche of new rules. Hoosier community banks and credit unions are spending as much as 70 percent of their time and 10 percent of their net income on compliance reporting.

Now it is one thing for CitiCorp, JPMorgan, and so forth, to hire a backroom of lawyers and technicians to deal with all these regulations. It's another thing for the community banks, credit unions,

and smaller banks that had nothing to do with the financial crisis, yet they have to go outside and outsource or hire their own cadre of lawyers, accountants, and others who will have to fill out all this paperwork as if at the same level that the major banks do.

So we need to have some distinction, I think. The numbers are eye-popping when you add them up. Regulators published $112 billion in net regulatory cost in 2013 alone.

Now I am pleased to welcome and introduce Dr. John Graham. Jay, we couldn't let Ohio State control the whole thing here. We had to get an Indiana counter balance here. Dr. Graham serves as Dean for the highly regarded School of Public and Environmental Affairs at the Indiana University. The school is ranked first among all state universities' public affairs programs. In March 2001, President Bush nominated Dr. Graham to serve as Administrator of the Office of Information and Regulatory Affairs. He was confirmed by the Senate, oversaw the regulatory information and statistical activities of the federal government.

Dr. Graham, while encouraging good regulations that save lives, prevent disease, and protect the environment, actually reduced the growth of regulatory costs by 70 percent during his tenure.

After his time at OIRA, Dr. Graham was Dean of the Frederick Pardee-Rand Graduate School at the Rand Corporation in Santa Monica, California. And then later assumed the deanship of Indiana School of Public and Environmental Affairs.

Dr. Graham, we appreciate your willingness to come and testify before us, as we do for all four of our witnesses, Mr. Chairman, and look forward to their testimony.

Chairman Brady. Right. Thank you, Senator.

Mr. Timmons, we will begin with you. As in most hearings, we have reserved five minutes for the opening statement so we will have an opportunity to explore the testimony further during questions. So you are recognized.

STATEMENT OF MR. JAY TIMMONS, PRESIDENT AND CHIEF EXECUTIVE OFFICER, NATIONAL ASSOCIATION OF MANUFACTURERS, WASHINGTON, DC

Mr. Timmons. Thank you, Mr. Chairman and Vice Chair Klobuchar——

Chairman Brady. Can you hit that microphone?

Mr. Timmons. All right. Well thank you very much, Mr. Chairman, and Vice Chair Klobuchar, Members of the Committee:

I really appreciate the opportunity to testify about the regulatory system that is facing manufacturers, and some of our ideas about improving the system.

Now from the opening statements today, bipartisanship is clearly breaking out all over the place when it comes to regulation, and that is a very good thing. I have to say, Mr. Chairman and Madam Vice Chair, manufacturers really appreciate your efforts to find common ground on regulatory reform.

The legislation you have each offered would go a long way toward adding balance and transparency to the regulatory process. And, importantly, your proposals represent ideas that both parties can support.

And as I said, bipartisan cooperation is the key. It is crucial to any successful reform effort, and frankly it has been lacking in previous reform efforts. The inability of Congress to advance reform measures has led presidents of both parties to exercise their executive authority. And, to his credit, President Obama has signed Executive Orders seeking to enhance regulatory review. As you know, President Bush undertook similar initiatives. So did President Clinton, and so did President Reagan.

Yet, look at where we are today. The regulatory state is growing in size and it is growing in complexity. Now I happen to be optimistic that we can get something done. Whether you are on the left, the right, or somewhere in between we all want clean air. We all want clean water. And we want healthy communities for our families.

So step one is changing the rhetoric. The conversation about regulation all too quickly turns partisan. But from the perspective of the business community, particularly manufacturers, our position on regulation is often mischaracterized.

Manufacturers believe that regulation is critical to the protection of worker safety, to public health, and to our environment, and our record backs up that fact. We have supported regulations such as the enhanced corporate average fuel economy rules in 2009, and legislation such as the Food Safety Modernization Act of 2011 and its accompanying regulations.

And indeed, some critical government objectives can only be achieved through regulation. But that does not mean that Congress or the Executive Branch should be off the hook. By simplifying regulations, reducing overlap—or even conflicting rules—and ensuring that regulations are based on good data, we can ease the burdens placed on manufacturers and other businesses alike.

New regulations are often poorly designed, poorly analyzed, and inefficient. Many times they are unnecessarily complex and duplicative. Their critical inputs—scientific and other technical data—are sometimes unreliable and fail to account for significant uncertainties.

Regulations are allowed to accumulate with no real incentives to evaluate or clean up the past, and they too are often one-size-fits-all, without the needed sensitivity to their impact on small businesses. Frankly, we can do better.

I constantly hear from members of the National Association of Manufacturers about the challenges they face in dealing with the regulatory system in our country.

One small company, a die-caster, estimates that $1 out of every $5 of the company's pretax profits is spent on complying with a dizzying array of new regulations.

Another small manufacturer had an inspector at its facility, and that inspector told him that a fire extinguisher was affixed too low on the wall, making it difficult for employees to use. So the manufacturer corrected the problem, only to have another inspector come to his plant a few weeks later to inform them that the fire extinguisher was now too high and therefore it was in violation of the Americans with Disabilities Act.

Yet another manufacturer told me that they spend upwards of 80 percent—80 percent—of their R&D budget on regulatory compli-

ance. It all boils down to a manufacturer's ability to succeed in a highly competitive global economy.

Today we see the nascent signs that manufacturing in America is making a comeback. We are now a $2 trillion sector of the economy, and that is larger than all but seven world economies. But imagine how much stronger this comeback could be if Washington removed impediments to growth; if manufacturers could focus on making better products and innovating instead of spending hours figuring out which rules that they must follow and then how to comply with those rules.

Manufacturers are committed to common sense regulatory reforms that protect the health of our workers and the environment, as well as prioritize economic growth and jobs.

We look forward to working with Congress in a bipartisan manner to make that a reality. Thank you very much, Mr. Chairman.

[The prepared statement of Mr. Timmons appears in the Submissions for the Record on page 71.]

Chairman Brady. Thank you, sir.

Dr. Greenstone.

STATEMENT OF DR. MICHAEL GREENSTONE, 3M PROFESSOR OF ENVIRONMENTAL ECONOMICS, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, CAMBRIDGE, MA

Dr. Greenstone. Thank you, Chairman Brady, Vice Chair Klobuchar, and Members of the Committee, for inviting me to speak today.

The purpose of my testimony is to describe in concrete terms how we can improve our regulatory system, and to wholeheartedly offer my support for Senate Bill 1472, Strengthening Congressional Oversight of Regulatory Actions for Efficiency, that was introduced by Senator Klobuchar and is co-sponsored by Senator Collins and Senator King.

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 safety of our workplaces, the investments we make, and 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 system is that we generally do not have the information necessary 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 regulations' "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 bar, it generally goes on the books and can stay there unexamined for years. In practice, some regulations work out exactly as we intended them to do, and in some instances they 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 are 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 their costs.

The first is to make three reforms that build on the President's 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 rule, the review 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, as well as the expected costs—so that the terms of the subsequent review would be known in advance, which I think bears some similarity to your bill, Mr. Chairman.

Second, the relevant agencies 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. The new rulemaking should also operate under a time limit.

And third, these efforts would be strengthened if they were accompanied by triggers to ensure that they are undertaken within the prescribed time period. One approach would be for agencies to post on their websites 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 a review timeline, or to act upon its results.

There are some difficulties with this 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 quite difficult. I find it difficult in my own life. So my second recommendation is to establish a new, independent body for regulatory review. The nonpartisan Congressional Budget Office provides a very appealing model.

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 benefited 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.

I believe that Senator Klobuchar's bill, Senate Bill 1472, which creates a regulatory analysis division in the nonpartisan CBO, is the best solution. The regulation analysis division would be charged with conducting independent regulatory impact evaluations.

Of course the creation of a regulatory analysis division within the CBO would require resources. My best estimate is that it would cost less than $10 to $15 million a year, and that that is very likely—it would very likely pay for itself 10, or 20, or 100 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 regulatory analysis division within the Congressional Budget Office. We live in a rapidly changing economy and need a new 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 better 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 in the discussion.

[The prepared statement of Dr. Greenstone appears in the Submissions for the Record on page 83.]

Chairman Brady. Thank you, Dr. Greenstone.

Dr. Graham.

STATEMENT OF DR. JOHN D. GRAHAM, DEAN, SCHOOL OF PUBLIC AND ENVIRONMENTAL AFFAIRS, INDIANA UNIVERSITY, BLOOMINGTON, IN

Dr. Graham. Good morning, Mr. Chairman, Members of the Committee:

The focus of my remarks will be on what Congress can do to bring smarter regulation from the Executive agencies. But before I go to those points, I want to underscore the importance that Congress itself needs a more evidenced and analytic approach to these issues. And I want to add my voice of support for expanding the Congressional Budget Office, as Dr. Greenstone indicated, to have regulatory analysis as a division that routinely introduces itself into the regulatory process.

By way of comparison, I was in Brussels last week working on the effort for a Free Trade Agreement between Europe and the United States, and it turns out the European Parliament—which is often considered a primitive and developing legislative body; it has its own regulatory impact assessment unit now that checks the power of the European Commission. And I think for Congress, something like that at CBO would be quite sensible.

Now moving to reforms at the agencies, the first point I would like to make is we need to remember that a lot of the burdens that occur for businesses and the private sector, and state and local governments, they occur before the regulation is proposed or adopted.

There are quasi-regulatory determinations made early in the process—a technological hazard determination, a guidance document. The information quality that underpins these quasi-regulatory documents needs to be very strong if the ultimate rulemaking is going to be done.

I give examples in my written testimony of both the housing industry and the coal industry, where a lot of harm was done because of problems in these early quasi-regulatory documents.

The second point is state and local regulation. You might say, oh, but we are here in Washington; we are talking about the federal government; we cannot solve all the world's problems. In many cases, the federal government has the authority to preempt or to oversee state and local regulation and shape it in a specific direction.

So for example we have in the automotive industry a regulation in California which is starting to be binding which requires manufacturers who do business in California to sell a zero-emission vehicle—practically speaking, an electric car in most cases—in California. Up to 15 percent of their fleets have to be ZEVs by 2025.

These vehicles cost $10- to $20,000 more. And while there are savings in fuel costs, the cost-benefit analysis is pretty speculative on the advantages of this type of rule.

It turns out the federal government already has incentives to promote electric cars. There's a $7,500 Federal income tax credit for purchasers of electric cars. Manufacturers are allowed to count each electric car twice in their compliance for CAFE and carbon standards.

You might say, well, aren't there big environment advantages to having a mandate from California for electric cars? Well, it turns out manufacturers, because they have a national binding carbon constraint, if California forces more electric cars to be sold there that means the manufacturers will simply sell more higher-polluting vehicles in the non-California states.

So it is a whole regulation that is actually not very well thought out. The federal government gave an official waiver to allow California to do this, and the federal government never did a cost-benefit analysis of that waiver decision.

So we need to keep in mind that the state and local governments and the federal government needs to coordinate in a way that makes sense for regulatory policy.

Point three, we need to look hard at regulation by litigation. The basic strategy here of a regulatory agency—and I was done in by this several times while I was an administrator—they get sued. They get into a negotiation. And then they agree, in a sense, to force certain regulations by a certain deadline.

This prejudges all of the analytic and cost-benefit process that the Executive Orders put in place. So I think clearly we need some transparency in that process. We need some public comment process on whether there should be a settlement. And there needs to be some evidence-based analysis before agencies actually sign consent decrees that force mandatory rulemakings.

The fourth point, we need more regulatory cooperation with our trading partners in Europe and Asia. And I applaud the Obama Administration for trying to get action moving in the direction of freer trade between Europe and the United States.

Of course the signature examples of this that we complain about, with justification, are in agriculture where genetically modified seeds are still not available throughout most of Europe. But we have a lot of problems in our own regulations.

Our automotive safety regulations, and our automobile tailpipe emission standards are not aligned with the European standards, so manufacturers have to separately design and test their vehicle in Europe and the United States.

I think Congress should be pushing the agencies to find a way to find common ground, or at least mutual recognition that European cars are clean and safe enough to be imported here, and ours are clean and safe enough to be put into Europe. So we have a lot of work to do there in terms of making that progress.

I hope these points are constructive and point the direction for some stronger, better regulation initiatives, and I look forward to the comments and questions.

[The prepared statement of Dr. Graham appears in the Submissions for the Record on page 87.]

Chairman Brady. Thank you, Dr. Graham. Mr. Mandle.

STATEMENT OF MR. SHAYE MANDLE, EXECUTIVE VICE PRESIDENT AND CHIEF OPERATING OFFICER, LifeSCIENCE ALLEY, ST. LOUIS PARK, MN

Mr. Mandle. Chairman Brady, Vice Chair Klobuchar, Members of the Committee, thank you for the opportunity to be here this morning.

My name is Shaye Mandle and tomorrow I will take over as President and CEO of LifeScience Alley, the Nation's largest regional life science association.

This year we celebrate our 30th anniversary of leading Minnesota's medial alley, the most densely concentrated medical technology cluster in the world, and home to some of history's greatest therapeutic and health care innovations. Our members include: 3M, Medtronic, Boston Scientific, St. Jude Medical, Covidien, Endo/AMS, Mayo Clinic, and hundreds of small companies that will bring new innovation to the health care marketplace.

I personally would like to thank Senator Klobuchar as well as Congressman Paulsen for their leadership on behalf of patients and the companies that serve them, especially for those of us who call Minnesota home.

Today this Committee is interested in taking the first step to cutting red tape through better analysis, and we agree that better analysis is needed, and that a regulatory environment that is smarter and more collaborative would serve patients and the U.S. health care system well.

It is also important for broad-based analysis of the entire ecosystem, including tax and regulatory policy. It is critical for Congress to address repeal of the Medical Device Tax if we want to keep our jobs and competitive advantage, as well as providing a permanent fix to the FDA user fees and sequestration issue to ensure that FDA has access to the funds committed by industry.

In 1957, Earl Bakken and Medtronic introduced the first battery-operated external pacemaker. In 1976, the Federal Food, Drug and Cosmetics Act was amended to include the regulation of medical devices. At the beginning, innovation came from doctors and engineers working together to save lives.

For the first 25 years of medical technology innovation, there was no FDA oversight. So is it our position that medical devices shouldn't be regulated? Quite the contrary.

When medical devices were added to the FDA's regulatory responsibility, something unique happened. An agency with no expertise in the field connected with the patients, doctors, and innovators to form a collaborative relationship. They taught each other.

If you talk to anyone from industry or the FDA from those early years of regulation, they will amaze you with stories of working together to accomplish a shared goal: delivering the safest and most effective therapies in the world to the patients whose lives depended on them.

Both the medical device industry and the FDA want the same outcome: safe and effective devices invented in the U.S. and available first in the U.S.

For a couple of decades, this is exactly what we got. Over the past decade or so, this dynamic has changed and an adversarial relationship has emerged.

As a result, patients outside of the U.S. frequently gain access to innovation and technology before American patients do. In fact, Eucomed claims that European patients get innovative technologies 3 to 5 years earlier than the U.S. patient does. In fact, they even have a website called "Don't Lose The 3" as in the 3 years of therapeutic advantage that European patients have over Americans.

But things are improving. So passage of FDASIA in 2012 was a welcome update to our regulatory government, and MDUFA III should promote a more collaborative and effective pathway to approval.

This legislation, if fully implemented as intended, will be a real benefit for patients, innovation, and our economy. The FDA is working hard to collaborate with industry and is focusing now on practical priorities, including:

Improving efficiency in clinical trials;

Balancing the premarket and post-market process; and

Identifying ways to shorten the lag between product approval by the FDA and reimbursement approval by CMS and/or private payers.

Dynamic public-private solutions are also happening. Since 2011, LifeScience Alley has been working closely with CDRH Director Jeff Shuren to find a solution that would re-engage the agency and industry in a conversation of collaboration and cooperation.

As a result, we created the Medical Device Innovation Consortium, a public-private partnership that still has its roots in Minnesota but now includes a national consortium from industry and key members from government, including CMS and the NIH.

Through the MDIC, we are working to identify opportunities for technical collaboration in the pre-competitive space where industry and the FDA can work together to share knowledge and improve the regulatory environment.

Better analysis means constant improvement. As one of the few U.S. industries with a positive trade balance and an average wage of more than $70,000 annually, the medical device industry is a U.S. success story.

Regulation is vital. Smart regulation is even more vital. We look forward to working with the Committee to ensure that the U.S. regulatory environment represents the safest and smartest in the world.

And I thank you for the opportunity to be here today.

[The prepared statement of Mr. Mandle appears in the Submissions for the Record on page 101.]

Chairman Brady. Thank you, Mr. Mandle. Congratulations on your new title.

I thank the witnesses for your thoughts and insights today. A couple of thoughts. We had another disappointing GDP number today—some of it was weather-related; we hope it picks up next quarter—but it has been a disappointing recovery. We are all hopeful we can do better.

Regulation I think has dragged, helped drag down the economic recovery. What I have noticed, I come from a Chamber of Commerce background, so you create a local business climate. You help start small businesses, help them survive tough times. You recruit new industry. You create a business climate for growth.

There is always a natural tension between business and regulation. There should be a healthy tension. I have never seen it at the level we see today. It doesn't matter what size businesses, or where they are, regulation, aside from the economy, is the number one concern facing them as they try to expand and in some cases survive.

So today is about how we remove that drag on the economy and actually help our economy grow. A couple of questions.

Does anyone on the panel object to expanding cost-benefit analysis to independent agencies like the SEC, the FCC, and the Fed, as it is now applied to the Executive agencies? Does anyone have a—think that is a bad idea?

[No response.]

Does everyone believe in closing loopholes so that no agencies or regulations are exempt from an objective cost-benefit analysis if they are a major rule? Does anyone object to that principle?

[No response.]

Third question. And this is the one I need your insight on. How do we end agency bias? How do we, or at least mitigate it, and realize the thought that agencies develop regulations and then are tasked with determining whether their benefits outweigh their costs?

As you would imagine, the rare times it occurs, 3 out of every 1,000 new Federal regulations have gone through this objective analysis, 3 out of 1,000, when that occurs, oftentimes the agency, as you would imagine, decides their own regulation is in fact a good one. Not surprising.

So how do we create the transparency up front—and I think Dr. Graham you made the point that there are a number of quasi-regulatory decisions made early on that have a huge impact—how do we create transparency? How do we end agency bias? Is it requiring them to identify up front how they are going to measure this cost-benefit analysis? Invite public comments? So in an increasingly complex world some assume we have to have complex regulations; I assume we have to have more complex analysis up front.

So, Mr. Timmons, Let me start with you. Your ideas on how we mitigate or begin to address agency bias?

Mr. Timmons. Well I think several of the proposals that the other panelists made here today are vital to that. Specifically with regard to agencies, you referenced when you introduced me that I had experience working for a governor, and states are—well, the states that really want to see economic growth and economic development—are very focused on the things that make them competitive. And the regulatory environment is clearly one of them.

The governor that I worked for immediately seized the reins on the regulatory process through executive order and he demanded then, and required through executive order, a review of every single regulation. It was a retrospective review of whether the regulations were still relevant, and ordered a top-to-bottom review of their cost-benefit.

And in the process, Virginia ended up either amending or abolishing 75 percent of those regulations. That is not getting directly to your question, but one of the things that he did insist on—and it created, just very honestly it created a firestorm at the beginning when he insisted that—those that are regulated had a seat at the table to present their analysis, their experiences—because oftentimes the regulators, as well intentioned as they are and were in Virginia, did not have the real-world experience of how the, perhaps, either the intended or unintended consequences of a regulation might impact that business.

In the end, there was unanimous praise from all sectors—from folks on different sides of the philosophical divide—on that process and how effective it was. And I think it is a model for the rest of the country. I think that would be very helpful at the Federal level.

Chairman Brady. Thank you.

Dr. Greenstone, your thoughts?

Dr. Greenstone. Thank you for the opportunity.

I want to come back to the first question you asked. I think there are lots of—there are some opportunities for bringing the independent agencies under the same rules and requirements that the other agencies face.

I think that would probably have to be examined, though, on a case-by-case basis. I don't know that we want to be overlooking what the monetary policy is of the Federal Reserve. So I just want to put that note of caution out there. I think it probably should be considered on a case——

Chairman Brady. But on the regulatory function, you would not object to that. Obviously the Fed, as you know, has a pretty robust regulation agenda and has a major impact on our financial institutions. They have been given more power there.

I agree on the monetary side of that. On the regulatory side, though, I think the impact is fairly strong.

Dr. Greenstone. Yes. No, I think one could make a very strong case, actually, that what came out of Dodd-Frank should have been subject to IORA oversight, to be honest. And because it went in the Fed and supposedly in the Treasury, that didn't happen.

Chairman Brady. Got it.

Dr. Greenstone. And then, you know, I think, does anyone object to widespread cost-benefit analysis? You know, I think the

more cost-benefit analysis the better. We will be able to make better decisions. It will help our economy. And as you pointed out, it has been a disappointing recovery, and I think having a clear look at things in advance would help.

I think there is—the easiest opportunity to change things in a positive way is to change the culture of regulatory analysis. And that, as you highlighted, Mr. Chairman, right now almost all analysis of regulation comes from the people who are doing the regulations.

And, you know, I have a very high view of myself as a father and a husband, and occasionally my wife is able to cut through the noise in my head and highlight that maybe there is an alternative viewpoint.

And I just think history is very unkind to institutions that only engage in self-evaluation. And so how can that be done? As I outlined in my testimony, I think the easiest way to do it is to introduce a new player. And the CBO has been unbelievably effective at changing the quality of analysis that goes into budgeting, and I think it is just lying there as a slam dunk for regulatory analysis.

And it would make the agencies' analyses better, as well, knowing that they would face—their analyses would face scrutiny from a CBO-style organization.

Chairman Brady. Thank you, Doctor. I too hate those marital cost-benefit analyses. They never work out well for me.

[Laughter.]

And we are running out of time. Dr. Graham, or Mr. Mandle, thoughts on agency bias?

Dr. Graham. Just very quickly, OIRA had about 50 full-time equivalent staff when I served for Mitch Daniels in the Bush Administration. And it is now at 38. It has been in a steady erosion.

So if you want inside the Executive Branch a reasonable check on the agencies, we need to staff OIRA appropriately.

Chairman Brady. Got it. Good point. Thanks. Mr. Mandle.

Mr. Mandle. I would just add, through FDASIA in 2012, you know, we required much earlier connectivity with the agency. I think those interactions are important.

The one thing, you know, that I would urge the Committee to really work with regulators on is an analysis around what activities are actually value-added. So in our business, for example, the legal requirements are to make sure that medical devices are safe and effective. And certainly the regulation process, whether it is through submissions, or inspections, includes a lot of other activities that do not go to that value-add to American businesses and patients, which is, you know, fulfilling the legal responsibilities.

And so, you know, staying true to their legal responsibilities but also asking the question: Are we adding value to our economy, to patients, I think is an important question.

Chairman Brady. Great point. Thank you.

Former Chair Maloney.

Representative Maloney. Well I want to thank all of you for your very thoughtful testimony. And I think we can all agree that agencies should be able to reexamine and adapt policies to new developments and changing circumstances.

It strikes me that many of our most important regulations seek to prevent catastrophic events or crises, and evaluators may find it difficult to quantify the benefit of avoiding a disaster before it strikes. That is a lot of the movement that was in Dodd-Frank. That is a lot of the legislation that came out of the financial crisis.

For example, a report published last year by the Dallas Fed found that the 2007 and 2009 financial crisis cost our country nearly a year's worth of economic output, $14 trillion, up to $120,000 for every household in America.

And at this hearing, really, in our body here at the Joint Economic Committee, economists have testified that it was the first crisis that was totally preventable by better regulation of risky financial products.

Just in my home State, it is estimated that rebuilding after the devastation of Hurricane Sandy will cost our State alone $41 billion. We are implementing certain programs to try to get ready for the next Sandy—how do you evaluate that? Surely avoiding another financial crisis or an environmental crisis like Sandy is a great benefit to our country. But these benefits are very difficult to quantify, and how can we better account for these benefits of policy and regulation?

I will give you an example now, right before Congress. It is the Anti-Terrorism Risk Insurance. After Sandy—excuse me, after the financial crisis, no one would insure anyone in New York, Illinois, or L.A., or Washington. We had to go to Lloyd's of London to get insurance. It was very costly.

And then we developed a program to be ready for the next crisis, and to respond to it. We put it in place, and it has not cost this country one cent. But the program was in place and ready in the event, God forbid, we had another crisis.

There is still tremendous opposition to another Terrorism Risk Insurance Act (TRIA) program. So I would like to throw that out for anyone who would like to comment on it, because I think a lot of our thought process after a lot of Dodd-Frank was how do you prevent it in the future, how do you prevent and respond in the future? The Sandy regulations we are putting in place in New York City, maybe in other cities. So maybe we could start with Mr. Timmons, and anyone else who would like to make a comment. Mr. Greenstone.

Mr. Timmons. I am probably going to defer to some of my colleagues here that have studied this in more detail, but I think it is really important to note—and I think all of us have said this—not all regulation is bad. Not all regulation is—in fact, in most cases the intent of the regulation is good.

Eliminating all risk from everything that we do in American life is probably not an achievable objective if we want our economy to grow and we want to be able to maintain the quality of life that we have as Americans.

But trying to minimize risk certainly is a goal. And doing it in a way that is smart and, again, is transparent and puts all—put all options on the table from not only the regulators but the regulated, I think, is the goal that we seek to achieve.

Representative Maloney. I would also say that, in response to TRIA, the opposition to it, if this country is attacked again, if an

attack happens here in the Capital, the country is going to respond. The government will respond.

So it seems like, if we are going to respond anyway, we might as well put mechanisms in place that help us during an emergency.

My time is about to run out, and I want to throw out another question because I think it relates directly to what Mr. Greenstone and Mr. Graham and others were saying.

Earlier we had a program that was very debated called "Sunset," that every regulation after five years had to be reviewed. And it was basically a cost-benefit analysis. And I would like your response on Sunset, whether it worked, and if some agencies implemented and others did not, or if the better approach that Congresswoman Klobuchar and really Mr. Greenstone and Timmons have spoken in support of having a special office in CBO.

But how did Sunset work? Did Sunset work? That whole bill that every five years you've got to review every single regulation on whether or not it works? Any comment from anyone?

Dr. Graham. I am not aware that it ever passed at the Federal level. There are some states that have tried to do Sunset legislation.

One thing I want people to keep in mind is that a lot of the costs of regulation that are substantial are actually one-time capital costs early in the implementation period of regulation. This is particularly true in energy and in manufacturing.

And if you look after the fact at what the costs and benefits are and you find it is not a good idea, it is frankly oftentimes too late. It is very important to get the analysis done right, properly, up front. And that is why a lot of this emphasis on the transparency and peer review and quality of information, when the rule is adopted in the first place, is very important.

Representative Maloney. I think my time has expired.

Chairman Brady. Thank you, Madam Chair.

Senator Coats.

Senator Coats. Mr. Chairman, thank you. And thanks to all of you for the good information here.

It occurs to me there is a pretty good consensus among the four of you that cost-benefit analysis, retrospective reviews, perhaps a new division at CBO or a new involvement for an outside player, approval process, state and local coordination, alignment of standards on trade, that all that is, I probably could say, pretty much supported on a bipartisan basis, and pretty much a consensus, unless someone wants to say that should not be in there, or something else should be in there.

Of all those, I would think that the cost-benefit is most important because it is a metric that we need before we pass legislation, or before we deal with responding to regulatory proposals, to really be able to make the case.

I mean, does that rise to the top of priorities? Just a "yes" or "no." Would anybody think that there is something more important that we ought to focus on relative to the role of Congress in terms of dealing with either proposed rules or dealing with legislation?

Mr. Timmons. From our perspective, that is a very important objective.

Senator Coats. Secondly, I think there is probably a consensus that tax reform, regulatory reform, fiscal reform, including entitlement reform, are the three big issues for things Congress ought to deal with. And we are dealing with regulatory here.

I am struck by the fact that, while there is this consensus, while Chairman Brady and I and Members on the other side, pretty much have come to agreement on all of this, we introduced a lot of ideas. We talked about a lot of potential reforms. But we never seem to get to the final piece where it is actually enacted and put into place.

And that goes to the question, or to the matter that I think Mr. Greenstone raised about the need for a change of culture.

Dr. Graham in particular, based on your experience at IRA, I always get that acronym wrong, based on your past experience, what does it take to achieve that change of culture, that change of mindset?

Does it take legislation to force it? Is there something you can do through leadership of the particular agencies, or what comes out of the White House? It just seems that we keep talking about all these legislative proposals and ideas, but if even those are implemented would that force the change of culture? Or is the change of culture—is the culture so ingrained in the past, and not understanding and recognizing the negative impact of regulations, is that too hard to do?

Dr. Graham. Well it's a great question. The agencies—it's important to see the agencies as mission-oriented professionals trying to accomplish a certain objective. And some people might interpret that as bias, but they really do have a pretty kind of single-minded orientation, if you are at FDA, or EPA, et cetera.

So I think Dr. Greenstone's analysis of this is right at the heart of the cultural issue. Because you need to create a culture, a kind of a checkpoint about the value of the economy, and the value of cost-benefit, and so forth.

And historically we have tried to do that through OIRA and through the Council of Economic Advisors. But OMB's role over time has really diminished relative to the agencies, and this is well quantified by studies on staffing and so forth.

So I think his point that maybe you bring CBO in as a player, but the basic point is the culture—you need multiple cultures, cultures that clash a little bit with each other. That is not necessarily a bad idea to have these people with different missions and different orientations, and getting their information on the table.

So moving in that direction—which I think a lot of these bills that we are talking about do in modest ways, will lead to culture change.

Senator Coats. I would like to get other comments on that, perhaps for the record since my time is running down. I want to ask if Mr. Mandle suggests a tax policy ought to be incorporated in the cost-benefit analysis. Is there agreement with that? Or do you have some reservations of the other three here?

Dr. Greenstone. I'm not sure I completely understand the connection——

Senator Coats. Well——

Dr. Greenstone. I'm not sure I completely understood the connection between tax policy and regulatory policy, so I am reluctant to agree to something I don't understand.

Senator Coats. Okay. Mr. Mandle, just very quickly?

Mr. Mandle. Sure. No, my comment was simply that the regulatory environment itself also, from the Congressional perspective, you have to look at the entire ecosystem and those impacts on things like early stage investment.

So in our business specifically it is the combination of cost controls through the Affordable Care Act, the Medical Device Tax, the expanded costs of going through the regulatory process. And so, you know, if we are asking questions about how does all of this impact our economy and job growth? You know, it is a quite complicated process and we just think it is again important to, as you are looking at regulatory changes, to also know that for every action there is a reaction in both—tax policy, you know, is a piece of this puzzle.

Senator Coats. Well my time has expired. Mr. Chairman, thank you very much. I just hope that we seem to have a consensus here in terms of the direction that we ought to go, at least, and I just hope we can bring this home and put it into practice.

Chairman Brady. I agree.

Senator Coats. It will require bipartisanship, but it can be done because there does seem to be a consensus that it needs to be done.

Thank you, Mr. Chairman.

Chairman Brady. You are right, Senator.

Mr. Paulsen.

Representative Paulsen. Thank you, Mr. Chairman. I want to thank you for holding this hearing, because, part of the Joint Economic Committee's responsibility is to gather this type of input and make recommendations to our colleagues to take actions on some of these policies.

The regulatory environment and the red tape environment has definitely risen to the top of what I am hearing from my manufacturers, from small businesses, and from the medical device companies in Minnesota, for instance, in terms of how challenging it is.

I want to ask one question on the tax policy, because Senator Coats asked about that. The Medical Device Tax, which you just mentioned, Mr. Mandle, has been front and center as a high priority of mine, and Senator Klobuchar has been pushing that issue in the Senate to repeal that tax.

There have been some estimates that say maybe 25 percent of the tax might be paid out of a State like Minnesota where we have a big ecosystem, as you mentioned, in this area. We have the Medtronics and other large companies in Minnesota, but there are all these small companies that are directly impacted in particular too.

What are you seeing on the ground that we are not seeing or hearing about in the press, or in the media?

Mr. Mandle. I will be happy to answer that question. As you know, your Congressional District is the most densely concentrated medical device cluster in the world. You know, the medical device industry is different than pharmaceuticals and other industries.

Most of the companies, 80, 90 percent, have less than 50 employees. And, you know, it's really where a lot of innovation takes place that can have an impact on cost, as well as increase and deliver new therapies.

What we are seeing is a real challenge for those early stage companies. So there's the Medical Device Tax, there's an Excise Tax; it hits first sales. So in order to get a company started, and to get a medical device on the market, you are talking 3, 5, 7 years, $50-, $100-, $150 million. And as soon as you begin to sell to work toward profitability, you are paying the tax.

Probably the biggest impact on innovation that the Medical Device Tax is having is it is really drying up early stage investment. So you're an investor. Ten, twenty years ago you put your money in medical devices and it was a great return for investors, as well as great for patients.

Today, with the regulatory timetables being significantly longer, the cost of going through them being significantly longer, the tax hitting first sale, if you are an investor there are frankly in some ways better places to put your money.

So we do see growth in places like health IT software, a lot of the consumerization, I'll say, of health care. And it is really harming the next generation of medtech companies that frankly either won't get started, or won't survive this period of time.

Representative Paulsen. So just to follow up now on the regulatory side of that equation, you mentioned a lot of small companies get hit, and a lot of companies are developing not only traditional medical devices but also maybe creating medical software applications, for instance.

On the regulatory side of the equation, you've got the FDA classifying "devices," and so the tax may apply to software, for instance. Does it apply to software upgrades? And can you just talk a little bit about maybe what the regulatory environment has done in our ecosystem for companies that are looking for that venture capital startup? Are companies putting the FDA approval process, are they factoring that in to attracting venture capital as part of their business plan?

Mr. Mandle. Again, I'm happy to answer that question. Actually, we saw something change about three or four years ago. You know, at LifeScience Alley we work with entrepreneurs in medtech specifically. We see business plans all the time. Haven't seen a business plan that intends to take a product through the FDA process first in about three years now.

So if you have a business plan today that does not go to Europe first, your likelihood of getting that company or that business plan funded is I would say almost nonexistent.

Representative Paulsen. And Europe is bragging about getting products, your testimony said, three years earlier for their patients versus our patients, right?

Mr. Mandle. Correct. Yeah. Look up the website. It's called "Don't Lose The 3." So it's a marketing campaign in Europe.

Representative Paulsen. Senator Klobuchar mentioned the least-burdensome principle and some of the provisions in the User Fee legislation that we passed, Mr. Chairman, in both bodies and in law now. We need to follow through on it, and I will give some

compliments to Jeff Shuren who we continue to meet with on a quarterly basis to make sure we are tracking and benchmarking the law. We need to make sure that that cultural issue which we were just talking about is actually going to be moving forward, as well, so that we are not stifling growth and innovation in a very important industry.

Thank you, Mr. Chairman.

Chairman Brady. Thank you, Mr. Paulsen.

Senator Lee.

Senator Lee. Thanks so much for your testimony.

I appreciate having each of you here. Mr. Graham, why don't we start with you. One of the difficulties that we have here involves measuring regulatory costs, and doing so in a way that is understandable to Members of Congress, that Members of Congress can get behind.

So by way of analogy, in the budgeting context we have come up with a baseline. And so even though not every Member of Congress will necessarily agree with the baseline methodology that is used, it at least does give us some metric according to which we can kind of navigate our discussion.

Do you think that it would be possible for us to construct sort of a baseline definition set that would allow us to estimate the cost of a particular regulation, or the aggregate costs of all regulations in a particular year? And what do you think some of the uses of that might be, if we could do it?

Dr. Graham. There is a former colleague of mine at OMB, Dr. John Morrall, who has written extensively on the concept of a regulatory budget, which would be analogous to the appropriations process, but it is for costs that are imposed upon businesses and state and local governments that are not showing in the Federal budget.

His idea is that you would try to basically expect Congress to exert discipline in this process by setting limitations on maybe an annual, or every-other-year basis on how large these regulatory costs, or unfunded mandates, could be over time.

It is a complex business of trying to define those baselines. But your point is well taken. The budgetary baselines are pretty complicated to do.

So I think in principle it is possible to do. I think the avenue that I would like to see is that you do a pilot project of this on maybe a couple of agencies. You do that for a couple of years, and you see how it goes. And then if you are comfortable, then you could try to do that on a government-wide basis.

I think to try to just leap and do that on a government-wide basis, you know like through next year in legislation, I think that is a prescription for the UK's problem. The UK actually tried to do a government-wide regulatory budget, and after passing the legislation and trying to implement it, they just basically gave up.

So in a sense they tried too hard, and they didn't take off a modest amount that they could actually learn from.

Senator Lee. You think it might be better, for example, then to start with saying okay we're going to try to develop such a model in the context of EPA and FDA, or, you know, pick any two regulatory bodies?

Dr. Graham. Right. Pick a couple of big regulators and have them do that as a regulatory budget, and try it as a pilot for a couple of years. Yes.

Senator Lee. And you think that would be helpful to the economy to have Congress at least move in the direction of developing some kind of measure for aggregate regulatory compliance costs?

Dr. Graham. Yes. Because one way to think about this is Congress never actually deliberates and votes on the overall impact they are imposing on the business community and state and local governments every year.

Senator Lee. Right.

Dr. Graham. And I would argue that you should have some heat on you to have to actually deliberate on that and vote on that. And the regulatory budget is explicitly designed to induce that, but it is a complicated idea and it needs——

Senator Lee. It is deliberately designed to what?

Dr. Graham. It is deliberately designed to compel the legislature——

Senator Lee. Right.

Dr. Graham [continuing]. To assume the responsibility for saying this is how much regulatory burden we are willing to impose for the next year, or the next two years. So it requires that deliberation and those votes.

Senator Lee. Are you familiar with the REINS Act? The REINS Act is a bill that has been introduced. It has been passed by the House for the last two or three years in a row. It has been introduced in the Senate, but we have not had occasion to vote on it. It stands for Regulations from the Executive in Need of Scrutiny.

It says basically that for any new major rule to take effect—"major rule" as defined by OMB with an aggregate economic impact of $100 million or more—that it would need to be passed affirmatively into law. It would need to pass the House and the Senate and be signed into law by the President.

This is an approach that would put Congress, as I see it, back in charge of actually making the law. In other words, what you described as a problem in which you've got Executive Branch agencies run by men and women who are well educated, very well intentioned, and very hard working and knowledgeable within their subject field matter areas, and very skilled, are not elected by the people and are therefore not accountable to the people as Members of Congress are.

But if you had those major rules act as sort of proposals, and proposals that could not take effect, could not bind the general public unless or until they were enacted into law by Congress, then you would have Congress do the legislating. Do you think this would help address some of the problem you have described?

Dr. Graham. What I would do is couple that idea with Dr. Greenstone's Congressional Budget Office regulatory analysis branch, because I think Congress would need fairly indepth assessment of each of these rules from an independent body.

So my suggestion would be: Start with Dr. Greenstone's idea. Get the CBO regulatory analysis branch up and running and have it issue reports on legislation and regulation. And then take the step—I think jumping right to the REINS Act, and then have Con-

gress vote on all these rules, I think that is too—I think it is not realistic. Because you don't have the evidence and analytic base to be deliberating on this level of specificity that we have in each of these regulations that we've talked about in the testimony. I think we are a ways from that.

Senator Lee. Although arguably that is part of the problem, though, isn't it?

Dr. Graham. It is part of the problem, but we need to build the culture and the capability to get Congress involved in a meaningful way on a regulation by regulation basis. That is a big change from where we are now.

Senator Lee. Yes.

Dr. Graham. And we're not anywhere close to having the evidence and analytical infrastructure in the Congress to do that.

Senator Lee. I think Mr. Greenstone wants——

Dr. Greenstone. Yes, if I could just—you know, I am just going to underscore what Dr. Graham was saying. I think the first-order problem in regulatory policy is the almost near complete opacity on what the impacts both on the cost side and also on the benefits side are. And the fact that we do not have like a reliable set of information about that means people can say anything, and anything could be true or not true, and there is no basis to judge what is false and what is true.

And so I think any regulatory reform that is going to be successful is going to have to seed that environment with information that would allow all of you to make judgments. I mean, right now I don't think, candidly, there is the information for all of you to make judgments on a lot of the regulation.

Senator Lee. Right, right. Although I—and I understand the point you are both making. I would add to that, though, that in the meantime we are subjecting the American economy to an estimated $2 trillion, nearly $2 trillion in annual regulatory compliance costs.

So by doing nothing, we continue through our own past delegation of authority, recklessly broad delegation of authority I might add, we are subjecting the American people to a lot of laws that are basically legislated without any elected official being involved in it.

Dr. Graham. The European Parliament feels the same way. They feel that in Brussels the European Commission is imposing an enormous burden throughout the European economy, and where did they start, the European Parliament? They started by creating the analytic capacity, impact assessment unit, to actually independently analyze what the European Commission was giving them.

Okay? And if we don't have that step, the rest is not going to be smooth.

Senator Lee. I want to remain in good standing with our Chairman. Thank you very much.

Chairman Brady. You are. Thank you, Senator. I think your point that the regulatory horse is now out of the barn and we chase it with poorly designed unworkable regulations means we just fruitlessly chase it. And is there a better way at the outset? I think that is very key.

We are very mindful and respectful of our witnesses and Members. Thank you for being here today. You have given us great insight. I wish every Member of Congress could hear the ideas you have outlined, because there is a frustration and there is a need to act. You have been very helpful in building momentum for action in a bipartisan way on smart regulation.

So again, thank you for being here today, to all our witnesses. The hearing is adjourned.

(Whereupon, at 11:15 a.m., Wednesday, April 30, 2014, the hearing was adjourned.)

SUBMISSIONS FOR THE RECORD

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

Too often congressional hearings are given titles that merely attract attention. But I believe the title for today's Joint Economic Committee hearing accurately describes what our witnesses are here to talk about and what we should take to heart, namely that the first step toward reducing red tape and achieving regulatory goals is better analysis.

Every Member of Congress recognizes the economic justification and constitutional authority under the Commerce Clause in Article I, Section 8 of the U.S. Constitution for balanced Federal regulation to protect public health and safety, preserve our environment, and prevent fraud of all kinds. At the same time, many Members of Congress also recognize that federal regulation has become overly burdensome and costly to job creators and the economy alike. Some regulations, regrettably, are even counterproductive.

As the volume of federal regulation has grown, regulation has done less to advance its stated goals and imposed ever more costs. These costs include slower economic growth, higher uncertainty that inhibits business investment and job creation, foregone product and process innovations, a lessening in the international competitiveness of American businesses, and stagnant incomes for hardworking American families. Unnecessarily burdensome regulation also aggravates our country's long-term fiscal imbalance by inhibiting the natural growth of federal revenues under existing tax law.

Consider the following facts:

- In 2013, the federal government issued 3,659 final rules contained on 26,417 pages, a record number in the Federal Register. Including proposed rules, the Federal Register finished 2013 with 79,311 pages.
- Four of the five highest regulatory page counts have occurred during President Obama's administration; the all-time record being 81,405 pages in 2010.
- Mr. Wayne Crews, the author of Ten Thousand Commandments: An Annual Snapshot of the Federal Regulatory State, estimates the overall annual cost of regulatory compliance to be $1.9 trillion, about equal to the economy of Australia, Canada, or Italy.
- Mr. Crews estimates that U.S. households face an annual hidden regulatory "tax" of $14,974.
- In last year's draft report to Congress on the benefits and costs of federal regulation, the Office of Management and Budget (OMB) stated that executive agencies and independent regulatory agencies promulgated a combined total of 68 major rules during 2012, (each of which have an impact of $100 million or more). Alarmingly, OMB presented a cost-benefit analysis for a miniscule 14 of them.
- Looking longer term, during the decade ending in 2012, federal agencies published 37,786 final regulatory rules—with OMB presenting cost-benefit analysis for only 115 regulations. That is 3/10 of one percent—meaning only three in every 1,000 regulations were subject to a complete analysis of their effects on the U.S. economy, job creators and families. For a nation seeking a smarter, more efficient government, that is just shameful.

America's regulatory system should be designed to achieve the greatest good at the least cost. Both Republicans and Democrats should be able to agree on that principle.

Smart, effective regulations should seek to reduce rates of illness, mortality and pollution—but not by reducing economic growth, job creation, and the incomes of hardworking American families out of neglect or disregard.

Safety and security must not come at the cost of stagnation, unemployment and lower incomes that rob from the middle class. Yes, there will be tradeoffs, but too often our federal regulatory system pursues singular objectives blind to the unintended consequences of its methods—and indeed often does not even focus on realizing the intended results.

We need a better way to sift through regulations both proposed and existing; transparently identify their true costs; and find the least costly, least intrusive way to achieve the goals on which we all agree.

We cannot do that without better analysis.

My colleague, Senator Dan Coats, and I have introduced the Sound Regulation Act to improve the regulatory process through better analysis.

The Sound Regulation Act would:

- Expand accurate cost-benefit analysis to all federal regulatory agencies—beyond executive branch agencies to independent agencies as well—and close loopholes

that allow some federal agencies to skirt the requirement for objective economic analysis.

- End agency bias and establish more public transparency by requiring agencies to clearly identify the nature and significance of the market failure or other problem that necessitates regulatory action; establish an achievable objective for regulatory action; and publish for public comment in advance the method and process for objectively weighing the costs and benefits of the proposed regulation;
- Encourage more innovative solutions by requiring the development and evaluation of the costs and benefits of at least three regulatory options ranked by cost from lowest to highest;
- Justify the choice of any option that is not the least cost method of achieving its regulatory objective; and;
- Review existing regulations on a timely basis to determine the success and costs of the regulation in the real world.

The Sound Regulatory Act would not dictate solutions or how to achieve them; instead, it would provide a better framework for rule-making by federal regulators so that regulations work more effectively and at less cost to the American economy. I believe that all Members of Congress in both chambers and both parties can ascribe to this goal.

With that, I look forward to the testimony to today's witnesses.

Joint Economic Committee
Republicans Representative Kevin Brady
Chairman

THE NEED FOR ECONOMIC ANALYSIS IN FEDERAL REGULATION

April 30, 2014

FAR TOO LITTLE ECONOMIC ANALYSIS IN RULEMAKING. Federal regulatory agencies rarely conduct complete and thorough economic analyses of the things they set out to regulate, the rules they write, and the actual effects their rules have once implemented. Only about a quarter of "major" rules, principally those with an impact of $100 million in a given year, and less than half a percent of the more than 3,500 rules in total that federal agencies issue each year are analyzed for their costs and benefits. Moreover, it is common for agencies to perform an analysis only after they have decided what the rules should be and then to understate their costs and overstate their benefits. Once in effect, agencies generally do not analyze the actual economic effects of their rules in the real world.

FEDERAL OFFICIALS CLAIM TO KNOW BEST. Federal regulation is based heavily on the presumption that regulators know when and how to intervene in a market and that the rules they promulgate are in the "public interest." But while markets may not perform perfectly, neither does the government. In reality, federal officials face basic problems in prescribing outcomes that are better overall than develop in the marketplace:

SYSTEMIC PROBLEMS OF GOVERNMENT REGULATION

- ***Principal-agent problem***: Divergent interests between voters (principals) and officials (agents) lead to policies that may not reflect public preferences.
- ***Asymmetric information***: Federal agencies, the political parties, and special interest groups interact to make policy based on information that may not be available and considerations that may not be transparent to the public.
- ***Incomplete information***: A central authority cannot fully capture, process, or replicate the new information that markets continually generate.
- ***Rent-seeking***: Special interest groups seek favorable regulation from government at the public's expense and waste resources in the process.
- ***Organizational problems***: Bureaucratic inefficiency and inertia impose administrative costs and delay, and jurisdictional divisions cause overlap, frictions, or leave gaps in regulation.
- ***Monopoly power***. When government officials supplant market outcomes with mandates, they limit choice, competition, adaptability, experimentation, technological development, and the standards for comparison of their performance.

CHOOSING EFFICIENT RULES REQUIRES ANALYSIS. Given the problems of the administrative state, the presumption is unwarranted that federal officials have superior knowledge, motivation, and skills to produce the best outcomes without as much as analyzing the costs and benefits of alternative approaches. Agencies have many different approaches to choose from, and even a partial list suggests it is impossible to know the best one for a given set of circumstances without comparative analysis:

- Improve existing rules rather than issue new ones;
- Better define property and market trading rights;
- Impose fees in place of mandates;
- Improve information dissemination;
- Set performance standards and let the regulated decide how to meet them;
- Prescribe product design and production methods;
- Prohibit production and/or consumption.

Regulatory agencies do not report to Congress as a matter of standard practice on the efficiency of their regulatory regimes or when statutory language may hinder adoption of the most efficient approach to achieve a statutory objective. They should be required not only to conduct comparative analyses and report their findings but also to make recommendations for saving costs to the congressional committees of jurisdiction so that Congress can consider accommodating changes in the law.

UNBOUNDED SOCIAL REGULATION. Economic regulation of price and output had become visibly counterproductive by the 1970s and was pared back in the Carter and Reagan administrations, but social regulation has since ballooned. Social regulation as practiced, such as by the Environmental Protection Agency, Occupational Safety and Health Administration, Consumer Product Safety Commission, and the Consumer Financial Protection Bureau, has no limiting conceptual framework; it can be activated by any condition that is deemed unsatisfactory in some respect and the claim of a "market failure." Without objective determination of the tradeoffs involved and full consideration of alternative responses, agencies can proceed to impose requirements they simply declare to be in the "public interest." But, agencies engaged in social regulation especially tend, among other things, to:

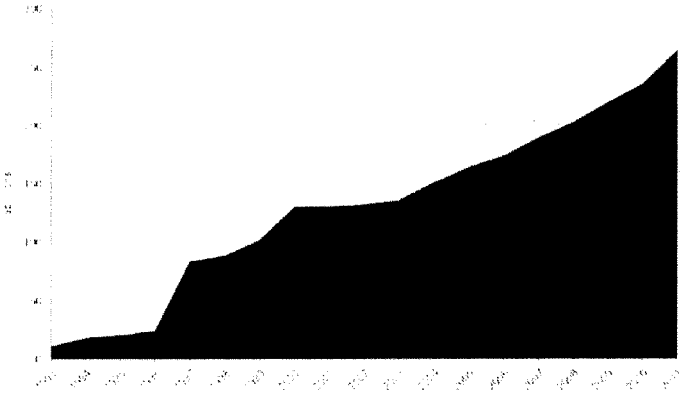
- ignore the government's own policies as the source of problems;
- confuse social problems with ill-defined property and market trading rights;
- target private choices in addition to public benefits; and
- ignore their rules' costs in terms of job losses, higher retail prices, impaired international competitiveness of U.S. firms, and limiting the choices of consumers.

GOOD AND BAD REGULATION. The best kind of regulation improves the market's functioning so that people and businesses can make their own decisions and focus on productive achievement rather than on regulatory compliance or influencing the rulemaking process. The more prescriptive regulation becomes the more discretion it gives to regulators, the more it tends to multiply, the more uncertainty it creates, and the more likely it is to produce unintended consequences and unnecessary costs. Problems with prescriptive regulation—agency capture by the regulated and government looking to make political trades with its rulemaking—long have been recognized by economists, for example, by Nobel

laureate George J. Stigler in "The Theory of Economic Regulation" (1971) and Gordon Tullock in "The Economics of Special Privilege and Rent Seeking" (1989). To protect the public interest, regulation should be stable and generally applicable with rules that are set in advance, known to everyone, and not frequently or arbitrarily changed.

RISING COSTS FROM REGULATION. A summation of the costs agencies themselves had initially calculated for only a portion of the rules currently in place shows the aggregate cost rising dramatically.

Figure 1: Cumulative Costs of Regulations 1993 to 2011 (Billions of Constant 2010 Dollars)



Source: NERA analysis for MAPI. *Macroeconomic Impacts of Federal Regulation of the Manufacturing Sector, August 21, 2012.*

NERA Economic Consulting estimates the direct cost of compliance with federal regulations was between $265 and $726 billion in 2011. Figure 1 shows the lower bound of the range over time. Other regulatory cost estimates are far higher; for example, one by Clyde Wayne Crews, Jr. of the Competitive Enterprise Institute in "Ten Thousand Commandments" (2014) places the cost at $1.863 trillion. NERA finds that from 1998 through the end of 2011, the cumulative inflation adjusted cost of compliance with major regulations grew by an annualized rate of 8.8 percent, compared with a GDP growth rate of 2.2 percent and physical manufacturing output growth rate of 0.4 percent. U.S. firms' international competitiveness also is impaired by the surge in regulation, which reduces American exports.

EXECUTIVE ORDERS ARE NOT ENOUGH. Ever since President Reagan institutionalized cost-benefit analysis in federal rulemaking via executive order, every administration has endorsed it. But the directives in the executive orders (a) have omitted independent regulatory agencies such as the Security Exchange Commission and the Federal Reserve, (b) are enforced based on an administration's preferences, and (c) are not legally binding. The Office of Information and Regulatory Affairs (OIRA) has developed elaborate instructions for regulatory cost-benefit analysis, but in practice they are not applied to the vast majority of rulemakings or the huge volume of existing regulations. (The Code of Federal Regulations had 174,545 pages at the end of 2012.)

MORE PROCEDURAL MEASURES ARE NOT THE ANSWER. There already exist many procedural steps for federal rulemakings (see the "Reg Map" on the OIRA website), but agencies manage to navigate the legal and procedural patchwork of requirements for rulemaking without basing their rules on comprehensive analysis. The need for analysis by objective standards of markets, regulatory options, and existing regulations' actual effects, however, is heightened by the fact that many difficult tradeoffs have not been settled by statute and increase the role of unelected regulatory officials in policymaking for health care, banking, energy, the environment, and more. The ill effects of inadequate regulatory analysis then also can include contributing to gridlock in litigation after an agency has adopted a rule.

NO VALID OBJECTION TO COST-BENEFIT ANALYSIS. Objections to cost-benefit analysis essentially come down to the difficulties of monetizing certain costs and benefits and making decisions by objectively measurable criteria. But no one questions the need for public accountability with respect to federal spending. A federal budget and appropriations process have been created to provide such accountability. Regulation can induce transfers, move resources, and cause economic gains or losses as has been recognized long ago, for example, by Richard A. Posner in "Taxation by Regulation" (1971). Those affected deserve to know the likely extent. Researchers outside the government analyze the costs and effects of government regulations and special government commissions at times are formed for that purpose; it seems obvious that those who make the rules in the first place should do so as a matter of standard practice.

CONCLUSION. Federal agencies need to do more than declare a market failure, prescribe the outcomes they envision and pronounce their prescriptions to be in the "public interest." The agencies need to explain the tradeoffs of their pursuits within a coherent analytical framework, and how they can achieve their objectives at minimum cost. The public interest is advanced by the most cost effective means to achieve an objective, and regulators cannot presume to know what they are without analyzing them. Economic analysis can help to develop market process enhancements—such as by introducing property and trading rights where none exist or improving information flow—that are more efficient and stable than proliferating mandates and prohibitions. In the social realm especially, where objective data can be difficult to obtain, regulation should be least strident and restrained from extending boundlessly.

At a Joint Economic Committee hearing entitled "Reducing Unnecessary and Costly Red Tape through Smarter Regulation," on June 26, 2013, there was bipartisan agreement among the witnesses that: (1) legislation is needed to make cost-benefit analysis a legally binding requirement applicable to all federal agencies; (2) regulatory reviews are needed so corrections can be made to rules that are not working as intended; and (3) independent oversight of agencies is needed to cut down on overlaps in regulation and hold rulemaking to common, objective standards.*

* The witnesses were professor Susan Dudley, Director, Regulatory Studies Center, George Washington University; Dr. Michael Greenstone, Director, Hamilton Project and 3M Professor of Economics, MIT; Dr. Jerry Ellig, senior research fellow, Mercatus Center, George Mason University; and Dr. Robert Kieval, Executive Vice President and Chief Technology Officer CVRx, Inc.

Joint Economic Committee
Republicans Representative Kevin Brady
Chairman

THE NEED FOR ECONOMIC ANALYSIS IN FEDERAL REGULATION

Objective Analysis can lessen the Costs of Regulations
April 30, 2014

INTRODUCTION[1]

Are federal regulatory agencies providing the public good value? Are regulations accomplishing their purpose? Might there be ways to regulate more effectively and at lower cost? Notwithstanding the fact that—for the last quarter century—executive orders have required executive agencies to base rulemakings with significant effects on cost-benefit analyses and recommend them for independent regulatory agencies, federal regulators rarely perform analyses that answer these questions. Of the more than 3,500 regulations issued in a typical year, only a tiny fraction—less than half a percent[2]—is analyzed for the costs and benefits. And, when agencies do analyses, stakeholders often consider them perfunctory and meaningless or contrived and biased.

Federal regulatory agencies in general do not credibly analyze the effectiveness and costs of their regulations.

Why is this? To choose the best course of action, one must consider the costs and benefits of the alternatives. Regulations obviously can vary in effectiveness and give rise to differential costs, direct and indirect, which cannot be fully understood much less minimized without analysis. Why are federal regulators not consistently conducting such analysis? The answer may reside in a set of beliefs endemic to the federal government: that there are limits to the functions markets can or should perform; that federal officials know those limits; and that beyond those limits, problem-solving is the province of these officials.

No one in government would claim that federal agencies should not observe good management practices; hence the formal directives to assess costs and benefits remain in place. When federal officials deem market solutions inadequate, however, officials want the power to implement their own. Under the observance of elaborate rulemaking procedures, federal agencies then promulgate rules that by their judgment are in the "public interest," a claim that all agencies make with respect to all of their rules.

Federal officials claim to generate greater public benefits with their prescriptions than markets can but do not necessarily feel the need to prove it.

[1] Table of Contents provided on page 37.
[2] "Federal Regulation: The Costs of Benefits," Wayne Crews, *Forbes*, January 7, 2013.

From an agency perspective, cost-benefit analysis serves no real purpose other than to validate its judgment and show how large the benefits are of its rules.

Federal regulation commands economic resources and demands accountability the same as federal spending.

From the public's perspective, however, objective analysis is essential to establish the extent to which regulations indeed are serving public interests. No one questions the need for public accountability with respect to federal spending; and a federal budget and appropriations process have been created to provide such accountability. Regulation can induce transfers, move resources, and cause economic gains or losses just the same,[3] and those affected deserve to know the likely extent. Given the absence of a budget for regulatory costs imposed on the economy, federal agencies should account for the economic consequences of their actions. Furthermore, good judgment requires an understanding of quantitative effects. No responsible business or household makes decisions that have important economic consequences without financial analysis, even when there are considerations that cannot be precisely valued. The federal government is not omniscient. Transparent analysis by generally accepted methods is necessary to assure appropriate diligence by federal regulators to maximize the chances for successful outcomes.

Governments do not inherently know the optimal division of market and agency functions.

The lines are drawn differently in different countries, over time, and even by different parts of the same government.

The efficient division of private and governmental functions is not self-evident; and government officials do not know inherently what it is. Outside the United States during most of the 20th century, it was commonplace to provide telecommunication, television, radio and postal services through government-owned national monopolies called Postal, Telephone & Telegraph Administrations (PTTs), but in recent decades many countries have been privatizing these services. In the United States, private firms used to provide telecommunication and broadcast services in federally segmented markets under varying forms of regulation. Prior to 1982, the Federal Communications Commission (FCC) had been regulating the national telephone company, AT&T, as a public utility on the premise that its Bell System was as a "natural" monopoly, then the Justice Department broke it up into eight separate companies. The U.S. Post Office always has been and remains a federal agency.

The public interest is not government's only motivation. Bureaucratic and special interests also influence it, and the electorate often is disconnected from what federal officials decide.

Last, the idealized view of government presumes it is motivated purely by the public interest, but bureaucratic and special private interests also shape government actions. The civil service relies on firmly structured, seniority-based personnel policies that can have the unintended effect of deemphasizing merit. Private sector employment and compensation practices that help to align employee with ownership interests (*e.g.*,

[3] See, for example, "Taxation by Regulation," Richard A. Posner, *Bell Journal of Economics and Management Science*, 1971.

commissions, stock options) do not lend themselves readily to the government sector. The voting public is relatively unfamiliar with the details of most of what government does, and referendums in any event are rare. The effect on government decisions of an individual vote is infinitesimal, whereas the cost of acquiring subject matter knowledge can be large. Hence, interest groups form around particular issues to exert influence on government officials.

In reality, the government's performance is impaired by principal-agent and asymmetric information problems, and once the government controls a market function it generally faces little competition to discipline its performance.

Therefore, one cannot take on faith that agencies make rules in the public interest, nor can one rely exclusively on procedural measures, of which there are plenty, to assure that they will. Objective analysis and data are necessary to provide credible justifications for the form and scope of government intervention into the economy and people's lives.

Procedural measures alone cannot produce good regulations. Objective analysis is needed.

GOVERNMENT IMPERFECTIONS AND MARKET IMPERFECTIONS

Government imperfections. Vehicle fuel regulations, for example, reflect the faith placed in federal officials to determine how best to reduce dependence on foreign crude oil and lower harmful emissions, but their decisions lack comprehensive analysis and are largely uncoordinated.

Ethanol—Refiners are required to blend ethanol into the gasoline supply in amounts that increase each year, and even the permissible types of ethanol feedstock are prescribed to them. However, the fuel mandates have collided with reality. Beyond certain concentrations, ethanol may damage pipelines, storage tanks, and engines intended for petroleum products and invalidate manufacturers' warrantees. There also are state laws that limit concentrations of ethanol in gasoline to 10 percent.[4] Further, cellulosic ethanol, as opposed to corn ethanol, is not available in the quantities refiners are mandated to use.[5]

Federal vehicle fuel policy exemplifies disjointed regulatory requirements that are not based on comprehensive analysis yet are claimed to be in the public interest.

[4] Ten percent is widely regarded as the "blend wall" for ethanol based on state regulations limiting its concentration in gasoline and the technical concerns of automobile manufacturers, fuel distributers, and filling station operators.

[5] Transportation fuel producers and importers may purchase or use renewable fuel credits banked in prior years, but as their inventory dwindles the credits' price rises raising fuel cost and eventually forcing reductions in the quantity of fuel produced (see, "Economic Impacts Resulting from Implementation of RFS2 Program," NERA Economic Consulting, October 2012). The Environmental Protection Agency (EPA) has authority to adjust the mandated fuel volumes; its administration of the Renewable Fuel Standards (RFS) program has been contentious, however. See, "The Ethanol Tax," and "Put a Corn Cob in Your Tank," *The Wall Street Journal*, July 20 and August 17, 2013. For 2014, the EPA has proposed to lower the ethanol mandates for the first time.

Electric cars—The Obama administration has a preference for electric cars and has promised one million of them on the road by 2015.[6] The administration decided to continue production of GM's electric car, the Volt, when reorganizing the company in bankruptcy and offers financial incentives both to produce and purchase electric cars. Yet it is far from clear that putting more electricity-powered vehicles on the road is the best way to protect the environment. From a lifecycle perspective, electric vehicles generate nowhere near zero emissions as is often suggested.[7]

There are alternative vehicle and fuel technologies with the potential to reduce oil import dependency and harmful emissions.

Natural gas—In recent years, large domestic natural gas reserves have become accessible through breakthrough drilling technology and greatly enhanced the potential of natural gas as a motor fuel that is cleaner than gasoline or diesel. Electric-powered vehicles produce no less greenhouse gas emissions than natural gas-powered vehicles. But electric vehicles receive much larger subsidies through income tax credits than do vehicles that run on compressed natural gas, and the Federal Renewable Fuel Standard as outlined in the *Energy Independence and Security Act of 2007* does nothing to encourage the use of natural gas. Natural gas is not a renewable fuel, but its use would clearly advance the mission of the Act, which is to promote energy independence and clean fuel sources.[8]

The federal government has made its choices without comprehensive analysis, even though the costs of implementation obviously are very large.

Clean diesel—In Europe, more than half the cars on the road have diesel engines and many run on what is considered "clean" diesel (which generally is *not* biodiesel) for reasons of fuel economy and lower emissions—an option whose costs and merits the federal government has not presented to the American public.

The Obama administration insists on its energy choices despite encountering practical obstacles and growing evidence that there are better alternatives.

The Obama administration pursues its energy preferences unmoved by the promise of natural gas as a fuel, and unimpressed by the fact that declines in both U.S. oil imports and emissions have less to do with its energy policies than advances in oil and gas drilling. Vehicles running on increasing concentrations of ethanol, electricity, or natural gas, need very different fueling infrastructures from each other and from what is in place for gasoline- and diesel-powered vehicles, but there is no indication that the infrastructure costs of any, much less varying combinations of them

[6] Why one million is not clear. The government has not shown what the optimal market share is for battery powered cars. As an aside, they actually outnumbered cars with combustion engines for a time in the early 20th century.

[7] See, "Green Cars Have a Dirty Little Secret," Bjorn Lomborg, *Wall Street Journal*, March 11, 2013.

[8] MIT professor and former chief economist of President Obama's CEA, Michael Greenstone, gave testimony entitled "The True Costs of Alternative Energy Sources: Are we Unfairly Penalizing Natural Gas?" at a U.S. Congress, Joint Economic Committee Hearing on April 26, 2012 as director of the Brookings Institution's Hamilton Project.

have been fully analyzed and entered into federal government policy choices. Meanwhile, producers of the various fuels and types of cars compete to influence the government to further their own interests whereas the public has had no direct say in what their government mandates or subsidizes.

The problems described are not new or unusual. Government efforts to drive technological, economic, and social developments often are characterized by limited understanding of how markets work, ignorance of—if not disregard for—consumer preferences, and failure to produce a *net* benefit. These are among the reasons why centrally planned economies tend to stagnate at relatively low levels of economic performance and why only a few of them are left.

Federal regulation is reminiscent of centrally planned economies that supplant market activity, operate inefficiently, and are not in tune with public preferences.

The problems with government decision-making and its lack of adaptability when assumptions prove wrong or circumstances change fall into distinct categories that represent ever-present challenges to efficient and publicly beneficial government actions:

1. **The agency problem**. Divergence of interests between voters (principals) and political representatives (agents) lead to policies that do not accurately reflect public preferences.
2. **Information problems**.
    a. **Asymmetric information**. Federal agencies, the political parties, and special interest groups have an information advantage over the voting public.
    b. **Incomplete information**. A central authority cannot fully capture, process, or replicate information in kind and volume that markets continually generate.
3. **Rent-seeking**. Special interest groups seek favors from activist government, which come at the public's expense and create economic waste.
4. **Organizational costs**.
    a. **Diseconomies of scale**. Large organizations slow decision-making, inhibiting flexibility and adaptability.[9]
    b. **Intra-governmental problems**. Different branches and levels of government can give rise to overlap, frictions, or

The challenges that face private endeavors also face the government:

- ***Representing the interests of stakeholders,***
- ***Acting on the best information,***
- ***Maximizing efficiency,***
- ***Using power judiciously.***

[9] Economics Nobel laureate George J. Stigler illustrated this general problem well: "[A]nyone who watches a line of automobiles start forward as a traffic light changes will be impressed by how each additional driver starts a little later than his predecessor, so it takes considerable time for the motion to be committed to the twentieth car, even when all the drivers can see the light change." *The Theory of Price*, 3rd edition, 1966, Macmillan Publishing Co., Inc., p. 156.

gaps among them if policy development and execution are not properly assigned and coordinated.

5. **Monopoly power**. Government can supplant competition and with it experimentation, choices, instructive comparisons, and disciplining of its performance, leaving the public to rely on government monitoring itself.

Market imperfections. A market-based price system continually signals information to buyers and sellers, and competition motivates them to discover and seize opportunities. Competition also drives the dissemination of superior solutions. The U.S. market economy has a remarkable record of long-term economic growth and technological progress that lift American living standards. Based on that record, it has become an article of faith that the economy will continue to grow and advance technologically. A basic assumption by the Office of Management and Budget (OMB) and the Congressional Budget Office (CBO) in their analyses of federal budgets and programs is the steady increase in potential and actual GDP over time, and this assumption is generally shared by macroeconomists. However, when a particular condition is unsatisfactory, the government invokes the fact that real world markets do not function exactly as depicted in textbook models with their abstractions of optimal self-organization, perfect competition, zero transactions cost, and perfect knowledge by all participants. The common types of market failure invoked are:

The market system produces advancements that transcend many problems. Federal agencies, on the one hand, take this for granted, but on the other, invoke market imperfections whenever they want to impose their own will.

1. **Monopoly power**. The term "natural monopoly" describes the exclusive control of an important natural resource for which there is no close substitute and economies of scale that exceed the size of a market, effectively limiting the number of suppliers to one. However, monopolies usually persist because the government grants them exclusive rights.[10]

2. **Public goods and externalities**. A "public good" confers benefits that cannot be effectively apportioned for sale. Because it is possible to consume them for free, public goods that exist in nature are at risk of being depleted, and public goods that require production are supplied in smaller quantities than their value would justify. Externalities are similar but may be either positive or negative (leading to under- or overproduction). They also represent costs or benefits that are not paid for, because they are not readily apportioned for sale. However, in many cases the government could help to establish tradable property rights if it chose to.

[10] For a discussion of the topic see, for example, "The Myth of Natural Monopoly," Thomas J. DiLorenzo, *The Review of Austrian Economics*, Vol.. 9, No. 2 (1996): 43-58.

3. **Asymmetric information**. Some parties may have an inherent information advantage that favors them in market transactions. For example, car dealers have an information advantage over car buyers. So-called lemon laws that confer the right to return malfunctioning vehicles for a refund aim to offset this advantage. However, the market only fails if honest merchants cannot gain a reputation advantage over dishonest ones.

4. **Behavioral anomalies**. Good market outcomes depend on the participants behaving rationally—making choices in their own best interest with the information they have. Market outcomes may not be optimal otherwise. However, in a complex world it is difficult to discern what considerations and practices are reasonable for making choices and what methods would yield consistently better results. The government is not all-knowing and also behaves in anomalous ways; it is taking a drastic step when it claims that people do not know what is good for them and denies them choices.

5. **Income redistribution**. Markets are concerned with efficiency but also affect income distribution. Much government intervention concerns income redistribution, whereby regulation does so much less transparently than taxation and transfer payments.

Imperfect regulation applied to imperfect markets. Rules should improve a process with little distortion, dislocation, or drag.[11] Unfortunately, most of the rules in the steadily expanding Code of Federal Regulations, which had 174,545 pages in 2012, are not the product of efforts to improve market mechanisms but to prescribe specific methods and solutions. The costs of the former are mainly in administration, enforcement, and compliance whereas the latter can substantially widen the scope of costs.[12] Federal agencies nevertheless tend to take a narrow view of regulatory costs because they claim to prescribe outcomes that markets would produce on their own if they were working properly. For example, the government justifies imposing mandates to reduce pollution on the claim that market transactions do not account for pollution's costs. Jobs lost or consumer choices that disappear, among other negative fallout, are not costs of regulation in this view because they would not exist but for the market's failure to function "correctly." Federal officials presume they are acting in the public interest and claim huge social welfare gains for their regulations, failing to acknowledge the flaws in

Federal agencies impose rules without much regard for how the market system works.

[11] All rules affect the nature of what they regulate to some extent, which is why rule changes in sports, for example, may be hotly debated.
[12] For further discussion of the distinction between rules that facilitate a process and prescriptive rules, see "Designing and Evaluating Regulation," page 20.

their regulations that arise from the challenges facing the administrative state—the *government* imperfections enumerated above—and the costs that are associated with them.[13]

ECONOMIC AND SOCIAL REGULATION

Failures of economic regulation. The federal government's prescriptions may not be at all what a competitive, efficiently functioning market would adopt and very well may create inefficiency and obstacles to economic growth. Until the late 1970s, so-called economic regulation of price and output by federal agencies dedicated to particular industries were the predominant form of regulation. It is based on claims of correcting various competitive malfunctions, principally constraining monopoly power thought to be held by firms (as opposed to professional groups or unions) that antitrust measures cannot solve. The classic reason for economic regulation is "natural monopoly," although it assumes that the fundamental technology stands still. Known as "utility" or "common carrier" regulation, it usually entails "universal service" and uniform pricing requirements that institute transfers through cross-subsidies from lower to higher cost customers.[14] The subsidies are said to serve a public goal, such as affordable telephone service for high-cost locations and low-income groups.

Government regulation of price and output often serves industry at the expense of consumers.

Such regulation goes hand-in-hand with government protection of incumbent firms from "cream skimmers," competitors that sell only in the low cost market segments at less than average prices. But regulators also prize order and stability for their own sake and disfavor potential market entrants for the disruptions they cause, whether or not they are cream skimmers. Hence, incumbent firms may actually prefer to be regulated. The government may justify its regulation of industry based on alleged competitive problems and support for disadvantaged or needy groups, but in fact, it supports prices by artificially stabilizing market shares. Regulators find it difficult to monitor costs and prevent incumbent firms from earning above-normal profits, and worst of all, they tend to entrench prevailing practices and slow innovation.

The economics profession has developed explanations of how government regulation may be "captured" by industry. Nobel laureate George Stigler

[13] See, "OMB's Reported Benefits of Regulation: Too Good to Be True?," Susan E. Dudley, Regulation, Summer 2013, pp.26-30. OMB reported annual ranges of $193 billion to $800 billion in benefits and only $57 billion to $84 billion in costs (2001 dollars) for major federal regulations it reviewed from October 1, 2002, to September 30, 2012, that had agency estimated monetized costs and benefits, "2013 Draft Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act," p. 3.

[14] See, "Taxation by Regulation," Richard A. Posner, *Bell Journal of Economics and Management Science*, 1971.

showed how interest groups advance their own goals by enlisting the government's "power to coerce" in *The Theory of Economic Regulation.*[15] The government responds to the demand for regulation by interest groups in exchange for their political support. The value to special interest groups of favorable regulatory treatment, in particular, is that it is durable. Regulators provide the public interest interpretation of their rules, while the practical workings of regulations obscure the true beneficiaries and costs.[16] The costs of regulation often are widely dispersed, which, even when recognized, makes it difficult for political opposition with the necessary counterweight to form against well-organized interest groups (known as the "problem of concentrated benefits and diffused costs").

The economic theory of regulation and public choice theory suggest that federal agencies may not choose the most efficient method to accomplish a goal and may produce regulatory failures.

The public choice branch of economics studies government motivation and behavior. Public choice economics points out that politicians and government employees are people, who like everyone else, have their own interests. One ought not to assume they are uniquely motivated to understand and solve problems and set aside their own interests.[17] Public choice economics also stresses that the effort by interest groups to shape regulation for their benefit—so-called rent-seeking—is a pure waste of economic resources.[18]

Leading members of both political parties have accused different agencies of regulatory capture on various occasions. While it proclaims confidence in the power of federal regulation to correct market failures,[19] the Obama administration has blamed the last financial crisis on the capture of oversight agencies by banking interests and the Macondo well drilling accident on the capture of the Minerals Management Service (MMS)[20] by oil companies.

Reduction in economic regulation. In the 1970s when productivity increases were abysmally small, the economy stagnated, and the true costs of regulation became apparent, the Carter administration began to

Starting with the Carter and continuing with the Reagan administration, the inefficiencies of economic regulation led to critical review and deregulation.

[15] *The Bell Journal of Economics and Management Science*, Vol. 2, No. 1, (Spring, 1971). Also see, Sam Peltzman, "Toward a More General Theory of Regulation," *Journal of Law & Economics*, 1976.
[16] See also, Bruce Yandle, "Bootleggers and Baptists: The Education of a Regulatory Economist," *Regulation*, 1983. Baptists favor Sunday bans on alcohol for moral reasons, regulators find such bans easy to administer, and bootleggers welcome them for blocking legal competition.
[17] See, "Public Choice: Politics Without Romance," by Nobel laureate James M. Buchanan, *Policy*, The Centre for Independent Studies, Spring 2003.
[18] See, *The Economics of Special Privilege and Rent Seeking*, by Gordon Tullock, Kluver Academic Publishers, 1989, pp. 55, 56.
[19] See, for example, "Improving the Quality of Life through Smart Regulation, Innovation, Clean Energy and Public Investment," *Economic Report of the President*, Chapter 8, 2012.
[20] MMS has been renamed the Bureau of Ocean Energy Management, Regulation, and Enforcement (BOEMRE).

deregulate various industries. The Reagan administration continued and broadened deregulation. Regulations were no longer justified on the mere presence of a market imperfection but put to the test of whether they actually made things better. Economists from outside the government provided regulatory analyses and recommendations, and even reformed or abolished entire agencies.[21] The Justice Department ended AT&T's national telephone monopoly in 1982.

President Reagan, by Executive Order, institutionalized federal regulatory cost-benefit analysis. Every President since him has endorsed it.

The Reagan administration institutionalized cost-benefit analysis in rulemaking by Executive Order, meaning that executive agencies had to analyze the different approaches to a problem systematically and demonstrate that the one they selected (a) was the most cost effective among the alternatives, and (b) produced benefits greater than costs. President Reagan also charged OMB with regulatory agency oversight. These requirements for rulemakings are so eminently sensible that every President since Reagan has officially endorsed them.

Booming social regulation. In the 1970s, the federal government began to focus on quality-of-life concerns and created mission-specific agencies with economy-wide responsibilities, the Environmental Protection Agency (EPA), Consumer Product Safety Commission (CPSC), the Occupational Safety and Health Administration (OSHA), and recently the Consumer Financial Protection Bureau (CFPB). The public interest theory seems to

Social regulation has long been expanding at an accelerated pace and become, by far, the predominant form of regulation. The federal government has no limiting conceptual framework for it.

Figure 1: Annual Budgetary Costs of Federal Regulation, Adjusted for Inflation

Source: "Fiscal Stalemate Reflected in Regulators' Budget: An Analysis of the U.S. Budget for Fiscal Years 2011 and 2012," by Susan Dudley and Melinda Warren, 2012 Annual Report, May 11, 2011, Weidenbaum Center, Washington University and the Regulatory Studies Center, the George Washington University.

[21] Alfred Kahn at the National Aeronautics Board and Darius Gaskins at the Interstate Commerce Commission.

fit this so-called social regulation better. Even when markets are competitive, externalities and incomplete information in particular can play a role in social problems. The public may show greater sensitivity to air and water quality, for example, than to the details of airline or telephone regulation, and different industries have to compete for regulatory influence with cross-cutting regulatory agencies offsetting each other's efforts to some extent. However, there remain ample grounds for caution in adopting the public interest theory for social regulation. The federal government has not adopted a conceptual framework for declaring social problems or limits to what it might prescribe—what washing machines or cars people may buy; what light bulbs to use, etc. The list is potentially endless. Social regulation has long been expanding at an accelerated pace and become, by far, the predominant form of regulation (see Figure 1). If the government can override any private choice it does not like, it becomes a threat to personal freedom.

For social regulation, the government invokes mostly market externalities, information problems, and private behaviors for which it can find no rational explanation, inferring that market participants are not acting in their own best interest. On these grounds, it prescribes methods and outcomes that it deems to be in the "public interest," meaning supposedly better than what existed before it intervened and with little regard for the creativity of the private sector to overcome problems by itself. The mindset that government knows best is particularly pronounced in the social realm and leads to misdiagnoses of the causes of market malfunctions and even misinterpretation of what is and is not a malfunction. Common problems with the premises and justifications government invokes for social regulation include the following:

In the social realm especially the federal government professes to know best.

Focusing on externalities and ignoring tradeoffs. Everyone wants to be safer, healthier, and enjoy a cleaner environment, but these are not the public's only concerns; there are tradeoffs to be decided. This is a fundamental problem with social regulation. Pollution and other health risks associated with work and consumption, for example, generally are not the deliberate or avoidable result of pure neglect but the byproduct of the processes and products that raise our material standard of living. The tradeoff between environmental controls and economic growth is on display in many countries right now. China's national leadership has spoken openly of the economy-versus-environment tradeoff, acknowledging that it "must appease an increasingly pollution-conscious public without undermining economic growth."[22] China's government has the power to force reductions in pollution by cutting back industrial

Some other countries openly acknowledge the tradeoffs between social and economic goals.

[22] "China Clean-Air Bid Faces Resistance," Brian Spegele and Wayne Ma, *The Wall Street Journal,* January 23, 2013, p. A16.

production as it did during the Beijing Olympics, but afterward it allowed industrial production and the attendant pollution to resume for economic reasons. Arguing for the primacy of economic concerns, the Environment Minister of Poland, Marcin Korolec, last year said that higher carbon emissions permit prices (Europe has a cap-and-trade system) would make electricity more expensive and threaten his country's economy.[23] It may not be clear what the right price is for carbon emissions in Europe, but it is clear to the Polish Environment Minister that industry is not the enemy of his people.

In the centrally planned economies of the former eastern bloc countries, pollution was far worse than in the West. This held true even within the same country, the divided East and West Germany. There was no profit motive or externalities to blame in the East because the communist governments had nationalized industry. The governments there made a choice between economic growth and environmental quality and presumed to know what was best. They chose to tout their industrial accomplishments to the population while revealing little about environmental damage and health consequences.

Federal agencies place social goals above economic growth and avoid acknowledging the tradeoff.

Federal regulatory agencies tend to do the opposite, they make a risk assessment, a determination of what is safe in terms of air and water quality or the use of machinery, vehicles, child car seats, toys—their reach knows no limit—and ignore the value of "substandard" products. They attribute product features or production processes that fall short of their standards to failures on the part of the marketplace, not to failures in the way they set their standards—a phenomenon known as the "planner's paradox."[24]

Free markets settle on tradeoffs among many risks, costs, and many rewards that incorporate consumer preferences. Market imperfections may affect tradeoffs in which case the government might present to the public what incremental sacrifice it would take to reduce a risk and let the public decide; but government officials should not presume to know what the public prefers and should not presume that the public would always choose less risk.

Market externalities, such as may be associated with pollution, can cause suboptimal resource allocation but invoking them as a blanket justification for government agencies to impose their standards suppresses a key part of the issue. There are tradeoffs to be decided and the question is how to do that. While policymakers and administrators who make choices for the public may believe in their superior understanding of a problem and prefer

[23] "Europe's Emissions Plan Hits Turbulence," *Wall Street Journal*, February 20, 2013.
[24] "The Planner's Paradox," Brian Mannix, *Regulation*, Summer 2003, p. 9.

not to have their judgment questioned, they have not validated their claim of acting in the public interest unless they demonstrate the quality of their choices and the effectiveness of their regulations once implemented with comprehensive, transparent analysis.

Ignoring problems arising from government policies. For example, well-meaning government protections and guarantees may cause people to take more risk, which may prompt still more government intervention, when a better response would be less intervention. The housing market collapse and financial crisis in 2008, at least in part, resulted from socially motivated government supports and guarantees that increased private risk-taking. The government has identified the problem as deficient market oversight and responded with thousands of pages of laws and regulations that leave many unconvinced the true problems have been solved.[25] Government policies have unwanted consequences because they affect incentives in unanticipated ways. People, businesses, and markets are not passive entities for the government to mold as it envisions. Minimizing unintended consequences in rulemaking, therefore, requires careful study as much of the reactions existing rules have produced as of the reactions new rules under consideration may produce.

Regulation can have unintended consequences. Before they impose new rules, it behooves agencies to rescind the ones that are not working as intended.

Confusing social problems with ill-defined property rights. Nonexistent or ill-defined private property rights lead to problems that are viewed as "social," but that could be fixable without social regulation. For example, problems of overuse such as overfishing or overgrazing can occur because the scarce resource in question—a body of water, a parcel of land—is not owned by private parties with a sufficient individual economic interest and/or legal authority to manage it. Sought-after game may be hunted to extinction because there are no owners motivated to protect and authorized to sell it. The fewer there are of a species, the higher its value may be, yet its price is zero. In such cases, the government may be able to establish property rights and terms for trading them to create a functional market mechanism rather than declare a "market failure" and take over. There is no market failure with respect to domesticated livestock.[26] Accordingly, as part of rulemakings regulators should provide an analysis of property and trading rights that discusses the options for improvements in place of imposing prescriptive rules.

Some "social" problems could be solved with better definitions of property and market trading rights.

[25]See, for example, *Bad History, Worse Policy: How a False Narrative about the Financial Crisis Led to the Dodd-Frank Act*, by Peter J. Wallison, The American Institute for Public Policy Research, Washington, D.C., 2013, and "Stopping Bank Crises Before They Start," John H. Cochrane, *Wall Street Journal*, June 23, 2013.

[26] See, for example, "Treat Elephants like Cattle," Doug Bandow, *Providence Journal*, March 8, 2013, and *Free Market Environmentalism*, Revised Edition, Terry L. Anderson and Donald R. Leal, Palgrave, 2001.

Information is a scarce and costly commodity for government and private entities alike. Federal agencies should not presume to command a lasting informational advantage over the private sector.

Claiming to have information markets lack. Good decisions depend on good information, but good information is scarce and costly. Economics textbooks abstract from this reality to focus on the mechanics of market forces, but that does not mean a market malfunctions when this reality introduces itself. Market participants generally become cognizant of information problems and find ways to address them through the structure of payments, offers of contractual guarantees and restitution, investment in a reputation for honesty and reliability, and a whole host of other methods. It may be easy to disparage consumers' or businesses' choices after the fact when more information has become available, as in Monday morning quarterbacking, but the government is no fountain of knowledge nor does it receive relevant information easily and freely. Indeed, federal agencies are dependent on the private sector for most of the information they use in rulemaking. In any case, rather than impose the outcomes it believes would prevail if market participants had more information, government can provide more information if it is able, or require more information to be generated and distributed among the market participants, letting them decide how to use it.

When federal agencies justify their actions by claiming to provide private benefits in addition to public benefits, they position themselves to regulate anything.

Claiming to bestow private benefits in addition to public benefits. The choices that people and businesses make for themselves may be puzzling to observers who do not have to live with all the consequences and may have different perspectives. For instance, timesaving conveniences play a large role in people's decisions that are difficult to explain otherwise and that government observers may not appreciate. A prime example of government jumping to the conclusion that market participants fail to act in their own best interest is the so-called energy-conservation gap, which refers to energy cost savings people and even businesses supposedly pass up if left to their own devices. The federal government imposes energy standards on manufacturers of home appliances and light bulbs, for example, which raise purchase prices and preclude production of some products customers would prefer to buy. The federal government's justification rests not on public savings, but on the lower private usage costs it ascribes to the standards, which supposedly outweigh higher purchase prices in present value terms by its calculation. The standards cannot be justified based on costs or benefits to the public.[27] The government's contention that it is better able to weigh all the considerations relevant to private decision-making than those who have to live with the consequences of a decision is highly dubious and opens the door to government invading any private decision, even when it does not concern the public welfare.

[27] "Overriding Consumer Preferences with Energy Regulations," Ted Gayer and W. Kip Viscusi, *Journal of Regulatory Economics*, June 2013, Vol. 23, Issue 3, pp. 248-264.

Supporting regulations with claimed incidental benefits. Regulators increasingly have been attributing supposed incidental benefits to rules that will not cover their cost based on achieving their express purpose. This is a misleading practice by which the public may get the wrong impression of the costs of achieving different purposes, the reasons for imposing a rule, and the authority by which an agency does so. The EPA's Mercury and Air Toxics Standard (MATS) and its National Ambient Air Quality Standards (NAAQS) are examples. The express purpose of MATS is to limit mercury and other toxic emissions into the air by power plants pursuant to Section 112 of the Clean Air Act (CAA), but toxic emission reductions account for less than one ten-thousandths of the monetized benefit EPA estimated for the rule; nearly all the monetized benefit derives from reducing fine particle emissions.[28] The EPA sets NAAQS pursuant to Sections 108 and 109 of the CAA, and its standard for fine particle emissions at the time was above the level it gave MATS credit for. The EPA used its authority under one section of the CAA to pursue the purpose of other sections, counted as a benefit surpassing a standard it deemed safe, and adopted a new objective it had not justified. EPA subsequently lowered the fine particle standard by 20 percent and presented a cost-benefit analysis that assumes power plants are compliant with MATS. So the costs attributed to reducing the standard for fine particle emissions do not include the cost of MATS, one of the most expensive rules ever issued.[29] EPA should have compared the cost of MATS only with the benefits that derive from the rule in terms of reducing mercury and air toxics emissions and should have shown the full cost of reducing its fine particle standard by 20 percent. Sections 108, 109, and 112 of the CAA direct EPA not to consider costs in rulemaking, so the results of its cost-benefit analyses would not require it to change the rules, but analyses that show the true causality of costs and benefits might motivate lawmakers to adjust the statutes. Rules have legitimacy only to the extent they serve a statutorily authorized purpose. Agencies that invoke incidental benefits to justify a rule have failed to fully specify its purpose and statutory authorization, and may have an alternative agenda. Stating unambiguous objectives supported by statute and measuring progress toward them should be a central function of regulation.

When federal agencies justify a rule by invoking incidental benefits, they have failed to fully specify its purpose and statutory authorization, and they may have an alternative agenda.

[28] See, Prepared Statement of Susan E. Dudley, Hearing on "Review of Mercury Pollution's Impacts to Public Health and the Environment," before the Committee on Environment and Public Works Subcommittee on Clean Air and Nuclear Safety, U.S. Senate, April 17, 2012; "Perpetuating Puffery: An Analysis of the Composition of OMB's Reported Benefits of Regulation," Susan E. Dudley, *Business Economics*, July 2012, vol.47, no. 3; "Technical Comments on the Regulatory Impact Analysis Supporting EPA's Proposed Rule for Utility MACT and Revised NSPS (76 FR 24976)," Anne E. Smith, NERA Economic Consulting, August 3, 2011.

[29] The analysis does not include the benefits from MATS either, but EPA played a kind of shell game with the costs and inflated the benefits; see, "The EPA's Implausible Return on its Fine Particle Standard," Susan E. Dudley, *Regulation*, Spring 2013, pp. 3-4.

Ignoring costs beyond compliance and enforcement. There are important reasons why federal regulatory agencies should consider all the costs of their actions. First, regulators acting in the public interest have a duty to minimize the adverse effects of their actions, and they obviously cannot minimize costs they do not consider.

Second, the public has a right to know not only what the objectives are that regulators aim for, but also what is likely to occur relative to existing conditions as a result of their actions. If a rule's implementation has adverse incidental effects, such as on present employment, prices, or product availability, then it is incumbent upon regulators to limit them as best they can and inform the public of adverse effects they cannot avoid. Susan E. Dudley, former administrator of the Office of Information and Regulatory Affairs (OIRA), testified with respect to the MATS rule that

Regulatory agencies should consider all the costs of their actions.

> *EPA quantifies or lists every conceivable good thing that it might attribute to a decision to set new emission limits, while on the cost side, it only considers the most obvious direct and intended costs of complying with the regulation. Thus it dismisses risks associated with reduced electricity reliability, the competitiveness of the U.S. economy in international trade, or the effect that higher electricity prices will have on the family budget.*[30]

It is grossly misleading for the EPA to present a cost-benefit analysis in support of its rule and leave out these costs.

Third, among the greatest costs regulation can impose are slowing the economy down and obstructing technological progress. Hence, federal regulators should justify their proposed regulation relative to a baseline that recognizes the economy's growth potential and the market potential for innovative solutions, convincing the public with its analysis that the proposed regulation will enhance positive market developments and not hinder them.

HOW GOVERNMENT CHOOSES ITS METHODS

Many options. The following list of a dozen approaches, from which many more combinations and modifications can be derived, demonstrates the need for analysis to make good policy choices. Depending on the context, any one of the approaches could be appropriate.

1. Investigate existing government policies for the source of the problem and modify rules, change the regulatory regime, or deregulate.
2. Defer to state and local authorities to regulate or tax (federalist approach).

[30] Ibid, p.5.

3. Allow advancing technology or economic growth to solve a problem (Executive Order 12866, September 30, 1993, explicitly includes "the alternative of not regulating.")
4. Focus on property rights and allow or encourage liability rules and litigation to resolve damage claims ("The Problem of Social Cost," Ronald H. Coase, *The Journal of Law and Economics*, October 1960).
5. Impose a fee or tax (A. C. Pigou, *The Economics of Welfare*, 4th ed., London, 1932).
6. Compensate parties adversely affected by externalities or subsidize their relocation.
7. Require dissemination of important information by certain market participants to facilitate efficient market transactions or generate such information through government research (*Nudge*, Richard H. Thaler and Cass Sunstein, 2008).
8. Utilize behavioral policies to address inefficient biases in people's decision-making ("choice architecture," *Nudge*).[31]
9. Set performance standards that leave the methods for achieving them to producers and permit averaging as with CAFE rules (command-and-control, "light").
10. Prescribe design standards, quality, or quantity of production (command-and-control "severe").
11. Impose price controls (ceilings or floors).
12. Outlaw production/consumption (Prohibition).

When considering a market intervention the federal government and its agencies have many options to choose from.

Government may not choose efficient methods. From a public interest perspective, the government should choose the most efficient approach to achieve an objective and that would require economic analysis. But the economic theory of regulation and public choice theory suggest that government officials may prefer approaches that create private costs and benefits tradable for political support, position them to negotiate, claim credit for benefits, and avoid blame for unwelcomed consequences. Following are two examples.

Examples from radio spectrum allocation and environmental protection illustrate the federal government's deviation from transparent objectives and efficient methods in its regulation.

Frequency spectrum allocation. In "Assigning Property Rights to Radio Spectrum Users: Why Did The FCC License Auctions Take 67 Years?"[32] Thomas W. Hazlett explains why the Federal Communications Commission (FCC) conducted comparative hearings to assign licenses for frequency use to broadcasters free of charge. Similar to land, the frequency spectrum is a valuable natural resource that the government more recently has been auctioning for a total of $50 billion in revenue so

[31] Such as default rules for retirement accounts that employees must decide to opt out of rather than opt into. See, "A Dozen Nudges," chapter 16 in *Nudge, Improving Decisions about Health, Wealth, and Happiness*, by Thaler and Sunstein, Peguin Books, 2009.
[32] *The Journal of Law and Economics*, vol. XLI (2), (PT. 2), October 1998.

far to the Treasury.[33] The hearings held by the FCC to compare license applicants and select those most likely to serve the "public interest" were an extremely inefficient method of allocating and managing the spectrum. The administrative assignment of spectrum use rights sacrificed public revenue and constituted highly valuable grants to private entities whose relative merit for the most part could not be established by any meaningful, objective criteria. The administrative method gave rise to rent seeking costs and paperwork burdens, thwarted incentives to conserve frequency use and innovate, and led to artificial spectrum shortages.

It took the FCC 67 years to introduce radio spectrum license auctions because awarding licenses based on comparative hearings conferred political power.

The FCC had argued that the "public trusteeship" of the frequency spectrum made it improper to sell frequencies (it is selling use rights now), and interference would become rampant if transmissions were turned over to market forces. But long ago, economics Nobel laureate Ronald Coase and others refuted these arguments.[34] The real reasons for the hearings that created artificial rents and made their distribution discretionary were the government's desire to control broadcast content without violating the First Amendment's "freedom of the press" clause and keeping broadcasters beholden to political interests with the threat of revoking their highly valuable licenses.[35]

Environmental protection. The social regulatory agencies created in the 1970s, from the outset to the present day, choose options that are among the most interventionist and aimed principally at industry, requiring manufacturers to use specific emission control devices and setting limits on industrial discharges that they have tightened progressively (#10 on the list of options above). In practice, when faced with the unattainability of their standards, federal agencies engage in a process of negotiation with industry and reach compromises. The federal government exercises much discretion in terms of the pressure it exerts and the methods it uses when negotiating. It can, on the one hand, publicly vilify the regulated, threaten to litigate, withhold operating permits, the list goes on; or, on the other, waive, suspend, defer, or loosen requirements, and this list goes on as well. Public interest theory might suggest that government imposes restrictions

[33] "The Broadband Engine of Economic Growth," Julius Genachowski, FCC chairman, *The Wall Street Journal*, March 6, 2013.
[34] Ronald H. Coase, "The Federal Communications Commission." *Journal of Law and Economics* 2 (1959): 1-40; "Evaluation of Public Policy Relating to Radio and Television Broadcasting: Social and Economic Issues," *Land Economics* 41 (1965): 161-67; "Concepts of the Broadcast Media under the First Amendment: A Reevaluation and a Proposal," Note, *New York University Law Review* 47 (April 1972): 83-109; "Law and Economics at Chicago," *Journal of Law and Economics* 36 (April 1993): 239-54.
[35] When cellular license applications reached volumes that were administratively unmanageable, the FCC first employed lotteries rather than auctions to award them, avoiding introduction of a revenue source that could be extended to the politically more sensitive broadcast license awards. Federal budgetary pressure eventually overcame the political resistance to spectrum auctions.

on polluters directly because that will reduce pollution the fastest, surest way possible. Command-and-control intervention, indeed, can produce substantial results when first applied to unattended problems; however, progressive application yields decreasing incremental benefits, and unwanted consequences become more difficult to avoid. Continually increasing or tightening restrictions is subject to a fundamental limitation known as the "law of diminishing returns." Economist Gary Vaughn writing for the Manufacturers Alliance/MAPI in 2006 had put it very well:

> *When the U.S. Environmental Protection Agency (EPA) was created more than 36 years ago, the first regulations could aim at large, obvious problems—yielding large benefits at relatively modest costs. The environmental challenges that remain in 2006 pose smaller targets that are far more difficult and costly to hit.*[36]

Over decades, command-and-control has remained the method of choice for environmental regulators who continue to tighten their requirements.

Diminishing returns increase costs disproportionately to the improvements achieved. Regulatory standards have been tightened long after the initial phase when direct measures may have had speed and clear improvements to recommend them. In 2013, 43 years after the EPA was created, the agency still is tightening emission standards and piling on more requirements. Now the gains may be infinitesimal and require augmenting with "co-benefits" (see page 15).

Regulating this way allows government to make political trades and blame industry for unwelcomed consequences.

When regulating this way, federal officials position the regulated to take the blame for unwelcomed consequences, such as price increases, loss of familiar product choices, or layoffs—actions by utilities, manufacturers and other businesses that may result from regulation, but that federal regulators do not expressly order. Federal regulators claim they are improving industry performance but do not publicize the unfavorable effects their regulations cause down the line. However, doing so is critical to an understanding of regulatory tradeoffs and ultimately to attaining better results overall.

In sum, the policies that would best serve the public interest are not self-revealing; to identify them, their full ramifications must be analyzed. Whether or not they are deliberately chosen and used as such, regulations can be a vehicle for pursuing nonpublic objectives and for political manipulation. Absent objective analysis, misuse, inefficiency, and unintended consequences of regulations imposed on the economy may be kept from public view for a long time.

[36] "Regulatory Sleight of Hand: How the EPA's Cost-Benefit Analyses Promote More Regulation and Burden Manufacturers," Economic Report, Garrett A. Vaughn, April 2006, Manufacturers Alliance/MAPI, p.1.

DESIGNING AND EVALUATING REGULATION

Good rules help a process function efficiently; they do not direct the allocation of resources or dictate specific solutions.

What is good regulation? F. A. Hayek made a distinction that is helpful in thinking about rulemaking. The distinction is between what he called the "Rule of Law" or "formal" rules that set conditions for the use of resources and "substantive" rules by which government directs resources to particular uses. Hayek explained:

> *The difference between the two kinds of rules is the same as that between laying down a Rule of the Road, as in the Highway Code, and ordering people where to go; or better still, between providing signposts and commanding people which road to take.*[37]

Participants in a process generally prefer rules that allow them to focus on achievement rather than compliance.

Good rules make a process work better. Good rules bring an order to useful activity that facilitates it and does not interfere with its purpose. Rather than perceive them as an intrusion, participants in a process generally welcome rules that allow them to focus their energy on substantive achievement rather than on what the rules mean and how to manipulate them. For instance, everyone realizes that traffic rules are necessary and enhance individuals' ability to drive anywhere in relative safety. In Hayek's words, rules of this kind "could almost be described as an instrument of production, helping people to predict the behavior of those with whom they must collaborate, rather than as efforts toward the satisfaction of particular needs."[38] To function this way, formal rules should be set in advance, made known to everyone, apply to everyone, and not changed frequently or arbitrarily. One can think of formal rules as "rules of the game" made clear at the outset to all players, applicable to all players, and not changeable midgame or midseason. In the context of public choice theory, good regulation is a stable, generally applicable structure that minimizes attempts at manipulation by special interests. Even assuming the best of intentions, regulation becomes problematic when it engages government in detailed decision-making. Says Hayek:

Generally applicable, stable rules minimize regulatory manipulation, whereas specific rules that require regulators to exercise discretion invite it.

> *When the government has to decide how many pigs are to be raised or how many busses are to be run, which coal mines are to operate, or what price shoes are to be sold, these decisions cannot be deducted from formal principles or settled for long periods of time. They depend inevitably on the circumstances of the moment, and, in making such decisions, it will always be necessary to balance one against the other the interests of various persons and groups. In the end somebody's views will have to decide whose interests are more important ... .*[39]

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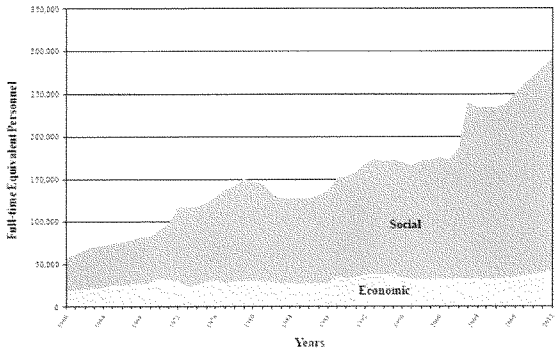
[37] *The Road to Serfdom*, F.A. Hayek, edited by Bruce Caldwell, The University of Chicago Press, 2007, p.113.
[38] Ibid.
[39] Ibid.

As regulators intrude further into the workings of the marketplace, they increasingly must make situation-specific decisions based on arcane information. Economist James W. McKie long ago aptly observed:

> *Extension of control in response to perpetually escaping effects of earlier regulation may be called the "tar-baby effect," since it usually enmeshes the regulatory authority in a control effort of increasing complexity with little gain in efficiency but a growing feeling of frustration.*[40]

Figure 2: Staffing of Federal Regulatory Agencies



Source: "Fiscal Stalemate Reflected in Regulators' Budget: An Analysis of the U.S. Budget for Fiscal Years 2011 and 2012," by Susan Dudley and Melinda Warren, 2012 Annual Report, May 11, 2011, Weidenbaum Center, Washington University and the Regulatory Studies Center, the George Washington University.

Situation-specific rules are prone to grow in number and complexity, increase the cost of compliance and enforcement, and are likely to produce unintended consequences.

Thicker rulebooks require more personnel for administration and enforcement (Figure 2), and, of course, for compliance by the regulated. Agencies resort to temporary provisions and discretionary waivers to accommodate rulemaking delays and unforeseen events. The resulting regulatory uncertainty *encourages* lobbying and "rent-seeking."[41]

In the pursuit of the specific visions and political rewards, government is drawn to order the economy where to go. But, the market-preemptive approach to social goals is a recipe for unintended consequences and progressive entanglements. Stable rules that leave the market room to

[40] "Regulation and the free Market: The Problem of Boundaries," James W. McKie, *Bell Journal of Economics and Management Science*, vol. 1, no. 1 (Spring, 1970), p. 9.
[41] A recent case of an EPA exemption from the ethanol mandates illustrates the problem; see "Washington's Latest Special Favor," "Behind an Ethanol Special Favor," both by Kimberly A. Strassel, and "No Special EPA Refinery Favor Here," letter to the editor, Janet McCabe, EPA, Washington, *The Wall Street Journal*, August 8, 14, and 26, 2013.

adapt to new circumstances require more thought and analysis, but ultimately will cost less and serve the public better.

Regulators view the profit motive as incompatible with social goals, but profit drives technological progress and economic growth that benefit society.

The profit motive. The public interest theory blames unwelcomed social outcomes on the profit motive; it presumes a basic tension between good social outcomes and selfish motives. Vigorous active competition and strong legal limitations must constrain self-interest from doing harm in this view. Consequently, market-based approaches to regulation can be viewed with suspicion as they do not counteract the profit motive directly. This perspective is problematic in several ways.

First, the profit motive in a competitive market system is the force that generates economic growth and technological advancement, which in turn lift material living standards far above those of economies operated without it. This advancement also leads to less pollution, safer products, and better working conditions—the very objects of social regulation. Pollution in the centrally managed economies of communist countries was higher than in the West partially because their economic growth was slower than the West's profit-driven market economies.

Astute entrepreneurs will purposefully deliver social benefits if it is possible to make a profit—they need not capture all the benefits. Others will experience competitive pressure to follow suit.

Second, there is a misperception that the mere presence of externalities or "public good" attributes cause markets to underperform or fail. But markets will directly address social needs, if it is possible to make a profit. Some companies invest in superior product safety (Volvo), environmental friendliness of their products (Toyota's Prius),[42] special employee benefits (Google), or a socially responsible supply chain (Starbucks) and tout the benefits to consumers and job applicants to the extent it pays off. Less astute firms face the loss of market share, the best workers, and profit if they do not keep up.[43] When private enterprise finds it difficult to capture enough of a public benefit to recover its costs and make a profit, the government should try to make it easier rather than mandate specific actions or investments.

Third, the profit motive does not just go away when government blocks or mandates a particular outcome. A basic fallacy of command-and-control regulation is that it thwarts the profit motive. Industry reacts when faced with a government constraint, and the reaction is driven by the profit motive. The profit motive is like a river that the government can channel to an extent but cannot stop from flowing. Regulation that ignores incentives does so at its own peril, because randomly redirected incentives may cause greater harm, including possibly defeating the very purpose of

[42] Hybrids receive government subsidies, but some other major carmakers were slow to offer hybrids failing to see the PR value.
[43] Other carmakers have caught up to Volvo, which no longer emphasizes safety in its advertising.

regulation. As it struggles against evasive maneuvers, government faults the profit motive, but rarely its own rules.

Government mandates do not thwart private incentives as much as misdirect them.

Alternatively, the government also may try to use the profit motive to manipulate business ostensibly for public ends by turning rules that should be generally applicable and predictable into "carrots and sticks" with selective enforcement or discretionary grants and denials of operating permits, for example. This is outcome-driven regulation that channels the profit motive to currying favor with the politically powerful. It leads to "crony capitalism," which ultimately operates at the public's expense.

Government efforts to manipulate the profit motive lead to "crony capitalism" that serves the politically powerful, not the public.

Dilution of economic analysis in regulation. Incentive-based rules may not lead to a preconceived solution and are therefore unsatisfying to regulators committed to a particular solution. Prescriptive rules are more suited to demonstrate compliance with administration directives and to specify the conditions negotiated with interested parties. Agencies prefer to have their attorneys write the rules and have in-house economists prepare a cost-benefit analysis to help justify them if one is required. Various studies of the role of economists and cost-benefit analysis in regulation have found that they can make a positive difference, but that overall the quality of regulations is poor and has stagnated.[44] Notwithstanding official pledges, OIRA as a part of OMB cannot be a reliable guarantor of sound cost-benefit analysis and efficient rulemaking unless an administration wants it to be. A prominent advocate of incentive-based regulation as an academician was chief of OIRA during a time when the EPA drastically ratcheted up its regulations.[45]

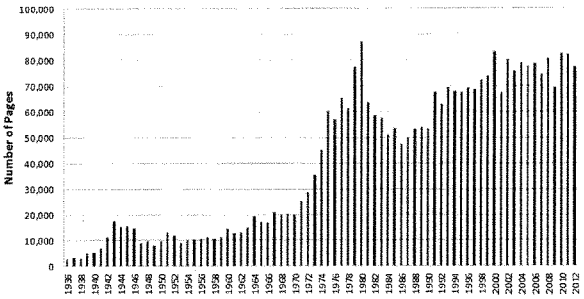
Economic analysis in the late 1970s and in the 1980s had a cleansing effect on regulation because the highest level of government endorsed it as a decision tool. However, the institutional moorings were insufficient to prevent the subsequent reversion to prescriptive regulation in the social realm. The regulatory bureaucracy contracted in the early 1980s as measured by agency budgets, staffing, and the number of pages in the Federal Register; but after several years of healthy economic growth, prescriptive regulation again expanded. The number of pages in the Federal Register has been about 80,000 pages in recent years (Figure 3).

Economic analysis could have a cleansing effect on regulation, but federal agencies coopt it to support the rules they favor.

[44] See Mercatus Report Card; "The Quality and Use of Regulatory Analysis in 2008, Jerry Ellig and Patrick McLaughlin, *Journal of Risk Analysis*, 2010; "The Influence of Regulatory Economists in Federal Health and Safety Agencies," Richard Williams, Mercatus Working Paper NO. 08-15, July 2008; "Has Economic Analysis Improved Regulatory Decisions?," Robert W, Hahn and Paul C. Tetlock, *Journal of Economic Perspectives*,.vol. 22 no. 1, Winter, 2008, pp. 67-84; "How Well Does the Government Do Cost–Benefit Analysis?", Robert W. Hahn, and Patrick Dudley. *Review of Environmental Economics and Policy*, 2007, 1(2): 192–211.

[45] Cass Sunstein, the author of *Nudge*. See, "The Jackson Damage," Review & Outlook, *Wall Street Journal*, December 27, 2012.

Figure 3: Federal Register Pages



THE COST OF REGULATION TO THE ECONOMY

OMB based its estimate of federal regulation's benefits and costs on only 14 regulations out of more than 3,500 issued in fiscal year 2012.

Few rules are fully analyzed. For fiscal year 2012, federal agencies conducted analyses of both costs and benefits with respect to only 14 regulations. OMB, in its 2013 draft report to Congress on federal regulation, based its estimate of total regulatory benefits and cost on only those 14 out of 47 major final regulations and over 3,500 total regulations issued.[46] Agency analyses are reviewed by OIRA, which is part of OMB, and subject to direction from the administration. Unless an administration favors rigorous regulatory reviews, there is no other critical examination and enforcement to ensure good analysis and good rulemaking. Agency cost-benefit analysis is:

There are indeed many problems with federal agency analysis of regulations.

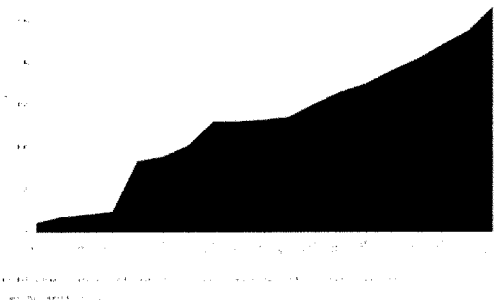
1. Not applied to the vast majority of rulemakings;
2. Not a uniform requirement across all agencies;
3. Not conducted in standardized fashion when agencies do use it;
4. Prone to agency manipulation with a pro-regulation bias, for example, in the choice of
    a. Methods and assumptions for valuing regulatory benefits;
    b. Types of benefits to claim for regulation (including private and co-benefits);
    c. Types of costs ignored (*e.g.*, international competitiveness of American business);
    d. Baselines for evaluating regulations.
5. Not applied to the huge volume of regulations already in place;

[46] "2013 Draft Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act," p. 3; *Federal Register Documents Published, 1976-2012.*

6. Not conducted adequately in the aggregate to determine the total burden on the economy of regulation because, in addition to the above listed problems—
    a. Interactive effects among different regulations are not addressed;
    b. State and local regulations are not included.

Data on rules that have been analyzed show a growing economic burden. Measuring the aggregate cost of regulation is difficult. A very credible effort in this regard is a study by NERA Economic Consulting[47] which basically adds up the individual costs that OMB has reported for rules issued between 1993 and 2011. NERA uses the 320 regulations from OMB reports to Congress for which quantitative cost estimates are available, mostly "major" rules,[48] and adjusts them for inflation. Figure 4 shows the annual cumulative direct cost of compliance with federal regulation estimated this way rising over time to $265 billion in 2011. There are major rules for which cost estimates are not available,

Figure 4: Cumulative Cost of Regulations over Time (Constant 2010 Dollars)



While it is difficult to fully measure the aggregate cost of regulation, quantification of some of the costs makes it clear they are large and increasing.

and NERA also identified 5,756 non-major rules from the same period whose cost it did not estimate for lack of sufficient data but it believes the cost could easily approach that of the major ones. NERA estimates that the total direct compliance cost of federal regulation is in the range of

[47] "Macroeconomic Impacts of Federal Regulation of the Manufacturing Sector," August 21, 2013; commissioned by the Manufacturers Alliance for Productivity and Innovation (MAPI). Figure 4 is reproduced from a graph on page 50 (Figure 16).
[48] A regulation is considered economically significant or "major" if OIRA determines that it is likely to have an annual effect on the economy of $100 million or more or 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.

$265 billion to $726 billion for 2011. State and local regulations are not included in the analysis. There are other studies whose estimates of regulatory costs are far higher than NERA's. Wayne Crews Jr., author of *Ten Thousand Commandments, An Annual Snapshot of the Regulatory State*, 20th Anniversary Edition, Competitive Enterprise Institute, 2014 (page 2), estimates an annual cost of $1.863 trillion.

The growth in cost of major regulations has far exceeded economic growth and growth in physical manufacturing output.

The regulatory burden on the economy is substantial and increasingly damaging. NERA points out that the growth in cost of major regulations has far exceeded economic growth, especially manufacturing sector growth. From 1998 through the end of 2011, the cumulative inflation-adjusted cost of compliance with major regulations grew by an annualized rate of 8.8 percent. Over this same period, U.S. inflation-adjusted GDP growth averaged 2.2 percent a year, and the annual growth in the physical volume of manufacturing sector output averaged a mere 0.4 percent.[49]

The federal regulatory burden impairs the international competitiveness of U.S. firms.

The federal regulatory burden leads to higher manufacturing costs making domestic goods less competitive internationally. NERA estimates that, on average, U.S. manufacturing exports in 2012 were between 7 percent and 17 percent lower as a result of the regulatory burden, whereby energy intensive subsectors experience much worse impacts.[50]

THE VAGARIES OF "REGULATING THE REGULATORS"

Patchwork of rulemaking requirements. Lawmakers delegate a measure of authority to regulatory agencies so they may exercise the judgment necessary for applying general laws to specific circumstances. In theory, procedural and analytical requirements for rulemaking limit regulators' discretion to assure their adherence to legislative intent. However, actual requirements for rulemaking have been added incrementally in disjointed fashion and in some cases with deliberate vagueness. Some requirements are little more than perfunctory, and some are practically inoperative because they have no enforcement mechanism or leave interpretation of critical concepts to the regulatory agencies (*e.g.*, the *Regulatory Flexibility Act*).[51] The requirements for conducting cost-benefit analysis of the Reagan administration and of subsequent administrations are contained in Executive Orders that apply to executive agencies but do not extend to independent regulatory agencies. Special procedures, reports and analyses are required for certain kinds of regulatory impacts, such as on the environment and small businesses, but in some rulemakings cost considerations are expressly disallowed by

[49] *Ibid*, p. 50.
[50] *Ibid*, p. 60.
[51] The Government Accountability Office (GAO) has repeatedly made the point that terms such as "significant economic impact" and "substantial number of small entities" lack clear definition and hinder the Act's effectiveness.

statute (although none prohibits cost-benefit analysis for informative purposes). "Regulation of the regulators,"[52] such as it exists, has been criticized as cumbersome and time consuming for federal agencies, supposedly "ossifying" rulemaking, but it obviously has not kept the rate at which they issue rules from increasing. Accusations of regulatory overreach have become common, and the lack of clear statutory instructions for rulemaking often leads to drawn-out litigation over agency rules.

Federal rulemaking requirements are disjointed and vague, and rules often end up in drawn-out litigation.

Impervious bureaucracy. Regulatory agencies also have important operational functions on which commerce depends, such as issuing permits, conducting safety inspections, or holding auctions for leases on federal land and offshore to produce oil and gas, for instance. In *The Rule of Nobody* (2014), Phillip K. Howard describes how agencies use rules to shield themselves from accountability. Creating highly specific, prescriptive rules relieves administrators of responsibility for their actions and even can lead to dysfunction when they are able to pass off or delay decision-making. As pointed out above, writing more rules may not to increase certainty or efficiency at all but become counterproductive.

Missing: consistent, objective analysis. The reason that federal rulemaking requirements form a patchwork lacking in effectiveness is that rules have wider impacts than exclusively on their stated public goals and difficult tradeoffs among the impacts have not been settled by statute. In some cases, new laws are needed but have not been passed, and the administration uses its authority over the executive agencies to pursue its own political agenda. In other cases, Congress deliberately passed vague laws that delegate politically difficult decisions to the agency level where it expected to control outcomes more readily by less transparent means.[53] Some regulatory agencies are ostensibly independent, but they still are subject to congressional oversight and appropriations. (See Appendix for a list of independent regulatory agencies).

Existing checks on regulatory agencies are compromised in several ways:

- ***Fragmented analytical requirements;***
- ***Interpretation of requirements left to the agencies themselves;***
- ***Vagueness in statutes;***
- ***Continuing political influence over agencies' implementation of statutes.***

The pressuring and maneuvering behind the scenes does not ensure that the benefits of regulation exceed its costs or that the costs of the regulations to which the country is subjected are at a minimum. Indeed, the behind-the-scenes part of regulatory decisions may have precious little to do with enhancing public benefits or minimizing costs. Agencies manage to navigate the legal and procedural requirements for rulemaking without performing comprehensive analyses and what specific analytical

[52] See the Reg Map in the Appendix (from OIRA's website).

[53] See, *Power Without Responsibility*, by David Schoenbrod, Yale University Press, 1993. The regulation of the frequency spectrum is an example of Congress actually prescribing the method. The FCC, an independent regulatory agency, had requested authorization to conduct spectrum auctions many times under both Democratic and Republican administrations but was denied by Congress.

There is no substitute for objective economic analysis to determine the cost and effectiveness of rules.

instructions are contained in Executive Orders and statutes do not add up to a consistent, uniform requirement for fully weighing all relevant costs in any event. Guidance from OIRA to the agencies on how to conduct cost-benefit analysis is often ignored. However, the need for comprehensive analysis of markets, regulatory options, and regulatory outcomes by objective standards is obvious and its urgency is heightened by the increased role of unelected regulatory officials in policymaking for health care, banking, energy, the environment, and more.

OBJECTIONS TO COST-BENEFIT ANALYSIS AND RESPONSES

The arguments advanced against cost-benefit analysis of government regulation fall into three categories:

1. There are human and societal values that inherently defy monetization and quantitative comparison, such as human life, health, and nature.[54]
2. Efficiency considerations alone should not determine regulatory decisions; the distribution of costs and benefits among different groups (*e.g.*, children, the elderly, people with low incomes, and others) should enter into the decisions. Concepts such as equity, fairness, and dignity cannot be precisely defined and mechanically applied; they must be incorporated through the political process and by exercising administrative judgment.
3. Aside from the objections on principle, monetization of important public costs and benefits, as a practical matter, is an artificial and essentially arbitrary exercise for lack of market transactions that establish meaningful, observable prices.

The basic response to these objections is that they may knock down a narrow and formulaic application of cost-benefit analysis, which is like saying that private companies should not use discounted cash flow analysis to evaluate projects because it does not incorporate strategic considerations. Of course, financial calculations alone are insufficient to make good business decisions, but they are necessary. No investor would commit substantial resources to a venture without a business case, and federal regulatory agencies should not choose to undertake a social project and pick their methods from the list on pages 16 and 17 without a similar analysis. Following are more specific responses.

1. Interpersonal comparisons of utility indeed are impossible; that is as true in the private sector as it is in the public sector. People

[54] See, *Priceless, On Knowing the Price of Everything and the Value of Nothing*, by Frank Ackerman and Lisa Heinzerling, The New Press, New York, 2004, p.8.

whose profession becomes obsolete due to automation may feel a greater personal loss than the gain experienced from lower prices by buyers of cars made by robots. However, the greater efficiency in production produces a material gain for the economy, from which government can compensate those suffering material losses (*e.g.*, with retraining assistance). If, as a matter of principle, we do not allow such calculation to help guide public policy, then we confer veto power to groups that can claim any subjective loss from progress; we cement the primacy of the status quo and stunt economic growth. There are car plants in Europe operating at a third of capacity, subsidized by the state to avoid layoffs.[55] Such policies shrink the collective wealth, which fact should not be ignored in policymaking. Our inability to quantify the value of everything should not predispose us to accept outcomes that are objectively inferior.

Rejecting quantitative analysis in rulemaking undermines the government's public interest mission:

- ***It obstructs progress,***
- ***Leaves government oblivious to resource misallocation and waste, and***
- ***Blinds it to more effective policies.***

2. The political and administrative processes by which government controls scarce resources do not measure efficiency. Hence, without quantitative analyses the government will misallocate and waste some of the resources it claims and generate less public benefit with them than it might. For example, the cost per life saved varies widely across different federal agencies charged with protecting public health and safety, which implies that resource reallocation among them would save more lives. There is no public interest justification for rejecting such analysis.

3. Academicians and think tank researchers analyze regulations on everything from police enforcement to education and then testify before Congress. At times, special government commissions are formed for the purpose of analyzing a particular regulatory regime. Why should the agencies that write the rules in the first place not do their own analyses and report their findings? It is necessary for lawmakers and regulators to try to understand the tangible as well as intangible implications of employing scare resources under alternative policies.

Some examples: The war on drugs concerns values that are not measurable but it still is important to know what its costs are and how well it is working by some objective metrics. In the anti-tobacco campaign, state and federal governments have used an assortment of methods including (numbered per list on pages 16 and 17): states attorneys' litigation (2, 4); substantial taxation (5); restrictions on advertising,

[55] "Unprofitable Auto Plants Multiply in Europe," *Wall Street Journal, European Business News*, June 18, 2013.

warning labels, public service announcements (7); product design prescriptions (10); restrictions on consumption, such as minimum age, no smoking areas, and on production, such as of flavored cigarettes (12). In the course of a half century, tobacco consumption has declined, but more analysis may have produced better design, sequencing, and combinations of regulations. With Prohibition, the federal government used the ultimate form of command-and-control, which led to a sharp increase in crime, undermined parts of the government itself, and proved unsustainable.

CONCLUSION

Problems with federal regulation. Federal agencies do not inherently possess better information than the private sector; on the contrary, they are largely reliant on private sources for information about the real world. Yet, the agencies collectively analyze costs and benefits for only a small fraction of the thousands of rules they issue each year. No coherent, comprehensive requirement to analyze costs and benefits exists either for making new rules or for evaluating existing rules. The instructions for agency rulemaking that exist are disjointed, unevenly enforced, and mostly ineffective. There even are statutes that instruct regulators *not* to consider costs in some rulemakings.

Regulations are proliferating at an increasing cost to the economy. A rudimentary summation of the costs agencies themselves had initially calculated for a small portion of the regulations in place shows a burden in the hundreds of billions of dollars *per year*. The growth rate of this cost burden far exceeds the growth rate of the economy, and there is no sign the pace of rulemaking is abating.

Whatever the statutory goal of a rulemaking, the public interest will be advanced by employing the most cost effective method to achieve it. To the extent that agencies do not use concrete indicators and metrics to measure the costs and benefits of what they are doing, they leave more room for errors in judgment and pursuit of non-public interests. And, to the extent agencies focus their attention on new rulemaking and not on the actual effects their existing rules are having, unintended consequences multiply.

The Joint Economic Committee (JEC) held a hearing last year on federal regulation[56] at which the witnesses expressed remarkable agreement:

[56] Hearing on "Reducing Unnecessary and Costly Red Tape through Smarter Regulations" June 26, 2013. The witnesses were professor Susan Dudley, Director, Regulatory Studies Center, George Washington University; Dr. Michael Greenstone, Director, Hamilton Project and 3M Professor of Economics, MIT; Dr. Jerry Ellig, senior research fellow, Mercatus Center, George Mason University; and Dr. Robert Kieval, Executive Vice President and Chief Technology Officer CVRx, Inc.

(1) executive orders, as internal government documents, are not legally binding and their analytical requirements do not cover all agencies and rulemakings; (2) the agencies often perform analysis only after they have decided what they want the rules to be; (3) the agencies are prone to "confirmation bias," (4) regulations among independent regulatory agencies overlap because OIRA does not oversee them, and (5) regulation is placing a large burden on the economy.

Improvements to federal regulation. Agencies need to do more than declare a market failure, prescribe the outcomes they envision and pronounce them to be in the "public interest." While the regulators' goals may be laudable, there are tradeoffs to the outcomes they seek and there are alternative measures they could use to pursue them that differ in cost and effectiveness. Regulators cannot presume to know what the most efficient tradeoffs and options are without analyzing them. Regulatory actions should be grounded in principles aimed to preserve and enhance market functions and individual choice and kept from extending boundlessly to any condition deemed unsatisfactory in some way.

Agencies need to explain the tradeoffs of their pursuits within a coherent analytical framework, state their objectives clearly, and show how they can achieve them at minimum cost. Regulation should be evaluated based on progress toward the stated objectives and on all the costs, not only those for compliance and enforcement. The same principles should apply to all agency analyses, and their application to different jurisdictions, such as finance and the environment, should be accepted by the stakeholders.[57]

Regulation should be least strident where objective data is difficult to obtain, such as in the social realm. Regulators should act less as "saviors" and focus more on facilitating market functions, minimizing economic tradeoffs, and containing regulation's unintended effects. Economic analysis can help to develop process enhancements—such as in defining property and trading rights and improving information flow—that are more efficient and stable than proliferating mandates and prohibitions, which tend to introduce more regulatory discretion and uncertainty.

Regulation should be least strident where objective data is difficult to obtain, such as in the social realm.

If regulatory agencies employed economic analysis to design rules rather than merely rationalizing them afterwards, they could be incubators of more sophisticated regulation. The 2012 Noble Prize in economics was awarded in part for an algorithm that better assigns students among sought-after schools and matches donated kidneys with suitable recipients.

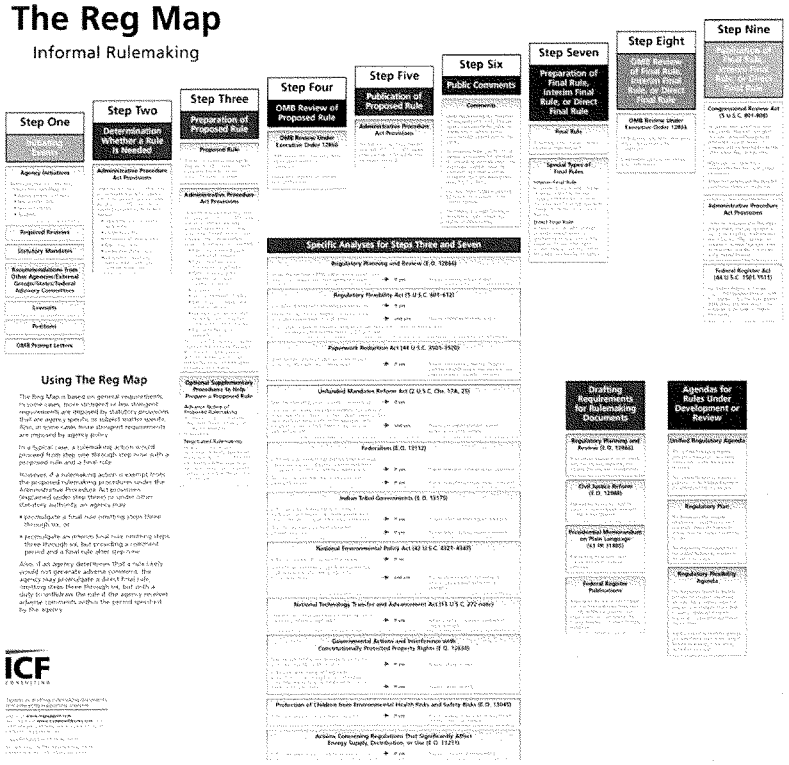
[57] An Advanced Notice of Proposed Rulemaking appears to be a particularly useful device to improve individual rulemakings; see, "Regulatory Process, Regulatory Reform, and The Quality of Regulatory Impact Analysis," Jerry Ellig and Rosemarie Fike, Working Paper No. 13-13, July 2013, Mercatus Center, George Mason University.

In both contexts it is not socially acceptable to use auctions; nevertheless economic analysis proved capable of improving the methods in use.

The JEC witnesses also agreed on the following: (1) Legislation is needed to make analysis a legally binding requirement that applies to all federal agencies and all rulemakings of importance; (2) retroactive reviews of rules in place are needed to make appropriate changes to the ones that are not working as intended; and (3) independent review of agencies' analysis and rulemakings is needed to cut down on overlap and hold rulemaking to common, objective standards.

Theodore W. Boll
Senior Economist

APPENDIX


The Reg Map
Informal Rulemaking
Step One
Step Two
Determination Whether a Rule Is Needed
Step Three
Preparation of Proposed Rule
Step Four
OMB Review of Proposed Rule
Step Five
Publication of Proposed Rule
Step Six
Public Comments
Step Seven
Preparation of Final Rule, Interim Final Rule, or Direct Final Rule
Step Eight
Step Nine
Specific Analyses for Steps Three and Seven
Using The Reg Map
Drafting Requirements for Rulemaking Documents
Agendas for Rules Under Development or Review
ICF

Executive Orders on Regulatory Analysis and Oversight and Regulatory Review Laws
(Susan E. Dudley's Prepared Statement, Joint Economic Committee Hearing, June 26, 2013)

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

Regulatory Review Laws

Regulatory Flexibility Act (RFA) of 1980. Requires agencies to assess the impact of a regulation on small businesses and provides for review by the Small Business Office of Advocacy.

Paperwork Reduction Act (PRA) of 1980 (amended in 1995). Established OIRA within the OMB to review the paperwork and information collection burdens imposed by the federal government.

Unfunded Mandates Reform Act (UMRA) of 1995. Limits regulatory agencies' ability to place burdens on state, local, and tribal governments.

Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996. Enforces requirements for small business impact analyses under the RFA.

Congressional Review Act (CRA) of 1996, contained in the SBREFA. 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.

Consolidated and Emergency Supplemental Appropriations Act of 1999 (section 638(a)). Requires the OMB to report to Congress yearly on the costs and benefits of regulations and to provide recommendations for reform.

Truth in Regulating Act of 2000. Gives Congress the authority to request that the GAO conduct an independent evaluation of economically significant rules at the proposed or final stages.

Information Quality Act of 2000. 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.

INDEPENDENT AGENCIES

(As described and grouped in "Independent Regulatory Agency Compliance with the Regulatory Flexibility Act," Microeconomic Applications, Inc. the SBA Office of Advocacy, May 2013)

Depository Financial Institutions

Independent federal agencies that regulate depository financial institutions include the following:

- **Farm Credit Administration (FCA).** The FCA provides credit and other services to agricultural producers, farmer-owned cooperatives, and other selected rural businesses.
- **Federal Deposit Insurance Corporation (FDIC).** The FDIC insures deposits in banks and thrift institutions, addressing risks to the deposit insurance funds, and intervenes to limit economic impacts when a bank or thrift institution fails.
- **Federal Reserve System (FRS).** The Board of Governors of the FRS supervises the financial services industry, regulates commercial banks and other depository institutions, oversees the nation's payments system, administers certain consumer protection regulations, and sets the nation's monetary policy.
- **National Credit Union Administration (NCUA).** The NCUA charters and regulates federal credit unions.

Non-Depository Financial Institutions

Independent federal agencies that regulate non-depository financial institutions include the following:

- **Commodity Futures Trading Commission (CFTC).** The CTFC regulates commodity futures and option markets to facilitate their competitive functioning, ensure their integrity, and protect market participants.
- **Securities and Exchange Commission (SEC).** The SEC enforces the federal securities laws and regulates the securities industry, the nation's stock and options exchanges, and other electronic securities markets, as well as participants in those markets.

Energy

Independent federal agencies that regulate businesses in the energy sector include the following:

- **Federal Energy Regulatory Commission (FERC).** The FERC regulates the interstate transmission of electricity, natural gas, and oil, as well as certain aspects of related infrastructure.
- **Nuclear Regulatory Commission (NRC).** The NRC regulates civilian use of nuclear materials – including reactors, nuclear waste, and other non-energy uses of nuclear materials - to protect the public health and safety.

Transportation

Independent federal agencies that regulate businesses in the transportation sector include the following:

- **Federal Maritime Commission (FMC).** The FMC regulates ocean borne transportation in the foreign commerce of the U.S.
- **Surface Transportation Board (STB).** The STB regulates railroad rates, service issues, and restructuring transactions of railroads and (to a limited extent) interstate trucking, ocean shipping, busses, and pipelines.

Consumer Protection

Independent agencies that regulate commerce more broadly, especially with respect to consumer protection, include the following:

- **Consumer Product Safety Commission (CPSC).** The CPSC regulates consumer products, under authority from nearly a dozen statutes, to protect the public from unreasonable risks of injury or death.
- **Federal Trade Commission (FTC).** The FTC has a dual mandate that includes: Anti-trust activities to promote and protect free competition, and protection of consumers against unfair, deceptive, or fraudulent marketplace practices.

Federal Activity

Independent federal agencies that regulate quasi-federal organizations include the following:

- **Recovery Accountability and Transparency Board (RATB).** The RATB provides transparency and investigates fraud, waste, and mismanagement of American Recovery and Reinvestment Act funds.
- **Federal Housing Finance Agency (FHFA).** The FHFA regulates government-sponsored enterprises in the secondary mortgage markets: The Federal Home Loan Mortgage Corporation (Fannie Mae), The Federal National Mortgage Association (Freddie Mac), and The 12 Federal Home Loan Banks.
- **Postal Regulatory Commission (PRC).** The PRC regulates the U. S. Postal Service.

Adjudicatory Agencies

Independent federal agencies that provide services of an administrative court include the following:

- **Federal Mine Safety and Health Review Commission (FMSHRC).** The FMSHRC provides administrative trial and appellate review of legal disputes arising under the Mine Act of 1977.
- **Occupational Safety and Health Review Commission (OSHRC).** The OSHRC provides administrative trial and appellate review under the Occupational Safety and Health Act of 1970.

Other Agencies

Independent federal agencies that have other distinct missions include the following:

- **Federal Communications Commission (FCC).** The FCC regulates interstate and international communications by radio, television, wire, satellite, and cable
- **Federal Election Commission (FEC).** The FEC administers and enforces the Federal Election Campaign Act, which governs the financing of federal elections.
- **National Indian Gaming Commission (NIGC).** The NIGC regulates gaming activities on Indian lands for the benefit of Indian tribes and to assure fair conduct of gaming.
- **National Labor Relations Board (NLRB).** The NLRB protects the rights of private sector employees to join together (with or without a union) to improve their wages and working conditions.

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Manufacturers

Leading Prosperity, Creating Opportunity, Powering Progress

Testimony

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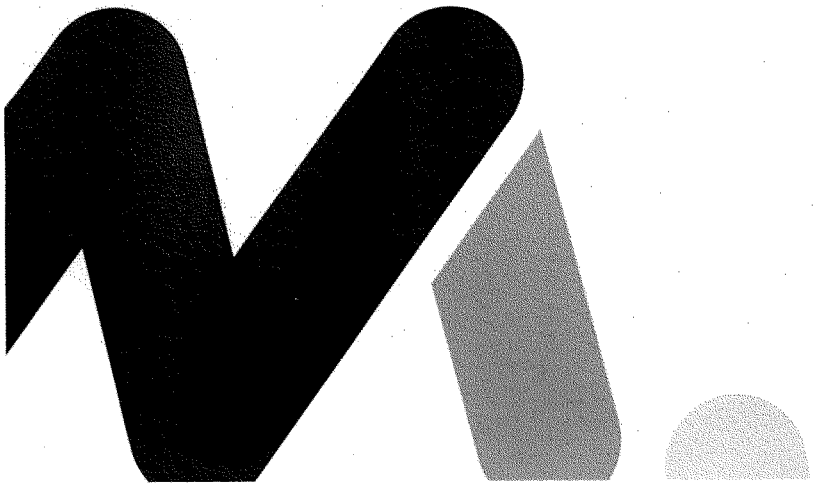
on The First Step to Cutting Red Tape: Better Analysis

April 30, 2014



COMMENTS OF THE NATIONAL ASSOCIATION OF MANUFACTURERS

BEFORE THE

JOINT ECONOMIC COMMITTEE

APRIL 30, 2014

Chairman Brady, Vice Chair Klobuchar and members of the Joint Economic Committee, thank you for the opportunity to testify about cutting red tape and improving the regulatory system through better analysis.

The National Association of Manufacturers (NAM) is the nation's largest industrial trade association and voice for more than 12 million men and women who make things in America. The NAM is committed to achieving a policy agenda that helps manufacturers grow and create jobs. Manufacturers very much appreciate your interest in and support of the manufacturing economy.

I. State of Manufacturing

Manufacturing output has increased 18 percent since the end of the recession in 2009. In the fourth quarter of 2013, manufacturers in the United States contributed $2.14 trillion to the economy (or 12.5 percent of GDP), up from $2.08 trillion in the third quarter. For every $1.00 spent in manufacturing, another $1.32 is added to the economy, the highest multiplier effect of any economic sector. Importantly, manufacturing supports an estimated 17.4 million jobs in the United States—about one in six private-sector jobs. In 2012, the average manufacturing worker in the United States earned $77,505 annually, including pay and benefits—22 percent more than the rest of the workforce.

Manufacturing in the United States lost 2.3 million jobs in the last recession. Since the end of 2009, we have gained back nearly 602,000 manufacturing jobs. To maintain manufacturing momentum and encourage hiring, the United States needs not only improved economic conditions but also government policies more attuned to the realities of global competition. Because of the significant challenges facing manufacturing in the United States, the NAM advocates federal policies that will ensure a robust and dynamic manufacturing sector that is ready to meet the needs of our economy and workers.

II. Regulatory Environment

The conversation about regulation too quickly becomes partisan. Democrats and Republicans have much in common on their views on regulation, but the rhetoric often fails to match that consensus. Similarly, the business community is often misunderstood about their views on regulation. Manufacturers believe that regulation is critical to the protection of worker safety, public health and our environment. We have supported regulations such as the enhanced corporate average fuel economy rules in 2009 and legislation such as the Food Safety Modernization Act of 2011 and its accompanying regulations. We believe some critical objectives of government can only be achieved through regulation, but that does not mean our

regulatory system is not in need of considerable improvement and reform. New regulations are too often poorly designed and analyzed and ineffectively achieve their benefits. They are often unnecessarily complex and duplicative of other mandates. Their critical inputs—scientific and other technical data—are sometimes unreliable and fail to account for significant uncertainties. Regulations are allowed to accumulate with no real incentives to evaluate or clean up the past. In addition, regulations many times are one-size-fits-all without the needed sensitivity to their impact on small businesses. We can do better.

Unnecessary regulatory burdens weigh heavily on the minds of manufacturers. In a NAM/*IndustryWeek* Survey of Manufacturers released in March, 79.0 percent of respondents cited an unfavorable business climate due to regulations, taxes and government uncertainties as a primary challenge facing businesses, up from 67.7 percent in the first quarter of 2013 and 62.2 percent in March 2012. The unfavorable business climate due to government policies exceeded rising health care and insurance costs, which ranked second (77.1 percent).

The cost disadvantage confronting manufacturers in the United States is a result of decisions made here in Washington, not by governments outside our borders. Our competitors in Europe, Asia and South America aggressively seek new customers, markets and opportunities. Countries know that a strong manufacturing sector is key to jobs, innovation and prosperity. They are strategizing for success in manufacturing and improving their global competitive positions. Government policies should support our global competitiveness, not impose increasing burdens. Manufacturers in the United States confront challenges that our global competitors do not have.

President Obama consistently discusses the importance of a strong manufacturing economy and "keeping America at the cutting edge of technology and innovation . . . to ensure a steady stream of good jobs into the 21st century."[1] Manufacturers agree, and the NAM has praised efforts by the Obama Administration to reduce regulatory burdens imposed on businesses. The President has signed executive orders focused on improving the regulatory process, and the Office of Management and Budget (OMB) has issued memoranda on the principles of sound rulemaking, considering the cumulative effects of regulations, strengthening the retrospective review process and promoting international regulatory cooperation. Unfortunately, these initiatives have yet to realize a significantly better regulatory environment for manufacturers and other regulated entities.

In October 2013, the NAM joined the Manufacturers Alliance for Productivity and Innovation (MAPI) in an event that highlighted the regulatory burdens placed on manufacturers. A MAPI study found that since 1981, the federal government has promulgated more than 2,300 regulations that target manufacturers, meaning federal agencies have issued an average of just under 1.5 manufacturing-related regulations per week for more than 30 years, with 270 of these considered major regulations. Individually and cumulatively, these regulations include significant burdens imposed on manufacturers in the United States and represent real compliance costs that affect our ability to expand and hire workers.

III. Regulatory Challenges Facing Manufacturers in the United States

Manufacturers recognize that regulations are necessary to protect people's health and safety. In recent years, the scope and complexity of rules have made it harder to do business

[1] February announcement of new Manufacturing Innovation Institutes, available at http://www.whitehouse.gov/the-press-office/2014/02/25/remarks-president-manufacturing-innovation-institutes.

and compete in an ever-changing global economy. As a result, manufacturers are sensitive to regulatory measures that rely on inadequate benefit and cost justifications. Despite existing statutory requirements placed upon regulating agencies, manufacturers are faced with the challenges of complying with inefficient and complex regulations that place unnecessary costs on the public.

The Environmental Protection Agency (EPA) is a significant contributor to costly and unnecessary burdens placed on the economy. The agency has embarked on a decades-long process to implement the Clean Air Act and its amendments. Regulations on emissions have resulted in enormous benefits, such as improved public health, but the continued ratcheting down of emission limits produces diminishing returns at far higher marginal costs. This means that each new air rule will have a greater impact on job creation than those in the past. Complying with these regulations is capital intensive. In a time of economic recovery where capital is extremely scarce, every dollar diverted from productive use creates additional pressure to reduce labor costs. In this environment, unnecessary or cost-ineffective regulations will dampen economic growth and continue to hold down job creation. For some firms, it will be the final marginal straw from which they cannot recover.

In 2012, the NAM released a study[2] that examines the EPA's cost-benefit analysis for six major proposed regulations. The study highlights widespread skepticism of the validity of the EPA's estimated costs and benefits.[3] In a worst-case scenario, the regulations could mean the annual loss of $630 billion, 4.2 percent of GDP and between 2 million and 9 million jobs. The EPA's calculations of estimated benefits have been criticized as uncertain, unrealistic and speculative. The agency often assumes compliance with technologically infeasible requirements, assigns the same claimed benefit to more than one regulation and incorrectly assumes a linear relationship between pollution abatement measures and benefits. In reality, as emissions standards are set to near unattainable levels, there are diminishing benefits for each dollar invested in pollution abatement. As a result, the EPA estimates of benefits could be highly inflated.

This year, the EPA will consider tightening the National Ambient Air Quality Standards (NAAQS) for Ozone. The agency abandoned a 2010 reconsideration that would have lowered the NAAQS, but EPA scientists are now recommending levels that would be at or very close to ozone levels that naturally exist in the atmosphere without any industrial activity. The difference between the EPA's suggested cost for the 2011 reconsideration of Ozone NAAQS and the industry's suggested cost was a factor of 10.[4] Even if the EPA sets the standard at the higher end of the range it is considering, this has the potential to be the costliest environmental regulation ever administered on manufacturers.

The EPA's push to lower Ozone NAAQS is only one part of the agency's highly aggressive regulatory agenda for 2014 and beyond. Over the next two years, the EPA is

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[2] *A Critical Review of the Benefits and Costs of EPA Regulations on the U.S. Economy*, ndp|Consulting, November 2012, available at http://www.nam.org/~/media/423A1826BF0747258F22BB9C68E31F8F.ashx.

[3] According to the EPA's own assessments, the likely annualized compliance cost with the six proposed regulations evaluated would be between $36 billion and $111 billion per year. For three of those six rules (Utility MACT, Boiler MACT and Coal Combustion Residuals), the EPA estimated the upfront capital expenditures needed for industry compliance at $63.1 billion. That significant expense falls far short of the $142 billion estimate provided by the industry.

[4] The EPA estimated costs and capital expenditures of the Ozone NAAQS reconsideration at $19 billion to $90 billion. A 2010 study by the Manufacturers Alliance/MAPI estimated that the proposal would add $1 trillion in new regulatory costs per year. The study is available at http://www.nam.org/~/media/21F1AC2179154220896445E0C37855B0/MAPI_Study.pdf.

expected to issue a new Cross-State Air Pollution Rule (CSAPR) and a series of major regulations concerning greenhouse gas emissions and domestic energy production. The agency is also seeking to accomplish an unprecedented expansion of its jurisdiction under the Clean Water Act. The economic analysis associated with the EPA's major regulatory proposals has a significant degree of uncertainty. As a result, virtually every major air regulation issued by the EPA in recent years has given rise to a host of economic studies from private-sector groups—both in support and in opposition—attempting to clarify the true impact of the regulation on the economy. Consider, for example, the following:

- When the EPA modeled the Mercury and Air Toxics Standards (MATS), it predicted only 4.7 gigawatts (GW) of coal retirements as a result of the regulation. The Energy Information Administration recently reported that 54 GW of coal-fired capacity will retire as a direct result of MATS by 2016.
- The EPA has never modeled the true economic impact of Prevention of Significant Deterioration permitting for greenhouse gases, which is a barrier to new manufacturing expansions and over time exposes 6 million stationary sources to regulation.
- The EPA suggested its now-overturned CSAPR would cost $3.6 billion annually; industry analyses placed the annual cost at $14 billion to $18 billion.
- The EPA suggested its proposed Coal Combustion Residuals Rule would cost $1.5 billion annually; industry studies estimated the rule would cost $7.6 billion annually.
- The EPA suggested its proposed Cooling Water Intake Structures regulation would cost between $0.3 billion and $4.6 billion annually; industry studies estimated the rule would cost $8 billion annually.
- The EPA has not modeled the cumulative impact of its recent regulations, which, by conservative estimates, could cost more than $100 billion annually and place 2 million jobs in jeopardy.

In much the same way manufacturers are acutely sensitive to environmental regulations, they are also concerned with changing existing and already effective rules focused on worker safety and health. Manufacturers understand that employees are the key resources in our facilities, and all employees deserve a safe and healthful workplace. Agencies should focus on smarter and better regulations that enhance worker safety and avoid rule changes that are unnecessary, have a far-reaching impact and are based on flawed data. In September 2013, the Occupational Safety and Health Administration (OSHA) published its proposed rule on respirable crystalline silica, which would cut the permissible exposure limit in half from its current levels. The rule would mandate certain engineering controls and restricted work areas as well as require additional medical monitoring, training and recordkeeping. Silica is one of the most abundant materials in the world; it is a critical component in many manufacturing, construction, transportation, defense and high-tech industries and is present in thousands of consumer products. The proposed rule would impact 534,000 businesses and 2.2 million workers, including 25,000 hydraulic fracturing employees and 1.85 million construction workers. OSHA's 1,400-page cost estimate states that the rule will cost regulated entities $656 million (an average of $1,200 per business), but that figure is based on flawed analysis and outdated information. Estimates by engineering and economic consultants show an impact of closer to $6 billion in annualized costs.

We find it troubling that OSHA's estimate relies upon data from a Small Business Regulatory Enforcement Fairness Act (SBREFA) panel that examined a draft rule in 2003, more than 11 years ago. Furthermore, OSHA's estimate relies on data points from the 2006-2007 time frame, which is prerecession information and may not properly represent today's economy.

In recent years, significant progress has been made in preventing silica-related diseases under the existing regulations and exposure limit, making proposed changes unnecessary and overly burdensome. During the comment period, the NAM and other industry stakeholders repeatedly asked OSHA to convene a new SBREFA panel so the most current analysis of costs and other impacts may be considered. These requests have gone unanswered. Manufacturers will now be faced with a new regulation that could force some of our members to shut their doors.

The regulations discussed above are simply a small sample of what manufacturers are facing. Agencies are failing in their responsibilities to conduct analysis that would better assist them in understanding the true benefits and costs of their rules. Despite clear directives from the President to improve existing regulations, agencies do not conduct the appropriate and necessary analysis needed to estimate benefits and costs properly, to determine the cumulative effects of their regulations and to make changes that would allow our regulatory system to meet policy objectives more effectively.

IV. Reducing Regulatory Impediments

Manufacturing in America is making a comeback, but this comeback could be much stronger if federal policies did not impede growth. If we are to succeed in creating a more competitive economy, we must reform our regulatory system so that manufacturers can innovate and make better products instead of spending hours and resources complying with inefficient, duplicative and unnecessary regulations. Manufacturers are committed to commonsense regulatory reforms that protect the environment and public health and safety as well as prioritize economic growth and job creation. The time is now for members of both parties to work together to find ways to improve the regulatory system.

Manufacturers thank you, Chairman Brady and Vice Chair Klobuchar, for your leadership in promoting commonsense reforms that would improve the regulatory system and chip away at the many challenges our nation's job creators and other businesses in the United States face. We need reform proposals, such as those included in your legislation, which will lead to systemic changes. Leaders in Washington must view regulatory reform as more than just a rule-by-rule process but instead as a system-by-system and objective-by-objective review. The NAM recommends a number of reforms outlined below that would improve the system through which modern rulemaking is conducted.

a. Strengthen and Codify Sound Regulatory Analysis

The complexity of rulemaking and its reliance on highly technical scientific information has only increased since the Administrative Procedure Act (APA) was passed in 1946. Our administrative process has not kept up with those changes, and agency accountability is lacking without meaningful judicial review. Moreover, the process by which the government relies on complex, scientific information as the basis for rules should be improved and subject to judicial review. Efforts to encourage peer review of significant data and to create consistent standards for agency risk assessment should be part of that process. The NAM supports legislative reforms to the APA to incorporate the principles and procedures of Executive Order 12866 into the DNA of how every rule is developed. We also support legislation that would improve the quality of information agencies use to support their rulemakings. President Obama reaffirmed the principles of sound rulemaking when he issued Executive Order 13563, stating,

> Our regulatory system must protect public health, welfare, safety and our environment while promoting economic growth, innovation, competitiveness and job creation. It must

> be based on the best available science. It must allow for public participation and an open exchange of ideas. It must promote predictability and reduce uncertainty. It must identify and use the best, most innovative and least burdensome tools for achieving regulatory ends. It must take into account benefits and costs, both quantitative and qualitative. . . . It must measure, and seek to improve, the actual results of regulatory requirements.

Manufacturers and the general public agree with these principles and believe the regulatory system can be improved in a way that protects health and safety without compromising economic growth. Chairman Brady and Sen. Dan Coats (R-IN) have introduced the Sound Regulation Act of 2014 (H.R. 3863 and S. 2099), which includes many important regulatory requirements that would improve the quality of an agency's analysis and the effectiveness and efficiency of its rules. Agencies should, among other things, use the best available science, better calculate the benefits and costs of their rules, improve public participation and transparency, use the least burdensome tools for achieving regulatory ends and specify performance objectives rather than a particular method of compliance to improve the effectiveness of regulatory measures. The Regulatory Accountability Act of 2013 (H.R. 2122 and S. 1029), introduced by Rep. Bob Goodlatte (R-VA) in the House and Sens. Rob Portman (R-OH) and Mark Pryor (D-AR) in the Senate, is comprehensive reform legislation that would instill sound rulemaking principles into the fabric of our regulatory system. Agencies would be statutorily required to conduct benefit-cost analysis and recognize the true regulatory impacts of their rules. The House passed H.R. 2122 earlier this year as part of a larger regulatory reform package (H.R. 2804).

Both the Sound Regulation Act of 2014 and the Regulatory Accountability Act of 2013 would require agencies to consider the cumulative costs of regulatory requirements, a principle that is also articulated by Executive Order 13563 and OMB guidance for agencies. Moreover, President Obama also issued Executive Order 13610, which directs agencies to consider "the cumulative effects of their own regulations, including cumulative burdens . . . and give priority to reforms that would make significant progress in reducing those burdens while protecting public health, welfare, safety and our environment." Agency adherence to each of these regulatory principles is vital if we are to implement fundamental change to our regulatory system that improves the effectiveness of rules in protecting health, safety and the environment while minimizing the unnecessary burdens imposed on regulated entities.

b. Improve Congressional Review and Analysis of Regulations

Congress is at the heart of the regulatory process and produces the authority for the agencies to issue rules, so it is also responsible, along with the executive branch, for the current state of our regulatory system. While Congress does consider some of the impacts of the mandates it may be imposing on the private sector through regulatory authority it grants in law, it has less institutional capability for analysis of those mandates than the executive branch. Congress does not have a group of analysts who develop their own cost estimates of proposed or final regulations. Over the past two decades, there have been proposals in Congress to create a congressional office of regulatory analysis. As Congress has a Congressional Budget Office (CBO) that is a parallel institution to the OMB, so too should it have a parallel to the Office of Information and Regulatory Affairs (OIRA) within the OMB.

This institutional change to the regulatory system could encourage more thoughtful analysis of the regulatory authority Congress grants in statutes, provide Congress with better tools in analyzing agency regulations and allow Congress to engage in more holistic reviews of the overlapping and duplicative statutory mandates that have accumulated over the years. The

NAM supports legislative proposals like Vice Chair Klobuchar's Strengthening Congressional Oversight of Regulatory Actions for Efficiency Act (S. 1472), which would establish a "Regulatory Analysis Division" within the CBO to conduct analysis of the prospective impact of economically significant rules. Not only would this office give lawmakers better information about the potential impacts of a proposed regulation, but it would also provide agencies with analysis conducted by an objective third party. This is an important rethinking of the institutional design of our regulatory system and could lead to regulations that more effectively meet policy objectives while reducing unnecessary burdens.

c. Streamline Regulations Through Sunsets and Retrospective Review

Our regulatory system is broken, unnecessarily complex and inefficient, and the public supports efforts to streamline and simplify regulations by removing outdated and duplicative rules. Through a thoughtful examination of existing regulations, we can improve the effectiveness of both existing and future regulations. Importantly, retrospective reviews could provide agencies an opportunity to analyze, revise and improve techniques and models used for predicting more accurate benefits and costs estimates for future regulations. As Michael Greenstone, former chief economist at the Council of Economic Advisers under President Obama, wrote in 2009, "The single greatest problem with the current system is that most regulations are subject to a cost-benefit analysis only in advance of their implementation. That is the point when the least is known, and any analysis must rest on many unverifiable and potentially controversial assumptions."[5] Retrospective review of existing regulations should include a careful and thoughtful analysis of regulatory requirements and their necessity as well as an estimation of their value to intended outcomes.

For an agency to truly understand the effectiveness of a regulation, it must define the problem that the rule seeks to modify and establish a method for measuring its effectiveness after implementation. These types of provisions are included in the Sound Regulation Act of 2014. In manufacturing, best practices include regular reprioritizations and organized abandonment of less useful methods, procedures and practices. The same mentality should apply to regulating agencies: the retrospective review process should be the beginning of a bottom-up analysis of how agencies use their regulations to accomplish their objectives. We are in the midst of a manufacturing renaissance in the United States, and agencies should look to the concept of "lean manufacturing" as a model for how to improve our regulatory system. Over the past two decades, many manufacturers have transformed their operations by adopting a principle called "lean thinking," where they identify everything in the organization that consumes resources but adds no value to the customer. They then look for a way to eliminate efforts that create no value. In the government setting, agencies might identify anything that is not absolutely necessary to achieve the regulatory outcome and eliminate it. This should be a consistent and systematic process, and it requires a discipline and incentive structure that does not currently exist in our agencies.

The Administration promotes the benefits of conducting retrospective reviews. Executive Order 13563 directs agencies to conduct "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." Retrospective review of regulations is not a new concept, and there have been similar initiatives over the past 35 years. In 2005, the OMB,

[5] Michael Greenstone, "Toward a Culture of Persistent Regulatory Experimentation and Evaluation," in David Moss and John Cisternino, eds., *New Perspectives on Regulation*, The Tobin Project, 2009, p. 113, available at http://tobinproject.org/sites/tobinproject.org/files/assets/New_Perspectives_Ch5_Greenstone.pdf.

through OIRA, issued a report, titled *Regulatory Reform of the U.S. Manufacturing Sector.* That initiative identified 76 specific regulations that federal agencies and the OMB determined were in need of reform. In fact, the NAM submitted 26 of the regulations characterized as most in need of reform. Unfortunately, like previous reform initiatives, the 2005 initiative failed to live up to expectations, and despite efforts by federal agencies to cooperate with stakeholders, the promise of a significant burden reduction through the review of existing regulations never materialized.

There are several legislative proposals in this Congress that seek to improve the retrospective review process. Chairman Brady's bill and Sen. Coats' companion legislation—H.R. 3863 and S. 2099—would require reviews of existing rules to ensure they are meeting regulatory objectives effectively. Vice Chair Klobuchar's bill—S. 1472—would require a new division within the CBO to analyze economically significant regulations that have been in effect for five years to determine if they are meeting the stated goals they were intended to provide. Sen. Angus King (I-ME) has introduced the Regulatory Improvement Act of 2013 (S. 1390), which would establish a bicameral and bipartisan Regulatory Improvement Commission to review outdated regulations and submit regulatory changes to Congress for an up-or-down vote. There is significant bipartisan interest in implementing federal policies that will tackle the problem of regulations that place unnecessary costs on manufacturers and businesses, yet are not benefitting society.

To truly build a culture of continuous improvement and thoughtful retrospective review of regulations, retrospective reviews must be institutionalized and made law. One of the best incentives for high-quality retrospective reviews of existing regulations is to sunset rules automatically that are not chosen affirmatively to be continued. The NAM supports the Regulatory Sunset and Review Act of 2013 (H.R. 309), introduced by Rep. Randy Hultgren (R-IL), that would implement a mandatory retrospective review of regulations to remove conflicting, outdated and often ineffective regulations that build up over time. If an outdated rule has no defender or continued need for existence or is shown to have decreased in effectiveness over time, it should be sunset.

Adopting lean thinking into the review of existing regulations could produce more robust and significant reductions in regulatory burdens while maximizing the benefits associated with protecting health, safety and the environment. If agencies were conducting this kind of review, we would see requests to Congress to change statutes to allow for greater flexibility in a number of regulatory programs. H.R. 309 includes a provision directing agencies to report to Congress on needed legislative changes that would assist them as they implement regulatory changes as a result of their reviews. The necessity of legislative changes should be an opportunity, not a roadblock, to any proposal.

The power of inertia and the status quo is very strong. If there is no imperative to review old regulations, it will not be done, and we will end up with the same accumulation of conflicting, outdated and often ineffective regulations that build up over time. These types of systems need to be put in place throughout the government to ensure regulatory programs are thoughtful, intentional and meet the needs of our changing economy.

d. Support Centralized Review of Agencies' Regulatory Activities

President Clinton's 1993 Executive Order 12866 defines OIRA's regulatory review responsibilities. OIRA reviews significant rules issued by executive branch agencies and the analyses used to support those rules at both their draft and final stages. The office applies a

critical screen to the contents of regulation, agencies' analytical rigor, legal requirements affecting the proposal and the President's priorities and philosophy. Nowhere else in the government does this take place. Single-mission agencies are frequently effective in accomplishing their objectives. This intense focus on a relatively narrow set of policies can weaken their peripheral vision, however, including their assessment of duplication between agencies, cumulative impacts of similar rules on the same sector of the economy or other broader considerations. OIRA is the only agency that brings to bear a government- and economy-wide perspective. For that reason, OIRA is a critical institution in our regulatory process for conducting a centralized review of the agencies' regulatory activities, facilitating interagency review, resolving conflicts and eliminating unnecessary duplication.

A key responsibility of OIRA is to ensure that regulating agencies are meeting the requirements of Executive Order 12866 for a significant regulatory action. The executive order states, "Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." Importantly, OIRA facilitates public participation in the regulatory process and helps ensure that agencies' analyses, to the extent possible, are accurate. Without quality analysis, it is difficult to ensure that regulations are meeting health, safety and environmental objectives "while promoting economic growth, innovation, competitiveness and job creation," as stated in Executive Order 13563.

Despite its critical function, even as the size and scope of the government has increased, OIRA has shrunk. As OIRA's staff was reduced from a full-time equivalent ceiling of 90 to fewer than 40 employees today, the staff dedicated to writing, administering and enforcing regulations has increased from 146,000 in 1980 to 290,690 in 2013. OIRA's budget has been reduced by more than 60 percent or nearly $11 million in real 2005 dollars, and the agencies' budgets have increased from $15.2 billion to more than $50 billion in real 2005 dollars. To ensure that OIRA can fulfill its current mission, additional staff and resources are necessary. Much has been made about the length of OIRA reviews, but additional resources would allow OIRA analysts to do their jobs more quickly.

By expanding OIRA's ability to provide objective analysis, to conduct thoughtful regulatory review and to work with regulating agencies, federal regulations will meet health, safety and environmental objectives more effectively at a much lower cost to businesses. A modest investment in this institution will pay back significant returns to the entire economy.

e. Hold Independent Regulatory Agencies Accountable

The President does not exercise similar authority over independent regulatory agencies—such as the National Labor Relations Board, the Securities and Exchange Commission and the Consumer Product Safety Commission—as he does over other agencies within the executive branch. The rules issued by these agencies can impose significant costs on manufacturers. These agencies are not required to comply with the same regulatory principles as executive branch agencies and often fail to conduct any analysis to determine expected benefits and costs.

The President's bipartisan Council on Jobs and Competitiveness made recommendations in their interim and final reports to encourage Congress to require independent regulatory agencies to conduct cost-benefit analyses of their significant rules and subject their analysis to third-party review through OIRA or some other office. Congress should

confirm the President's authority over these agencies. If there is consensus that this process makes executive branch rules better, why would we not want to similarly improve the rules issued by independent regulatory agencies? Consistency across the government in regulatory procedures and analysis would only improve certainty and transparency of the process. The case for the inclusion of independent regulatory agencies in a centralized review of regulations is clear, and Congress should act to make it certain.

There are several legislative proposals in this Congress that would improve the quality of regulations issued by independent regulatory agencies. The Sound Regulation Act of 2014 would apply the same requirements to all agencies for the analysis of benefits and costs and for the use of performance metrics. Comprehensive regulatory reform measures, such as the Regulatory Accountability Act of 2013, would codify analytical requirements and sound regulatory processes for independent regulatory agencies. Sens. Portman and Mark Warner (D-VA) have introduced the bipartisan Independent Agency Regulatory Analysis Act of 2013 (S. 1173), which would provide the President authority to require independent regulatory agencies to conduct benefit-cost analysis for significant rules and submit them to OIRA for third-party review.

f. Increase Sensitivity to Small Business

The Regulatory Flexibility Act of 1980 (RFA) requires agencies to be sensitive to the needs of small businesses when drafting regulations. It has a number of procedural requirements, including that agencies consider less costly alternatives for small businesses and prepare a regulatory flexibility analysis when proposed and final rules are issued. In 1996, Congress passed the SBREFA, which requires the EPA and OSHA to empanel a group of small business representatives to help consider a rule before it is proposed. In recognizing the importance of the SBREFA panel process, the 111th Congress expanded this requirement to include the new Consumer Financial Protection Bureau when it passed the Dodd-Frank Wall Street Reform and Consumer Protection Act.

The RFA provisions have received universal support from lawmakers, but Congress needs to strengthen the law and close loopholes that agencies use to avoid its requirements. Unfortunately, agencies are able to avoid many important RFA requirements by simply asserting that a rule will not impact small businesses significantly. Only a small number of regulations require a regulatory flexibility analysis because "indirect effects" cannot be considered. In addition, despite the success of the small business panel process, it only applies to three agencies. The RFA's requirements are especially important to improving the quality of regulations and have saved billions of dollars in regulatory costs for small businesses. In February 2013, the Small Business Administration's (SBA) Office of Advocacy—an independent office helping federal agencies implement the RFA's provisions—issued its annual report indicating that it helped save small businesses more than $2.5 billion in new first-year regulatory costs. Imagine the positive impact on regulations if agencies were not able to avoid the RFA's requirements so easily.

The House has already passed legislation that would close many of the loopholes that agencies exploit to avoid the RFA's requirements. The House passed the Regulatory Flexibility Improvements Act of 2013 (H.R. 2542) as part of H.R. 2804, and the NAM supports reforms that would strengthen the RFA. Agency adherence to the RFA's requirements is important if regulations are to be designed in a way that protects the public, workers and the environment without placing unnecessary burdens on small businesses. Through careful analysis and an

understanding of both intended and unintended impacts on stakeholders, agencies can improve their rules for small entities, leading to improved regulations for everyone.

g. Enhance the Abilities of Institutions to Improve the Quality of Regulations

As discussed above, the SBA's Office of Advocacy plays an important role in ensuring that agencies thoughtfully consider small entities when promulgating regulations. When Congress created the office in 1976, it recognized the need for an independent body within the federal government whose job it was to be an advocate for those regulated entities most disproportionately impacted by federal rules. The office helps agencies write better, smarter and more effective regulations. We urge Congress to support this office and provide it with the resources it needs to carry out its important work.

The Office of Industry Analysis is within the Office of Manufacturing and Services at the Department of Commerce's International Trade Administration and was created to assess the cost competitiveness of American industry and the impact of proposed regulations on economic growth and job creation. The office was created in response to a 2003 executive branch initiative to improve the global competitiveness of the manufacturing sector in the United States and was included as a recommendation in a January 2004 report, titled *Manufacturing in America: A Comprehensive Strategy to Address the Challenges to U.S. Manufacturers*. The report stated the office should develop "the analytical tools and expertise . . . to assess the impact of proposed rules and regulations on economic growth and job creation before they are put into effect." This office has developed the analytical tools necessary to perform those functions and to provide the Department of Commerce with a strong, thoughtful voice within the interagency review of proposed regulations. The department must speak for manufacturing when rules are being considered. Unfortunately, the office no longer engages in the type of regulatory analysis for which it was established. The cost of regulatory compliance is an important factor influencing our competitive profile within the global economy. The Office of Industry Analysis was created to reduce the unnecessary regulatory burdens placed on domestic firms, and its role as a provider of objective, third-party analysis to regulators should be restored and strengthened.

V. Conclusion

Chairman Brady, Vice Chair Klobuchar and members of the committee, thank you for your leadership on these issues and for holding this hearing. We can reform the regulatory system and improve analysis while enhancing our ability to protect health, safety and the environment. Manufacturers are committed to working toward policies that will restore common sense to our broken and inflexible regulatory system. The best way to meet regulatory objectives while ensuring continued economic growth and employment is by enacting a comprehensive and consistent set of policies that improve regulatory analysis, enhance the quality and transparency of scientific and technical inputs, eliminate waste and duplication and support the institutions and policies that are working. These policies must be applied to all agencies, and we must ensure that regulators are sensitive to the needs of small business.

PREPARED STATEMENT OF MICHAEL GREENSTONE, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, NON-RESIDENT SENIOR FELLOW 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 and a non-resident 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 in today's economy, it is absolutely essential to design a regulatory structure that protects the well-being 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 and to wholeheartedly offer my support for Senate Bill 1472, "Strengthening Congressional Oversight of Regulatory Actions for Efficiency," that was introduced by Senator Klobuchar and is co-sponsored by Senator Collins and Senator King.

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 sicker and shorter lives for 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 interest 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

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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 (2013).

[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).

often face prolonged periods of unemployment and become reemployed at lower wages.[3]

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 it is how we have historically approached government regulations.

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, a regulation may end up imposing larger costs on businesses than suggested by the prospective analysis. 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 potentially 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

[3] Reed Walker, "The Transitional Costs of Sectoral Reallocation: Evidence From the Clean Air Act and the Workforce," *Quarterly Journal of Economics*, 2013, 128(4).

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. Creating a Regulatory Analysis Division Within the Congressional Budget Office

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. The non-partisan Congressional Budget Office (CBO) provides an appealing model.

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.

I believe that Senator Klobuchar's bill S.1472, which creates a Regulatory Analysis Division in the non-partisan CBO, is the best solution. This Regulatory Analysis Division 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.

A Regulatory Analysis Division within the CBO 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, a Regulatory Analysis Division of the CBO 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

[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*.

for a check list.[5] Such a checklist could also be issued as guidance by the Administration to its agencies.

Of course, the creation of a Regulatory Analysis Division would require resources, which are difficult to come by in our current fiscal environment. My best estimate is that it could be funded for less than $10–15 million annually. To put this in context, the current CBO budget is about $50 million annually.

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 quite small in comparison. My judgment is that it is very likely that a Regulatory Analysis Division would pay for itself many times over.

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 Regulatory Analysis Division within 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.

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[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).

[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).

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Testimony Prepared for the Joint Economic Committee of the U.S. Congress

Hearing Title: The First Step to Cutting Red Tape: Better Analysis

April 30, 2014

Dean Graham's Qualifications

My name is John D. Graham. I am Dean of the School of Public and Environmental Affairs (SPEA) at Indiana University and former Administrator of the Office of Information and Regulatory Affairs, OMB in the George W. Bush administration (2001-2006). SPEA is one of the largest schools of public affairs in the country. The new graduate-school rankings of U.S. News and World Report rate SPEA's Masters of Public Affairs (MPA) degree program as second in the country out of 266 total programs. Prior to serving at Indiana University and OMB, I was a tenured faculty member and founding director at the Center for Risk Analysis, Harvard School of Public Health (1985-2001).

My technical expertise is in the application of risk analysis and benefit-cost analysis to health, safety and environmental issues. I have published eight books and over two hundred articles in this field. Several years ago, I was awarded the Distinguished Lifetime Achievement Award by my professional society, the Society for Risk Analysis. I am also an elected member of the National Academy of Public Administration.

I earned my BA degree (economics and politics) at Wake Forest University (1978), my MA in public affairs at Duke University (1980), and my Ph.D. in public affairs at Carnegie-Mellon University (1983). My doctoral dissertation was a benefit-cost analysis of automobile airbag technology. Before joining the faculty of the Harvard School of Public Health in 1985, I was a post-doctoral fellow at Harvard in environmental health (1983-84).

SUMMARY OF MAJOR POINTS

The theme of my testimony today is that the federal government's regulatory system could be much more effective and economically efficient if regulatory policies were developed based on high-quality regulatory analyses. Those analyses encompass tools such as risk assessment, cost-effectiveness analysis, benefit-cost analysis, decision analysis, uncertainty analysis, and value-of-information analysis.

It is not enough for Congress to insist that regulatory analysis be undertaken.
A regulatory analysis is no better than the quality of data used in the analysis and the quality of the analytical procedures that are employed. Congress needs to insist that the federal government's standards for information quality be respected by regulators.

Moreover, Congress itself often passes legislation with ambitious regulatory requirements but Congress lacks an institutional mechanism to perform regulatory analysis on its own bills and amendments. For example, the high-quality analyses that the Congressional Budget Office has applied to the health care industry under the Affordable Care Act are rarely applied to regulatory legislation that impacts other economic sectors such as agriculture, chemicals, energy, finance, higher education, information technology and manufacturing. The European Parliament recently established a "regulatory impact assessment" (RIA) unit to check the informational power of the European Commission; the U.S. Congress needs to move in this directions as well. Thus, a comprehensive approach to better regulation must include a more evidence-based analytic approach in both Congress and the executive branch agencies.

With regard to legislative reforms, I make five basic points: (1) reform must cover all quasi-regulatory actions, not just rulemakings; (2) federal reform can (and should) address some costly and conflicting state and local regulations, not just federal rulemakings; (3) reform must address the quality of scientific information that supports official hazard determinations, not just federal regulations that may flow from hazard determinations; (4) reform must bring evidence, analysis, and transparency to the consent-decree process that often leads to mandatory rulemakings; and (5) reform must contain a push for regulatory cooperation between U.S. regulators and their counterparts in Europe and Asia, where our principal markets for exports are located.

I now turn to an explanation of each of these points.

First, federal regulators are issuing press releases, memoranda of understanding, policy statements, and guidance documents with burdensome impacts on specific industries, yet these quasi-regulatory actions are often not subject to any formal benefit-cost analysis and/or OIRA review.

A vivid illustration of this behavior is the recent use of quasi-regulatory documents by federal regulators to institute dramatic changes in the policy toward granting permits for surface coal mining operations in Appalachia, especially new mining projects in Kentucky, Ohio, Pennsylvania, and West Virginia. Before considering the policy change, I consider why mountaintop mining is undertaken in the first place.

Over the last twenty years, coal mining in Appalachia has changed due to new technology, efforts to minimize labor costs, and the safety concerns about underground mining. While the practice of underground mining still accounts for almost 60% of the coal mined in Appalachia, surface mining at the top of mountains -- often called "mountaintop mining" -- already accounts for more than 40% of the coal mined in Appalachia and 45% in West Virginia (NMA, 2009). The coal mined in Appalachia is used as fuel for electric power plants in the United States, as in input to iron making in the United States, and as a valuable export to countries in the world that cannot mine enough coal to meet their own needs for electric power and steel making.

Both forms of mining in Appalachia are associated with risk: underground mines, even when operated properly, entail a certain amount of risk to the safety of coal miners; mountaintop mining, even when conducted with proper reclamation practices, entails a risk of surface water contamination and ecosystem damage. Thus, there is no such thing as zero-risk coal mining.

Specific mining projects, including reclamation plans, need to be analyzed for benefit, risk, and cost, and this project-by-project analysis has historically occurred at the state level under guidance and oversight from federal officials at the Army Corps of Engineers/Department of Defense, the Department of Interior and the Environmental Protection Agency. From 2000 to 2008, for example, about 511 mining reclamation projects were approved in the state of West Virginia alone under procedures spelled out by the Army Corps of Engineers in Nationwide General Permit 21. A key principle of this Permit is that mountaintop mining may proceed as long as adverse aquatic impacts are minimized through reclamation and mitigation measures (Copeland, 2010).

Mountaintop mining is controversial because there are important stakes on both sides of the issue. It is estimated that the practice creates about 14,000 direct jobs and 60,000 indirect jobs, with average salaries ($66,000) that are relatively high for rural Appalachia. In the state of West Virginia alone, almost 10% of the state's tax revenue is linked to the economic stimulus of mountaintop mining (NMA, 2009).

On the other hand, by its very nature the practice of mountaintop mining has adverse ecological impact. The tops of mountains are leveled (to access coal seams) and the excess dirt and rock is disposed of in the valley fills on the sides of the mountains. Entire streams are often buried. Although only a small percentage of streams in Appalachia are impacted by mountaintop mining, the impacted streams are a significant environmental concern. In theory, mines are reclaimed and disrupted streams are mitigated on at least a one-to-one basis. Buried streams are replaced, or new streams are created in another location, or already degraded streams are improved. However, reclamation and mitigation efforts are sometimes inadequate, and continued damages are found after mines have been abandoned (GAO, 2010). Recent evidence suggests that even reclaimed areas can become a significant source of surface water contamination, and the extent of contamination is proportional to the amount of mountaintop mining in the area (Lindberg et al, 2011). In some cases, contamination continues almost two decades after reclamation plans were implemented. The impacted streams have been shown to experience aquatic toxicity and other forms of ecological damage (GAO, 2010). More study is needed to determine how the precise placement and treatment of rock spoil in valleys affects the mobility and transport of pollutants in impacted watersheds.

A big change in regulatory policy occurred soon after President Obama took office. In June 2009 EPA issued a press release entitled "Obama Administration Takes Unprecedented Steps to Reduce Environmental Impacts of Mountaintop Coal Mining, Announces Interagency Action Plan to Implement Reform" (EPA, 2009). A memorandum of understanding signed by EPA, the Corps and the Office of Surface Mining and Reclamation and Enforcement (OSM) in the Interior Department accompanied the press release. Although the interagency plan contained a significant shift from existing regulatory policy defined in the Corps Nationwide General Permit 21, there was no prior request for public comment on the new plan and no benefit-cost analysis was conducted to support the major shift in policy toward more restrictions on mountaintop mining. While the Corps did formally propose a suspension of General Permit 21 (as applied to mountaintop mining) in July 2009 (EPA, 2009), the action was not finalized until June 2010, many months after regulators had changed their approach to issuing permits (EPA, 2010).

Basically, the Obama administration authorized EPA to make project-by-project determinations on water-quality issues rather than rely primarily on the states and the Army Corps of Engineers. Industry complained that the criteria for EPA's project-by-project determinations were not clear, and thus developers of mining projects did not know what was expected of them (Fahrenthold, 2010). Ultimately, after many months of uncertainty, on April 21, 2010, EPA issued a 31-page guidance document that did not prohibit mountaintop mining but called for minimal or no filling of valleys with mining debris (EPA, 2010). The guidance was effective immediately, even though no public comments were solicited and no benefit-cost analysis was undertaken. In particular, the new guidance expects mining projects to adhere to strict limits on

conductivity levels in streams (a measure of salinity in water). But EPA's numeric approach was based on two draft scientific documents that were not yet finalized (Copeland, 2012).

A year earlier (October 2009), EPA also stunned the industry by reversing a 2007 decision of the Army Corps of Engineers to approve a 2,300-acre mining operation in Logan County, West Virginia (Ward, 2009; Copeland, 2010). The Spruce #1 Mine in Logan County, which had been scaled back to address environmental concerns, was still the largest mountaintop removal mine in West Virginia history (Ward, 2009). Meanwhile, EPA took more than a year to make decisions on 175 proposed mining sites. It ultimately signed off on only 48 (EPA IG, 2011; Quinones, 2011; Fahrenthold, 2010). EPA argued that it was using legal authority under the Clean Water Act and its new technical approach to assessing water quality impacts. The industry countered that EPA's new, unprecedented regulatory approach would effectively prohibit a majority of surface coal mining in Appalachia, and the entire matter is now the subject of expensive, time consuming litigation in multiple federal courts (Copeland, 2011).

A key lesson from this example is that changes in regulatory policy accomplished through press releases, memoranda of understanding, policy statements and guidance documents can have the same costly impact, at least in the short run, as an official rulemaking under the Administrative Procedure Act. Congress should require agencies, when making significant shifts in regulatory policy, to support those shifts with a benefit-cost analysis that is informed by a public comment process. In effect, what is now required for rulemakings should apply to regulatory policy shifts initiated through press releases, memoranda of understanding, policy statements, and guidance documents.

Second, federal regulators are refusing to use their power to restrict or reform regulatory activities by the states that are unnecessarily costly to industry. Of particular concern are arbitrary inconsistencies in state regulations that burden companies that sell products across state lines. In some cases, federal regulators collaborate with state regulators in the promulgation of overly costly rules that completely evade benefit-cost requirements and/or OIRA review.

A sobering example of this behavior is the recent decision of federal regulators to allow the State of California to require that automakers produce an increasing number of zero-emission vehicles (ZEVs) from 2018 to 2025. (As a practical matter, a ZEV under California criteria is likely to be a plug-in vehicle that is powered entirely or partly by electricity, though some hydrogen-powered vehicles also qualify). By 2025, each major automaker doing business in California is required to sell enough ZEVs to comprise at least 15% of their new-vehicle sales in California (CARB, 2011). Since the cost of producing a ZEV is currently $10,000 to $20,000 per vehicle greater than the cost of producing a similar gasoline-powered vehicle, the ZEV program is certainly worth reviewing from a cost-benefit perspective. If California succeeds in compelling the sale of 1.4 million ZEVs by 2025 at an extra cost of $10,000 per vehicle, the overall cost to consumers will be in the neighborhood of $14 billion.

According to the State of California, the ZEV program is evolving from a traditional focus on public health protection from localized air pollution (smog and soot) to a new focus on control of greenhouse gases linked to the global phenomenon of climate change. Both rationales remain

but, due to the dramatic progress in reducing smog and soot from new gasoline-powered vehicles, California regulators acknowledge that the future rationale for the ZEV program will be the control of greenhouse gases (CARB, 2011).

Under the national Clean Air Act, California regulators are given special regulatory privileges because of the poor air quality in southern California but California is not permitted to issue its own rules without permission from the federal government. Congress wanted to make sure that California's regulatory actions are necessary and appropriate, since automakers might be forced to design and produce a different fleet of cars and trucks for California than for other states. (There are about ten states that have chosen to align with California's standards but I shall simplify the presentation by referring to compliance in California). Moreover, the statute underpinning the Department of Transportation's Corporate Average Fuel Economy (CAFE) program prohibits all 50 states (including California) from adopting any regulatory programs "related to" the fuel economy of vehicles, since that is the province of CAFE. There may be creative legal arguments that can rescue an unnecessary and costly California ZEV program from litigation trouble, but surely Congress, through new legislation, has the power to subject California's ZEV program to serious cost-benefit analysis and OIRA review under a national regulatory reform statute. So the key legislative questions are: Is the California ZEV program necessary and appropriate, and does it have any plausible benefit-cost justification?

The case for the California ZEV rule is certainly questionable, given the force of the following arguments:

--California regulators cannot slow global climate change to a meaningful degree unless China and India control their greenhouse gas emissions but the California ZEV program does not -- and cannot -- cover China and India;

--The Obama administration, through a joint rulemaking of EPA and DOT, has already mandated a sharp reduction in greenhouse gases from new cars and light trucks for model years 2017 to 2025 through a performance standard, a numeric standard based on carbon emissions that allows automakers to undertake some averaging of low-emitting and high-emitting vehicles (EPA-NHTSA, 2011);

--The joint EPA-DOT rule already provides generous compliance incentives for manufacturers who offer ZEVs (e.g., a ZEV's "upstream" emissions at the electric power plant are ignored and each ZEV may be counted more than once in the compliance process) to supplement the federal government's generous $7500 income tax credit to purchasers of ZEV-like vehicles;

--The California ZEV program may not accomplish additional greenhouse-gas control (beyond the control achieved by the EPA-DOT joint rule) because any extra ZEVs produced and sold due to California's rule will be offset in the production plans of automakers by extra sales of more high-emitting vehicles in the 50 states covered by the EPA-DOT rule; and

--The California ZEV program, by forcing automakers to sell more expensive vehicles that are cheaper to operate, will exacerbate greenhouse gas emissions due to two perverse behavioral responses: some consumers will hold on to their old, high-emitting vehicles longer than they

would otherwise (Gruenspecht, 2001), and those consumers who do purchase an expensive ZEV will drive them more miles each year because electricity is cheaper than gasoline (Tierney, 2011; Bialik, 2009).

Even if these arguments are overstated, and the ZEV program is determined to be a promising contributor to global greenhouse gas control, it is highly unlikely that the program would pass a cost-benefit test under the official technical guidance in OMB Circular A-4, which governs regulatory analysis in the federal government.

The staff of the California Air Resources Board released in December 2011 a rudimentary analysis aimed at providing some analytic justification for the tighter ZEV requirements for model years 2018 to 2025. The basic result of the staff analysis is that the energy savings provided by ZEVs, accumulated over the vehicle's life, are about equal to the $10,000 additional cost of producing a ZEV (CARB, 2011, Table 5.7).

The State of California does not have an OIRA-like office and thus CARB staff have considerable analytic discretion, more than EPA or DOT analysts have. Based on a careful read of the CARB analysis, I noted several analytical assumptions that would be unlikely to survive a careful OIRA review under OMB Circular A-4.

1. The cost of producing ZEVs will decline by about 40% between today and 2025 due to learning by doing in the manufacturing process. The 40% figure is at the top of the range of estimates in the literature on learning by doing in the manufacturing sector. However, the battery advances necessary to satisfy the consumer's demand for driving range may cause the cost of future ZEVs to increase, not decline. CARB staff have also ignored the possible increase in prices of rare earths and lithium -- these are inputs to lithium ion batteries and electric motors -- that may result from Chinese actions, once the U.S. transport sector becomes significantly dependent on ZEVs. Rare earths and lithium currently account for a small percentage of the cost of producing a ZEV but that percentage could rise significantly in ways that are difficult for the United States to control. The Obama administration has recently joined with the EU and other nations in a WTO action against China, citing Chinese price manipulation of rare earths through export restrictions (Lee, 2012).

2. The ZEV will last for an average of 14 years and be driven for 186,000 miles. These figures are on the high end of the range of estimates of average light-duty vehicle lifetime and mileage.

3. A 5% real discount rate is applied to future fuel savings to express them in present value. A 7% discount rate is typically applied to future fuel savings. Changing this assumption alone is likely to reverse the conclusion of CARB's "payback analysis".

4. A long-term gasoline price of $4 per gallon is assumed. This figure could be too low or too high in the short run but fuel prices in the USA can be brought well below $4 per gallon over the 2018-2050 period if the US enacts enlightened energy policies (e.g., expanded oil and gas production in the USA in conjunction with the tighter CAFE standards and other consumer-focused conservation measures to reduce demand for oil).

Overall, based on the implausibility of CARB's assumptions, it seems unlikely that a ZEV mandate would pass a careful payback analysis from the consumer's perspective, at least not ZEVs produced in the pre-2025 period. Consumers may be further disinclined to purchase PEVs if the federal and state tax incentives are reduced for fiscal reasons (California has already reduced its ZEV rebate from $5,000 to $2,500 and the U.S. Congress has not renewed the $2,000 tax credit for the costs of installing a recharging system in one's home).

If ZEVs prove to be a loser in the eyes of the consumer, automakers and dealers will have a difficult time selling them. The early commercial experiences with the Nissan Leaf and the Chevrolet Volt suggest that commercialization of ZEVs will not be easy. Moreover, surveys of consumers indicate that they are not willing to pay a large price premium to obtain the advantages of a plug-in vehicle (White, 2012; Woodyard, 2011; Child and Sedgwick, 2012). Under these circumstances, either the ZEV mandate will have to be relaxed (as has occurred in the past) or automakers and dealers will have to cut prices of ZEVs, incur substantial losses on each ZEV that is sold, and raise prices on all non-ZEV products to cover the losses. In effect, the ZEV mandate will become a price increase on all new vehicles sold in the United States (a troubling scenario that is acknowledged in the CARB document). If this occurs, the result will be fewer new vehicle sales throughout the United States and fewer jobs at plants where new non-ZEV vehicles are produced and at plants of suppliers of non-ZEV vehicles.

The job losses from the ZEV mandate are unlikely to occur in the State of California because very few automotive suppliers and vehicle assembly plants are located in California. This is a point noted in the CARB document. Here are some examples of plants that might be adversely impacted, since they are busiest North American plants that assemble non-ZEV vehicles (measured by 2011 production levels).

1. VW/Puebla, Mexico 514,910
2. Ford/Kansas City, Missouri 460,338
3. Nissan/Aguascalientes, Mexico 410,693
4. GM/Oshawa, Ontario 380,149
5. Ford/Dearborn, Michigan 343,888
6. Hyundai/Montgomery, Alabama 342,162
7. Nissan/Smyrna, Tennessee 333,392
8. Ford/Hermosillo, Mexico 328,599
9. Toyota/Georgetown, Kentucky 315,889
10. Ford/Louisville, Kentucky 310,270

The supplier community for non-ZEV vehicles also has a broad geographic distribution (including many plants outside the United States) but many suppliers locate their plants near assembly plants in the United States (e.g., in the Midwest and the South).

The CARB analysis does not make employment forecasts outside of California with and without the ZEV regulation. CARB does, however, forecast positive job impacts in California because a variety of the companies that makes recharging equipment for electric vehicles are located in California (CARB, 2011, 68-9). I think it is fair to say that the employment analysis of the

California ZEV mandate, if had been conducted under OIRA review, would have looked at many more regions of the United States than the state of California.

In summary, federal regulators have permitted the State of California to promulgate a costly ZEV mandate that, in reality, may do little or nothing to protect the world against the forces of global climate change. The economic impacts of the California program are likely to be significant and nationwide in scope. A comprehensive benefit-cost analysis of the ZEV program has not yet been performed, yet the program is already on a clear path toward implementation.

Congress can address this problem in a general regulatory reform bill. In particular, federal agencies should be required to use their powers to restrict or reform state regulatory actions to ensure that regulatory benefits justify costs. When a federal agency decides to allow state regulators to issue rules with national economic ramifications, the agency should be required to justify the decision with a benefit-cost analysis under OMB Circular A-4.

Third, federal regulators are issuing hazard determinations that appear to be at tension with findings reported by committees of the U.S. National Research Council/National Academy of Sciences. A hazard determination is a claim that exposure to a technology or chemical substance is known to be hazardous to human health. Congress can address this problem by requiring OIRA and/or the White House Office of Science and Technology Policy (OSTP) to resolve disputes about hazard, at least in cases where there have been clear determinations by NRC/NAS.

The federal government's recent handling of formaldehyde illustrates this conundrum. Formaldehyde is a widely used industrial chemical that is useful in activities ranging from housing construction to health care services. Each year sales of formaldehyde are worth about $1.5 billion and products that make use of formaldehyde are linked to about four million jobs and $145 billion in economic activity. It is estimated that, if formaldehyde had to be substituted in the U.S. economy, consumers would incur costs of about $17 billion per year. The industrial sector where formaldehyde generates its largest economic value is the housing industry.

Human exposures to formaldehyde are already heavily regulated by multiple federal agencies because high doses of formaldehyde are known to cause irritation of the respiratory system and a rare form of nasal cancer. Spurred by a provocative report (IARC, 2004) from an international organization in Lyon, France, EPA -- through the Integrated Risk Information System -- made a preliminary determination in 2010 that formaldehyde exposure is known to cause leukemia as well as nasal cancer (EPA, 2010). If the scientific evidence is definitive, EPA should make a definitive hazard determination, since it may help trigger a variety of regulatory and market-based actions that offer additional protection to workers, consumers, and the general public.

A hazard determination should not, however, be based on inconclusive scientific information. An official determination that formaldehyde exposure causes leukemia has the potential to cause a variety of adverse impacts on industry (e.g., lawsuits among people who have leukemia and may have been exposed to formaldehyde, and voluntary product withdrawals), even before any new federal regulation is adopted. The stigma of a hazard

determination, once imposed, is very difficult to erase, even if the technology or substance is completely exonerated through additional scientific research.

In this case, industrial scientists were skeptical of EPA's preliminary determination because the epidemiological literature on formaldehyde is difficult to interpret with confidence and the biological mechanism (i.e., how formaldehyde causes leukemia) is not clear. They persuaded Congress to compel EPA to subject their scientific evidence and reasoning to independent review by a panel of the National Research Council/National Academy of Sciences, an official scientific advisory group to the federal government. In a rather critical report, the NRC/NAS panel raised serious questions about EPA's theory that formaldehyde exposure causes leukemia while reaffirming the known link between formaldehyde exposure and respiratory cancer (NRC, 2011; Jacobs, 2011). NRC/NAS also raised broader questions about the scientific credibility of EPA's IRIS process since there is a pattern of NRC/NAS questions about EPA's hazard determinations (e.g., in the cases of dioxin and perchlorate).

Before EPA could respond to the NAS/NRC report, an entirely different federal agency -- the Department of Health and Human Services' National Toxicology Program (HHS-NTP) -- included in its Annual Report to Congress an addendum on formaldehyde. The addendum makes a strong claim about the formaldehyde-leukemia link that is similar to the preliminary EPA claim (NTP, 2011). NTP makes a limited effort to reconcile its view with the view of NRC/NAS but ultimately acknowledges that it agrees with NRC/NAS's view that it is not known -- from a biological mode of action perspective -- how formaldehyde is causing leukemia. NTP takes the position that a substance can be known to cause cancer even if the biological mode of action is unknown.

A key question becomes who in the federal government should be in charge of managing and resolving these issues. The actions of EPA and HHS-NTP may not appear to be "regulations" but they are "science-policy" determinations that can have the practical impact of a regulation (e.g., economic burdens). Before making these kinds of determinations, agencies should be expected to make an assessment of whether significant economic impact may result. If the impact is likely to be significant, an independent review by an organization such as NRC/NAS should be required, and federal agency compliance with the findings of the NRC/NAS panel should be overseen by OIRA and/or OSTP in consultation with other interested federal agencies.

In order to play this role effectively, OIRA and OSTP will need a modest increase in scientific staffing above their current levels. However, it is important to recognize that the roles of OIRA and OSTP are not to redo the agency's hazard determination. Instead, the OIRA/OSTP role is to determine whether a hazard determination should be referred to NRC/NAS and, if so, whether the agency has adhered to the determinations made by NRC/NAS in the agency's final determination. OIRA and OSTP will also supervise interagency discussions of these matters, since multiple federal agencies may have an interest.

Fourth, federal regulators, after being sued by pro- or anti-regulation activist groups, are entering into binding agreements with litigants that call for new rulemakings within specified deadlines. The rulemaking commitments are being made prior to any benefit-cost analysis or public comment and without OIRA review. Sometimes the deadlines are set in a manner that

ensures that benefit-cost analysis and OIRA review will be compromised. Congress should constrain agency powers to enter into such settlements without first conducting appropriate analysis (to determine whether a rule is necessary and desirable) and seeking public comment. Congress should require that ample time be made available for OIRA review.

During my tenure at OMB, I experienced the consequences of "regulation by consent decree" on several occasions. For example, EPA entered into a litigation settlement that virtually committed the agency to an expensive rulemaking aimed at reducing mercury emissions from coal-fired power plants. When EPA staff briefed me on the benefit-cost basis for the mercury rule, it became clear that many of the emissions reductions expected from the mercury rule were already to be accomplished by another rule aimed at reducing nitrogen dioxide emissions from coal plants. (The same control technology that reduces nitrogen dioxide also reduces oxidized mercury but not elemental mercury). According to EPA staff, the residual benefits (of reducing elemental mercury) were not sufficient to justify the entire cost of the mercury rule, yet the agency was legally committed to issuing a rule by a fixed deadline, and expectations for a rule had been established in the environmental advocacy community. EPA tried to craft a different rationale for the mercury rule based on the "co-benefits" resulting from simultaneous control of a different pollutant, particulate matter. In principle, co-benefits should be considered in such a rulemaking. The obvious counterargument to this position is that direct regulation of particulate matter from many sources (not just coal plants) might be a more cost-effective method of capturing those benefits. With a judicial deadline forcing our hand, we did work with EPA to issue a mercury rule but it had a weak benefit-cost justification. The rule was ultimately overturned in court for reasons unrelated to the benefit-cost issue.

The lesson I drew from this example is that regulators are not necessarily reluctant, during settlement negotiations, to commit themselves to rulemakings that have not yet been analyzed from a cost-benefit perspective. If we are serious about regulatory reform, this practice needs to be restrained.

Finally, regulatory reform needs to compel regulators to fashion rules in ways that facilitate international trade between countries through (a) sharing of best regulatory analysis practices across countries, (b) harmonization efforts on specific regulatory programs, and (c) mutual recognition pacts when regulatory systems are different but neither trading partner can demonstrate that its regulations are more effective or protective.

The World Trade Organization (WTO) is a useful international body but, by itself, it is not very effective at preventing or eliminating the non-tariff barriers that that raise the cost to businesses of operating around the world. WTO operates only after abuses occur; the proceedings take years to reach resolution; and WTO has only limited powers to enforce compliance with its decisions. For example, the U.S. has won at least two cases against Europe in the agricultural sector (one case on hormone-treatment of animals to boost dairy production and one on genetic modification of seeds to enhance corn and soybean production) but Europe has been very slow to open its markets in response to these WTO decisions. Another U.S. case against Europe concerning a ban on importation of U.S. poultry is underway but resolution is years away.

Congress needs to push the executive branch to minimize regulatory conflicts from the outset (when new regulations are developed) and work steadily to harmonize the existing regulatory systems. Congress itself needs to consider trade ramifications when it adopts new regulatory legislation. For example, the Toxic Substances Control Act of 1976 is currently a suitable topic for modernization. Careful thought needs to be given to how a new federal regulatory system for industrial chemicals should be designed to protect public health while facilitating trade with Canada, Europe, and Japan, where chemical regulatory systems have already been redesigned and are being implemented. Since many of the same chemicals and products are used in all these countries, it does not make sense to reinvent the wheel in each country or region.

President Obama should be applauded for moving in this direction with his call for a new free trade agreement with Europe. The Obama administration recognizes that there are only a few remaining tariff barriers that obstruct trade between Europe and the United States. The key obstacles to trade are primarily non-tariff barriers created by inconsistent regulatory systems.

The complexity of this challenge is now being confronted by Europe and the US in the field of automobile regulation. European and U.S. regulators have gone in different directions on hundreds of regulations covering tires, lights, brakes, safety belts, airbags, fuel economy, carbon emissions, and diesel engine exhaust, to name a just a few areas. EU and U.S. regulators disagree not only on the precise stringency of the regulatory requirements but the test procedures used to define compliance (e.g., how should a crash dummy used in a compliance test be designed? Should the dummy be wearing a safety belt when the compliance test is conducted – Europe says "yes", the US says "no"?). Sometimes the EU rules are more stringent (carbon emissions); sometimes the U.S. rules are more stringent (diesel exhaust, especially in California).

Despite the numerous differences, no one has ever demonstrated that, overall, US vehicles are safer or cleaner than European vehicles or vice versa. Under these conditions, it may make sense for Europe and the USA to explore a mutual recognition agreement that allows European-certified vehicles to be sold in the USA and American vehicles to be sold in Europe. Since automotive manufacturers are striving to use a single production platform for vehicles sold around the world, mutual recognition systems would be compatible with the efficient trend toward globalized manufacturing. In the long run, more efficient automotive production systems mean not only lower prices for cars in Europe and the United States but more affordable vehicles for consumers in emerging economies, whose needs can also be served with a single global production platform.

Thank you for the opportunity to submit this testimony.

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PREPARED STATEMENT OF SHAYE R. MANDLE, EVP & COO, LIFESCIENCE ALLEY

Vice-Chair Klobuchar, Chairman Brady, Members of the Committee—thank you for the opportunity to testify before you this morning. My name is Shaye Mandle and, tomorrow, I will take over as President & CEO of LifeScience Alley, the nation's largest regional life science association. This year, LifeScience Alley celebrates our 30th anniversary of leading Minnesota's Medical Alley—the most densely concentrated medical technology cluster in the world and home to some of history's greatest therapeutic and healthcare innovations. Our members include 3M, Medtronic, Boston Scientific, St. Jude Medical, Covidien, Endo/AMS, Mayo Clinic and hundreds of small companies that will bring new innovation to the healthcare marketplace. Before we get started, I would like to personally thank Senator Klobuchar for her leadership and advocacy on behalf of patients and our companies who serve them, especially for those of us who call Minnesota home.

Today, this committee is interested in taking the first step to cutting red tape through better analysis. We agree that better analysis is needed and that a regulatory environment that is smarter and more collaborative would serve patients and the U.S. healthcare system well. It is also important for broad-based analysis of the entire ecosystem, including tax and regulatory policy. It is critical for Congress to address repeal of the medical device tax if we want to keep our jobs and competitive advantage, as well as providing a permanent fix to the FDA user fees and sequestration issue, to ensure that FDA has access to the funds committed by industry.

In 1957, Earl Bakken and Medtronic introduced the first battery operated external pacemaker. In 1976, the Federal Food, Drug and Cosmetics Act was amended to include the regulation of medical devices. At the beginning, innovation came from doctors and engineers working together to save lives. For the first 25 years of medical technology innovation there was no FDA oversight.

Is it our position that medical devices shouldn't be regulated? Quite the contrary. When medical devices were added to the FDA's regulatory responsibility, something unique happened. An agency with no expertise in the field connected with the patients, doctors, and innovators to form a collaborative relationship. If you talk to anyone from industry or the FDA from the early years of regulation, they will amaze you with stories of working together to accomplish a shared goal—delivering the safest and most effective therapies in the world to the patients whose lives depended on them.

Both the medical device industry and the FDA want the same outcome—safe and effective devices, invented in the U.S., and available in the U.S. first. For a couple of decades, this is exactly what we got. Over the past decade or so, this dynamic has changed and an adversarial relationship emerged.

As a result, patients outside of the U.S. frequently gain access to innovation and technology before American patients do. In fact, Eucomed claims that European patients get innovative technologies 3–5 years earlier than U.S. patients. They even have a website called "Don't Lose the 3," as in the 3 years of therapeutic advantage that European patients have over their U.S. counterparts.

But, things are improving. Passage of FDASIA in 2012 was a welcome update to our regulatory environment and MDUFA III should promote a more collaborative and effective pathway to approval. This legislation, if fully implemented as intended, will be a real benefit for patients, innovation and our economy. The FDA is working hard to collaborate with industry and is focusing on practical priorities, including 1) improving efficiency in clinical trials 2) balancing the premarket and post market process, and 3) identifying ways to shorten the lag between product approval by the FDA and reimbursement approval by CMS and/or private payers.

Dynamic public-private solutions are also happening. Since 2011, LifeScience Alley has worked closely with CDRH Director Jeff Shuren to find a solution that would re-engage the agency and industry in a conversation of collaboration and cooperation. As a result, we created the Medical Device Innovation Consortium, a public-private partnership that still has its roots in Minnesota, but now includes a national consortium from industry and key members from government, including CMS and the NIH. Through the MDIC, we are working to identify opportunities for technical collaboration in the pre-competitive space, where industry and the FDA can work together to share knowledge and improve the regulatory environment.

Better analysis means constant improvement. As one the few U.S. industries with a positive trade balance and an average wage of more than $70,000 annually, the medical device industry is a U.S. success story. Regulation is vital. Smart regulation is even more vital. We look forward to working with this committee to ensure that the U.S. regulatory environment represents the safest and smartest in the world. Thank you!

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