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EXAMINING THE USE OF AGENCY REGULATORY GUIDANCE, PART II

HEARING

BEFORE THE

SUBCOMMITTEE ON
REGULATORY AFFAIRS AND FEDERAL
MANAGEMENT

OF THE

COMMITTEE ON
HOMELAND SECURITY AND
GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

ONE HUNDRED FOURTEENTH CONGRESS

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CONTENTS

	Page
Opening statement:	
Senator Lankford	1
Senator Heitkamp	2
Senator Ernst	9
Prepared statement:	
Senator Heitkamp	31

WITNESSES

THURSDAY, JUNE 30, 2016

Paul Noe, Vice President, Public Policy, American Forest and Paper Association and American Wood Counsel	4
Clyde Wayne Crews, Vice President for Policy, Competitive Enterprise Institute	5
Amit Narang, Regulatory Policy Advocate, Public Ciziten	7

ALPHABETICAL LIST OF WITNESSES

Crews, Clyde Wayne:	
Testimony	5
Prepared statement	41
Narang, Amit:	
Testimony	7
Prepared statement with attachment	93
Noe, Paul:	
Testimony	4
Prepared statement	32

APPENDIX

Responses to post-hearing questions for the Record:	
Mr. Noe	144
Mr. Crews	148
Mr. Narang	153

EXAMINING THE USE OF AGENCY REGULATORY GUIDANCE, PART II

THURSDAY, JUNE 30, 2016

U.S. SENATE,
SUBCOMMITTEE ON REGULATORY,
AFFAIRS AND FEDERAL MANAGEMENT,
OF THE COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 9 a.m., in room SD–342, Dirksen Senate Office Building, Hon. James Lankford, Chairman of the Subcommittee, presiding.

Present: Senators Lankford, Ernst, and Heitkamp.

OPENING STATEMENT OF SENATOR LANKFORD

Senator LANKFORD. Good morning. Welcome to today's Subcommittee hearing, "Examining the Use of Agency Regulatory Guidance, Part II." Doesn't that sound exciting? The sequel is always better than the first, right? [Laughter.]

This hearing builds on our oversight of the subject, including the hearing held last September.

Guidance is one of the most common ways that agencies communicate to stakeholders and the American public their interpretations of the statutes and regulations they administer and enforce. However, guidance receives little congressional oversight. A major reason why guidance attracts so little oversight is because guidance is hard to pin down, quite frankly.

In the positive, what is guidance as opposed to what it is not? Guidance, for example, is not a rule since it is not promulgated pursuant to the requirements of the Administrative Procedure Act (APA). Therefore, guidance cannot bind the public in any way that the regulation it interprets could not. Congress specifically exempted guidance documents from APA's rulemaking requirements because Congress saw the need for agencies to issue timely information to affected parties.

And timely information is indeed useful when it is used to clarify existing regulatory authorities, a need which has become even more apparent with the increasing complexity of the administrative state.

Small businesses, schools, and other regulated parties want to know how they must comply with Federal requirements, but it is also hard to tell when a guidance document merely clarifies existing regulatory authority as opposed to when it advances new sub-

stantive policies, polices that should have been subjected to the rigor of the rulemaking process.

Why is this distinction between guidance and regulation so important? Because guidance can be changed at the whim of an agency as an administration's policy preferences change. Guidance is additionally problematic because it comes by many names, and agencies do not post them centrally. Therefore, we cannot fully know how many of these documents exist or the economic effects of their instructions.

To the extent that agencies can get away with improperly issuing guidance documents, any administration, Republican or Democrat, can advance policies while running roughshod over procedures Congress has enacted to ensure broad public input and agency accountability. This results in unlawful procedure, uncertainty, unaccountability, inconsistency, and a startling lack of transparency.

Today we have witnesses with expertise in administrative law and institutional experience in overseeing and coordinating guidance processes. I hope to have a conversation about how we in Congress can better understand the role of guidance, the regulatory process, and the problems posed by improperly issued guidance documents.

With that, I recognize Ranking Member Heitkamp for her opening statement.

OPENING STATEMENT OF SENATOR HEITKAMP

Senator HEITKAMP. Thanks, Chairman Lankford.

And thank you all for coming in. It is the hardworking red-headed committee, I want you to know. [Laughter.]

I am sorry, Joni.

Senator LANKFORD. Joni is an honorary Member today.

Senator HEITKAMP. She is. Of course, we do not know what color her hair used to be, but I think we are going to call you a redhead. [Laughter.]

Thanks so much for coming in. This is a touchy subject because when you look at guidance, on one hand, it can be critically important to helping agencies kind of clarify their position, giving greater direction and knowledge to those who are regulated. But on the other hand, it can be used as a shortcut. And we have seen it used both ways, and one of the great challenges that we have is trying to figure out how we are going to balance those two things.

And as Chairman Lankford said, what are we going to do to actually get to the point where we feel comfortable here that guidance is not used as a shortcut to reinvent or to restate current regulation in a way that is inconsistent with either the law or inconsistent with past regulation?

And so I am going to just submit my opening statement for the record[1] and welcome you all, but tell you that that really is the challenge that we have on this Committee, is trying to figure out—because we have seen it both ways—trying to figure out how we do what we are supposed to do, which is provide oversight over agencies, but also give both the regulators and the regulated the

[1] The prepared statement of Senator Heitkamp appears in the Appendix on page 31.

option to have clarification. That can be enormously useful, especially in the business world.

Senator LANKFORD. Great. Thank you.

At this time we will proceed with testimony from our witnesses.

Paul Noe is the Vice President for Public Policy at the American Forest & Paper Association (AF&PA). Mr. Noe works on a wide variety of issues, including regulatory reform, renewable energy, environmental regulation, workplace health and safety.

Mr. Noe served as a counselor to the Administrator of the Office of Information and Regulatory Affairs (OIRA), where he helped lead the development of regulatory policy and the White House review of regulation in the George W. Bush Administration.

He also served as senior counsel to the Senate Committee on Governmental Affairs, focusing on regulatory improvement. Mr. Noe co-chairs the American Bar Association's (ABA) Administrative Law and Regulatory Practice Committee on Legislation and has published on the topic of regulatory policy.

Wayne Crews is the Vice President for Policy, and Director of Technology Studies at the Competitive Enterprise Institute (CEI), focusing on the impact of government regulation, anti-trust, and competition in environmental and privacy issues. Mr. Crews publishes an annual report on the Federal regulatory State called "Ten Thousand Commandments" and has written and edited many books.

Prior to joining CEI, Mr. Crews worked at the Cato Institute, the U.S. Senate, and the Food and Drug Administration (FDA).

Amit Narang is the Regulatory Policy Advocate for the Public Citizen's Congress Watch Division. I do not know why that would be so hard. He focuses on Federal regulatory process and has testified many times before Congress on legislative proposals and oversight of Federal agencies as it relates to the rulemaking process. He has been quoted in many media outlets and has appeared on television and radio broadcasts.

Mr. Narang also serves on the Advisory Board of the Administrative Law Review.

I would like to thank all of our witnesses today for coming, and I appreciate your expertise and your preparation time to actually submit the written testimony ahead of time.

It is the custom of this Subcommittee to swear all witnesses in, so I would ask you to please stand and raise your right hand.

Do you swear the testimony you will give before this Committee will be the truth, the whole truth and nothing but the truth, so help you, God?

Mr. NARANG. I do.

Mr. CREWS. I do.

Mr. NOE. I do.

Senator LANKFORD. Thank you. You may be seated. Let the record reflect all the witnesses answered in the affirmative.

We are using a timing system today so we can have ample time for us to pepper you with questions. So if you would, we will start with Paul Noe and ask you to go first. There will be a timing device there in front of you. Be as close to 5 minutes as you can. Obviously, if you go a little bit over we are fine. If you go under, you get bonus points. [Laughter.]

Fair enough?

Mr. NOE. Thank you, Mr. Chairman.

Senator LANKFORD. Mr. Noe, you are recognized.

TESTIMONY OF PAUL NOE,[1] VICE PRESIDENT, PUBLIC POLICY, AMERICAN FOREST & PAPER ASSOCIATION AND AMERICAN WOOD COUNCIL

Mr. NOE. Chairman Lankford, Ranking Member Heitkamp, and Senator Ernst, thank you for the opportunity and the honor to testify before you today.

The issue of agency use of guidance is an important and timely issue, and AF&PA and American Wood Council (AWC) greatly appreciate the fact that you are doing the hard work of oversight in grappling with these issues to make a better regulatory process, and that is very commendable.

I just wanted to note at the beginning that my wife, Wendy, and my children, Helen and John, are here to see the hearing today. And Wendy has put up with me for over 20 years talking about these issues at home. And my kids are kind of puzzled about what I do for a living, so I thought it would be good to show them today's hearing.

The issue of agency use of guidance was a concern back when I worked as senior counsel of this Committee under Chairman Fred Thompson, Ted Stevens, and Bill Roth, and when I was at the Office of Management and Budget (OMB) as a counselor to Administrator John Graham. And I can tell you from working for regulated industries that this is much more than an academic issue. It has profound consequences for the functioning of the regulatory process, important economic and also social consequences. And AF&PA and AWC applaud the work that you are doing and we hope further improvements can be made.

Simply put, we face a fundamental problem. We have had a well-established process for the review of regulations that has worked for over 35 years, with oversight from the Office of Management and Budget, but that process is quite deficient when it comes to guidance documents.

Originally, the Executive Order (EO) that President Reagan issued governing regulatory review and OMB oversight covered all rules. And by that I mean not only legislative rules known as regulations but also guidance documents in the form of interpretive rules and agency statements of policy.

When President Clinton came into office, he replaced that order with Executive Order 12866. And that order attempted to just focus on significant regulations, but the problem is it neglected guidance documents. By its own terms, it only applied to rules that, "the agency intends to have the force and effect of law." So that excluded guidance documents.

An attempt was made to address this issue, and the Administration of George W. Bush took two steps. First, OMB issued a Bulletin for Agency Good Guidance Practices. And simply put, it has a few basic elements.

[1] The prepared statement of Mr. Noe appears in the Appendix on page 32.

First, agency procedures for the approval and use of significant guidance documents, with approval by appropriate senior officials and direction that agency employees should not depart from guidance without appropriate justification and supervisory concurrence.

Second, there were standard elements, including that the agency employees were directed to avoid inappropriate, binding, mandatory language in guidance.

And third, there were public access and transparency and feedback procedures. There was the basic presumption that there ought to be pre-adoption notice and comment if a guidance was going to have a particularly significant impact—economically significant guidance.

This Bulletin was rooted in the recommendations of nonpartisan expert organizations that have stood for decades. It was not controversial. When President Obama came into office he retained the OMB Bulletin. And as you know, it is in effect today.

The second step was to amend the Clinton order to provide simple procedures for OMB review of significant guidance. And those procedures were streamlined compared to what is done for regulations. And it was simply the following three things:

First, agencies should provide OMB advance notification of the most significant guidance. Second, only if OMB asks, they should have the opportunity to call in a guidance for review with a brief explanation of the need for the guidance. The burden was on OMB to choose what to review and also to tell the agency if it needed a little bit of time to review it. These provisions were also non-controversial, but unfortunately they became wrapped up in other issues in that order that were controversial. So when President Obama came in, he repealed that order.

They did put in place a memo saying OMB will continue to review guidance the way they did under the previous Clinton order, but there are some serious problems with that. One, no clear authority existed. But more importantly, there were no procedures for OMB to have a heads up as to what was out there. And you cannot review what you do not know exists. I had desk officers telling me they first knew about a guidance from a story in the Washington Post. And you know there is a breakdown in the management and review process when that is the case. And that was common.

I will leave my remarks at that, but just thank you again for what you are doing.

Senator LANKFORD. Thank you. Mr. Crews.

TESTIMONY OF CLYDE WAYNE CREWS,[1] VICE PRESIDENT FOR POLICY, COMPETITIVE ENTERPRISE INSTITUTE

Mr. CREWS. I am Wayne Crews, Vice President for Policy at the Competitive Enterprise Institute. We are a libertarian public policy and advocacy group. And I really appreciate and thank the Committee for the invitation to address agency subregulatory guidance today.

I will give my conclusion first, which is to say that subregulatory guidance from the Executive and independent agencies needs to be treated more like regulation. That means codifying elements of

[1] The prepared statement of Mr. Crews appears in the Appendix on page 41.

OMB's 2007 Good Guidance Practices, Federal Register publication, more intense OMB review, and questioning agencies' self-assertions that guidance is not significant. Furthermore, the Web posting of significant guidance, which is all over the map, needs to be harmonized and expanded.

Congressional directives matter, too. We have seen recent directives regarding guidance disclosure and retrospective review in Financial Services, the Department of Labor (DOL), the Department of Health and Human Services (HHS), the Department of Transportation (DOT), and the Department of Housing and Urban Development (HUD), Appropriations. In addition, the legislative history indicates that the Congressional Review Act's Resolutions of Disapproval apply to guidance as well if the Congress chooses to elevate such concerns.

Guidance, to me, has become more worrisome in a system that already does not follow APA procedures for ordinary notice-and-comment rulemaking enough, or conduct enough OMB review. Senators may have noticed there is still no sign of the 2016 OMB draft report to Congress on the costs and benefits of regulations. So Congress has neglected its role in regulatory oversight, as June's House task force's looking at Article I issues, and regulatory issues, and delegation issues make clear.

Indeed, just as some guidance needs to be treated more like regulations, regulations, in turn, need to be treated more like normal laws passed by Congress and affirmed. In written testimony, I put guidance in context with ordinary laws, of which there are a few dozen annually, and with regulations, of which there are over 3,000 annually. But beyond those, Congress lacks and needs a clear grasp on the amount and costs of the many of the thousands of executive branch and Federal agency guidances and memoranda with sometimes practical, if not always technically legally binding, regulatory effect.

I have taken a partial numerical inventory, and there are 580 acknowledged, significant agency guidance documents now in effect, but many thousands of other secondary guidances are subject to too little scrutiny, democratic accountability, or true knowledge of significance. In an analogy to astronomy, I have taken to calling this material regulatory "dark matter."

On page 19 of my written testimony, I note several prominent examples, such as HUD guidance on rentals to those with a criminal record, and Labor Department guidance; guidances on independent contracting, and on joint employment. In the financial sector alone, the St. Louis Fed lists 74 pieces of significant guidance in play across final agencies, while the Conference of State Bank Supervisors points to over 1,400 so-called directives.

Guidance has been an issue for decades, of course, but today's frontier economy is highly complex, and subregulatory guidance can easily cross the line of economic significance, such as ominous advisory opinions promised by the Federal Communications Commission (FCC) in the wake of its new Net Neutrality rule. Similarly, the Federal Aviation Administration (FAAs) brand-new 624-page, highly prescriptive drone rule should have been a law from Congress, but in my quick survey of it I count at least six areas

where the agency anticipates issuing new guidance in this frontier sector.

I realize that businesses often regard guidance as vital, and I do not wish to dismiss those concerns other than to stress that safety, public health, financial stability, privacy, and the like, are competitive features too, and decentralized stakeholders have a disciplinary role to play that can be undermined by too much regulatory zeal.

Reforms should come from a stance recognizing that not every matter is a public policy question; that so-called market failures may have political causes and coercive central regulation is not always the answer, especially if guidance inappropriately takes the place of normal regulations or laws.

So I support the Subcommittee on increased OMB review and enhanced APA exposure, as well as establishing guidance principles and legislation. But keep uppermost in mind too that even normal rules are not always getting the proper APA scrutiny.

In Part I of this hearing last September, Senators fretted that the process by which an agency internally elects to issue guidance on the one hand or normal regulation on the other is something of a black box. Surely we do not want unknown aspects of the regulatory enterprise increasingly outweighing the known, so I urge close interaction between this important Subcommittee, the public, and the entrepreneurial sector not just to get things done but to see what can be undone for the public good.

Thank you very much.

Senator LANKFORD. Mr. Narang.

TESTIMONY OF AMIT NARANG,[1] REGULATORY POLICY ADVOCATE, PUBLIC CITIZEN

Mr. NARANG. Chairman Lankford, Ranking Member Heitkamp, and distinguished Members of the Subcommittee, thank you for the opportunity to testify today.

Public health and safety regulation has been among the greatest public policy success stories in our country's history. Regulations have made our air far less polluted and our water much cleaner. They have made our food and drugs safer. They have made our workplaces less dangerous. They have made our financial system more stable. They have protected consumers from unsafe products and from predatory lending practices. They have made our cars safer. They have outlawed discrimination on the basis of race and gender, and much more.

Guidance has played a crucial role in securing these benefits for American consumers, working families, and the broader public. A brief survey of guidance issued in the last year alone confirms its vital role in protecting the public's health, safety, and financial security.

In March of this year, the Centers for Disease Control (CDC) issued guidance to address the growing crisis of opioid medication addiction that has led to a dramatic increase in hard-drug addiction and fatal overdoses across the country.

[1] The prepared statement of Mr. Narang appears in the Appendix on page 93.

After the Flint, Michigan lead poisoning crisis, the Environmental Protection Agency (EPA) issued guidance to address allegations that certain localities and cities were cheating on that test by pre-flushing taps to lower the amount of lead detected in the taps. This week the environmental group Natural Resources Defense Council (NRDC) released a report showing that over 5,000 water systems across the United States violated lead testing standards in 2015.

The Equal Employment Opportunity Commission (EEOC) issued guidance this month prohibiting employers from discriminating against job applicants on the basis of national origin, meaning not only the applicant's place of origin but also ethnic origin. This continues the EEOC's traditional use of guidance to ensure American workplaces are free of racial, gender, or sexual orientation discrimination. It is important to note that Congress has prevented the EEOC from issuing binding rules to enforce Title VII of the Civil Rights Act.

The Consumer Financial Protection Bureau (CFPB) issued guidance late last year to curb increasingly egregious debt-collection practices at debt collection agencies across the country. Such practices include threatening consumers who owe debt; illegally visiting consumers at their homes and workplaces; and calling consumers' credit references, landlords, and supervisors at work to jeopardize the consumer's job and reputation.

Guidance is also routinely requested by and designed exclusively for the benefit of industry stakeholders. Among the most prominent examples are No Action Letters. Agencies routinely issue letters that provide safe harbors for businesses requesting clarity in the face of regulatory uncertainty. Agencies use these letters to give businesses confidence that their activities will not result in enforcement actions against them. The Securities and Exchange Commission (SEC), in particular, issues many No Action Letters, and a quick glance at the SEC's website confirms that it has already issued hundreds of No Action Letters to businesses this year alone.

In short, when our regulatory system works efficiently and effectively, the public benefits and regulatory uncertainty is reduced. Tragically, our regulatory system is currently in crisis, plagued by rulemaking delays that are unacceptable and growing, which in turn costs lives, leaves consumers and our economy vulnerable, and results in irreversible damage to our environment and climate.

As the saying goes, protections delayed are protections denied. This week Public Citizen released a groundbreaking report that comprehensively analyzed all rulemakings listed in the Unified Regulatory Agenda over the 20 years. The results were striking and deeply troubling. The full report is attached to my written testimony but I would like to share some key findings.

At many agencies charged with protecting the public's health and safety, such as the Department of Labor or the EPA, it takes longer than a Presidential term to complete an economically significant rulemaking. For example, at the Occupational Safety and Health Administration (OSHA), the primary regulator of workplace safety, it takes an astounding 12.5 years to complete an economically significant rule. Adding in optional but time-consuming procedural steps leads to substantially more delay.

Economically significant rules that included advance notice of proposed rulemaking took 4.4 years to complete across agencies, over twice as long as economically significant rules without an Advanced Notice of Proposed Rulemaking (ANPRMs). Conducting regulatory flexibility or small business impact analyses leads to longer rulemakings at most agencies, sometimes twice as long as compared to rules without these analyses.

And the trend is going in the wrong direction, with economically significant rulemakings taking longer and reaching new records under this Administration. So far, economically significant rules completed in 2016 took 3.8 years on average, contradicting those who claim that the Obama Administration is rushing rules out the door this year.

Our report finds that rulemaking delays are concentrated in economically significant rules, meaning the rules that provide Americans with the greatest benefits but also take the longest to finalize. The bulk of new regulations that are minor and technical in nature do not encounter significant delay. This is directly relevant to proposals which impose a process similar to the one for economically significant rules onto guidance documents, including notice and comment, cost-benefit analysis, and OIRA review.

These proposals will do nothing to fix the delays revealed in our report. Instead, the proposals simply expand those delays to another important area of agency action, which is designed to address regulatory uncertainty efficiently.

While the available empirical evidence demonstrates that there is no abuse of guidance documents in order to evade the notice-and-comment rulemaking process on a widespread basis, it is impossible to ignore the strong incentive agencies have to avoid what has become an increasingly inefficient and dysfunctional rulemaking process across regulatory sectors and at virtually every agency.

If the Committee believes that agencies should be taking action through a notice-and-comment rulemaking rather than through guidance documents, the solution is to make the notice-and-comment process more efficient and streamlined rather than forcing guidance documents into the notice-and-comment framework reserved for rulemaking.

Public Citizen stands ready to work with lawmakers across the aisle to make our regulatory system work effectively for consumers, working families, and the public.

Thank you, and I am happy to answer any questions you have.

Senator LANKFORD. Gentlemen, thank you for your testimony as well.

The Ranking Member and I will defer our questions toward the end, and I will recognize Senator Ernst.

OPENING STATEMENT OF SENATOR ERNST

Senator ERNST. Great. Thank you, Mr. Chairman. And thank you, Ranking Member Heitkamp.

To our witnesses, thank you for being here today. Wow, regulations; it is always really an exciting topic. [Laughter.]

It is for us anyway. So thank you for taking the time to join us today.

First, Mr. Crews, in your testimony you state that in the absence of Federal legislation or an APA-compliant legislative rule, regulatory "dark matter"—I love that—regulatory "dark matter" will continue to flow out of Washington and increasingly impact State and local governments—and I have worked at both the State and the local government before—and also our personal lives.

Mr. Noe also acknowledged the need for a legislative solution in his testimony. In your opinion, what would a legislative or regulatory solution to this problem look like? What does that look like?

Mr. CREWS. As I indicated too, part of the context for this debate is that, in the ordinary notice-and-comment rulemaking system that we have now, it is already the case, as the Government Accountability Office (GAO) report put out recently, that 44 percent of the rules come through with no notice of proposed rulemaking; 33 percent of major rules come out with no notice of proposed rulemaking. So we already have a breakdown in the rulemaking as it stands.

So what concerns me here is that we do need to strengthen the rulemaking process itself, and at the same time recognize we are in an era where agencies are tempted to use guidance and avoid the rulemaking process. And you can see these hints of things coming down the pipeline. As I had mentioned the FCC, for example, it says in its new rule—it is a 400-page rule. Page 80, it says, well, we are going to be like the Federal Trade Commission (FTC) from now on and we are going to issue advisory opinions to telecommunications infrastructure firms, so before you move, give us a call and let us know.

The same in the wake of Dodd-Frank. In the Consumer Financial Protection Bureau they have said, well, with respect to unfair trade practices, we are just not going to issue regulations. You have to check with—so you run a real risk if you have lost control of the regulatory process, which is already being debated heavily in Congress, looking at things like the Regulations from the Executive in Need of Scrutiny (REINS) Act, "one in, one out," Regulatory Reduction Commission. You already have that to deal with.

If you have guidance on top if it, where agencies are even getting instructed that, well, if Congress does not act, we are going to go ahead and do what we can without that action, you run into a real concern of losing control of it. So at the very least—you ask what you do legislatively. At the very least, you have to start treating the guidance more like the regulation should be treated but may not necessarily be getting treated, and review them.

And we will engage in some interesting things here, but you do have to be concerned about agencies not acknowledging when a rule or a guidance, whatever the case may be, is something significant that ought to get more scrutiny or that ought to actually even be a law. So in the beginning—so I think you want to give guidance more APA-type treatment, and do that legislatively if you can.

Senator ERNST. And what kind of obstacles would you see for us to try and do, such as those legislative fixes?

Mr. CREWS. Regulatory reform is difficult and it comes around every generation. In the 1980s you had Brookings and other groups getting together with free-marketeers and deciding we would deregulate telecommunications and transportation. Then in the mid-

1990s you had the Contract with America. And you mentioned State and local unfunded mandates, reform at that time, and things of that sort.

Now we are at a point where I think it is very difficult for both parties—and, I think that is the tone to take. Both parties have an interest in seeing a growing economy. And we do have issues that make that important. With the national debt, if interest rates were to—even if you balance the budget now, if the interest rates started going to normal rates now, you would quickly tamp down the economy again. So you will start thinking about regulatory reform, I believe.

The obstacles are—it is very controversial. And, there are clashes of visions about regulation, about what it is that really protects the public, and whether it is top-down regulation that does that or whether it is other kinds of disciplinary forces that do. So that is one of the obstacles.

But I do still think there are ways that groups can get together. The "one in, one out" notion, for example, was bipartisan. That had been proposed by Senator Warner a few years ago. I think there will be some—you could easily get some bipartisan interest on more disclosure for regulations. I do not think it is very objectionable that the amount of guidance that comes out, for example, that is not catalogued could be catalogued better, and that the amount of significant guidance that does not get acknowledged ought to be acknowledged, and things like that.

And you have precedents by which you can do that. There was a report back in the 1990s called "The Regulatory Program of the U.S. Government." It looked just like the Federal budget. It was a fat document. It was red, white, and blue, had the eagle on it. And at the back was an appendix that listed numbers of rules, pages in the Federal Register, whether there had been a cost-benefit analysis, whether there was cost analysis. And even just knowing things like the percentage of rules that do not have a benefit assessment is good——

Senator ERNST. Right.

Mr. CREWS [continuing]. But this needs to be applied to the regulatory State but also with a lot more awareness of the reality of guidance.

And for starters on that, when I did this inventory of guidance, it spread—the agencies were publishing it all over the place, calling it significant guidance and cataloging it and things like that. It should be harmonized better, but then you have also got to get the sub-significant guidance involved in there too.

I will leave it——

Senator ERNST. And my time is expired.

Do you mind if Mr. Noe answers that?

Senator LANKFORD. Go ahead.

Senator ERNST. Thank you.

Mr. NOE. Thank you, Senator.

I think there is actually a very clear, simple, straightforward solution here that should be absolutely bipartisan. I have had discussions with the Chairman's staff. In my understanding, he is considering elevating the Good Guidance Principles that are in the OMB

Bulletin and having a kind of process for OMB review in legislation.

We would enthusiastically support that because it would be based on recommendations of nonpartisan expert organizations that have stood for decades. The agencies would take it seriously. There is a compelling public need and it fits perfectly within the strong bipartisan tradition of this Committee to find commonsense solutions to the regulatory system.

As I said, the OMB Bulletin itself has been non-controversial, and it is no accident why. It is based on recommendations of the Administrative Conference of the United States (ACUS), an independent agency with great expertise in regulation, whose sole mission in life is to improve the regulatory process. They have recommendations from the mid-1970s and the 1990s that are the foundation for those Good Guidance Practices.

There are also recommendations of the ABA Section of Administrative Law and Regulatory Practice that I am a member of, from long before I joined the Section—on these basic principles.

So all of that has been utterly non-controversial and has enormous support in the academic literature. And, frankly, there is an agency right now that did this even before OMB had the Bulletin. The FDA has its own Good Guidance Practices established in regulation. And what happened is, in the late 1990s they did this on their own. They thought this would be helpful to the regulated community.

Congress liked the idea so much that when they modernized FDA in the Food and Drug Administration Modernization Act (FDAMA) of 2000, they mandated that the FDA do this by regulation. And they had basic elements that are in the OMB Bulletin about having an approval process so the supervisors in the agency know what is going on, having standard elements in guidance, stating it is nonbinding, making guidance transparent to the public, putting it on their website, et cetera. That is why the OMB Bulletin has been so non-controversial.

And the second piece about OMB review was non-controversial. The only reason, again, that order got rescinded was there were other completely unrelated provisions that got to be controversial, but the academic literature, the work of nonpartisan groups supports all of that.

So to me that is something concrete you could put in a bill. I think Members from both sides of the aisle could agree on this. I think you could march in people who worked on this for decades, and I think you would have tremendous consensus that this is a good thing, because it is about transparency, it is about public knowledge about what is going on, it is about people understanding when something really important is about to change.

An agency interpretation of its statute or a regulation can be enormously consequential. It can be, our policy is X, to, tomorrow it is going to be not X. And there ought to be notice and comment for that. Even though such interpretive rules are not required by law to go through notice and comment under the APA, as a matter of good government they should.

And that is what the Administrative Conference of the United States and the ABA have recommended for decades. And I think

that would be a wonderful piece of legislation to do and would help improve this process.

Senator ERNST. Thank you very much.

Thank you, Mr. Chairman.

Senator LANKFORD. Senator Heitkamp.

Senator HEITKAMP. Mr. Amit, I would like you to engage. Obviously nothing is going to happen here unless we do have steps that we can all take together. At some point, the paths may diverge, but I think there are some steps that we can all take together.

And I think that when you look at, kind of through the lens of, we are in charge now so we are happy, but tomorrow we might not be in charge and we might not be as happy, so these rules should set a framework or a foundation in which to evaluate rules no matter which side of the political spectrum is promulgating those rules.

And so I am curious about this path that we are talking about, taking these steps, whether this is something you guys have thought about. And, is this a process that you think folks who tend to be very concerned about limiting regulation could see some benefit to?

Mr. NARANG. Sure. Here are our concerns.

So, I do not see a problem with agencies, of their own volition, under their own discretion, like the FDA, instituting different processes for certain types of guidance documents—significant guidance documents. And my understanding is that the FDA still continues to do that. It is a process that has worked well for them.

At the same time, I do not agree that a one-size-fits-all approach that basically turns the FDA process for significant guidance documents into the process for significant guidance documents at all agencies is the right way to go.

One-size-fits-all approaches normally result in unintended consequences both for guidance documents that we believe are important in protecting the public, like the recent CDC guidance, but also guidance documents that are important in addressing areas of regulatory uncertainty quickly. And that is exactly what No Action Letters do.

The other concern I have is that guidance documents are distinct from rules. The distinction is based on guidance documents not being binding. Now, if you were supposed to—if Congress was to essentially create a process that resembled notice-and-comment rulemaking for guidance documents but kept those guidance documents nonbinding, it seems to me that agencies then really have no incentive to go—to issue guidance documents since they have to go through basically the same process as notice-and-comment rules, but with guidance documents they are nonbinding and with rules they are binding.

Senator HEITKAMP. Not many times but, we have seen significant changes. Let's say these are the rules, and all of a sudden in a guidance document those rules do not apply anymore.

So it seems to, say to me that something changed and that if you are simply interpreting a rule or a statute that gives clarity, but when you simply—when you turn the boat and say, now we are going to go in this direction, like OSHA did with some of the anhydrous rules, then we get a little suspicious and we say, wait a minute; for the last, decades, this was perfectly acceptable and

legal behavior. We had been communicating with OSHA. We had been complying with the rules. Now they are telling me we cannot do this and, in fact, we could be out of business.

Don't you think in that case you would argue that a guidance, albeit not binding but certainly terrifying in the case of the regulated entity, that there should be more notice and comment, there should be more availability in terms of oversight rather than doing it through a guidance?

And so I do not want to think that this is, like, "the" big issue in terms of regulatory reform, but I do believe that guidance is used as a shortcut, and that shortcut denies the ability of the agency to get enough input to maybe choose a path that could, in fact, be a better path and provide more safety, provide better outcomes for both the regulated and the regulator and the consumers.

So I think we are at this kind of impasse here where I am trying to find which steps we can take that could achieve some kind of consensus to actually open the dialogue.

So I am going to ask you, what about transparency? I mean, I think that is a fairly, bipartisan notion that no matter what an agency does we have government in the Sunshine in our States and we have Freedom of Information here. Isn't transparency pretty critical, that if you issue a guidance or a letter to my competitor, and I do not know about it and I am still operating under another set of rules or another set of, what I think the rule says, isn't it important that we have transparency?

And couldn't you agree with these two that a transparency step might be a good way to do oversight on our side but also level the playing field for the regulated industries?

Mr. NARANG. I agree that transparency is essential, generally speaking, to the regulatory system. And I think there is, actually, a great deal of transparency when it comes to guidance documents, at least the existence of them, the issuance of them. I think there is more transparency than they are given credit for from some sources.

Now, at the same time—so I will give you an example. No Action Letters, they are put on the website. Even though they are directed to specific parties, they are put on the website by agencies to make sure that other parties—competitors but also the types of businesses that do the same activities as the ones receiving the No Action Letters—also know that their activities are not going to result in enforcement actions against them.

Transparency, I think there could be ways to work with, in a bipartisan fashion, work with folks that are interested in transparency reforms for guidance documents. The devil is always in the details. And, generally speaking, I think the preferred way to go, in my mind, would be for Congress to push agencies to adopt, on an individual basis, when they feel it is appropriate, transparency guidelines for issuance of guidance documents that impact the public.

One-size-fits-all approaches in congressional legislation can result in unintended consequences, certainly can result in additional delay in the regulatory system.

Senator HEITKAMP. Mr. Noe, I have a question for you because this is a theme that I have sounded many times from this desk

here, is that Congress does big things like Dodd-Frank, they do big things like the Affordable Care Act, and they get bogged down and they cannot give a lot of direction because it is harder to do big things when you get into the details.

And they just throw this stuff to the agencies and say, good luck. And then we all pound the table when they do something that results in complaints from constituents and is contrary to maybe our philosophy. How do we kind of achieve a recapture of that responsibility for legislating in a world where we are doing big things that are so complicated?

Mr. NOE. That is a great question, Senator. And I think part of it is Congress helping to channel agency discretion in a way that is going to be reasonable. We could have a whole separate conversation about regulations on that, but since we are talking about guidance today, there are just very fundamentally basic principles that are good government principles. And this is not, I think, an occasion for partisanship, which is there ought to be basic approval procedures for guidance in the agencies.

That is not happening now. Our government should not be the worst form of government except for all the others. We ought to have a government that is something we brag about. And the idea that there are not basic approval procedures in the agencies being followed now, there is not basic compliance with these simple Good Guidance Practices that are laid out in basically a page, that there is not public access to all the guidance—right now, in Cabinet-level departments, that should be the envy of the world.

There is not public access to these documents. The GAO report that was done documents this in detail, but they found HHS—and of all departments, that ought to be one of our very best—that they did not consistently apply Good Guidance Practices. Their website did not link to the guidance documents. And GAO, with their experts, were not able to even find them on the website. I mean, that is no way to run a railroad station. And we are not meeting these basic principles for what is competent government? What is transparent government?

And in terms of public feedback procedures, well, just like OIRA staff cannot be expected to be responsible for something they never heard about, how can the public possibly be held to account for guidance documents the GAO cannot even find on the agency's website? But that is the State of where we are today.

So what has happened is it has been over 9½ years since these basic practices were issued by OMB in a Republican administration, reaffirmed by a Democratic administration, and there is gross noncompliance. I think it is embarrassing.

And I think it is time for Congress to step in, because no rulemaking of any kind, whether it is regulations or guidance, happens without the delegation of this authority from Congress. It is time for Congress to step in and say, we are going to have basic rules of the road for agency guidance, and we are going to do what has been bipartisan, has broad support in the academic community, and we are going to elevate that into law because the agencies are flaunting it.

I can give you some statistics. Amit talked about empirical evidence. I can tell you the numbers on how gross the noncompliance

has been with the Bulletin. In the entire 9½ years since it has been issued, the agencies have said there are about three economically significant guidance that merit pre-adoption notice and comment—three.

In terms of the significant guidance—those are not even expected to have pre-adoption notice and comment—just that you have an approval process for them; you list basic elements; you say you are not binding in the guidance. For those, here is what GAO found in a study:

The Department of Agriculture has issued a grand total of 34 in 9½ years. That is about four a year. The Department of Labor, about four a year. Education, about four a year. I can assure you those agencies issue hundreds of guidance a year. A House subcommittee looked into this a number of years ago, basically they looked at several major agencies and found that, in a 3-year period, they had done thousands of guidance.

So the notion that when that level of guidance even merit the standard, basic Good Guidance procedures being followed, and a grand total of three they acknowledge merit pre-adoption notice and comment, that is embarrassing. And I think it is time for Congress to step in and do something about that, and this Committee is the perfect venue for that. That is what is in your mission, is to improve the rulemaking process.

Mr. NARANG. Senator, can I add something quickly?

Senator HEITKAMP. Yes.

Mr. NARANG. So good government requires resources, and what we are seeing currently is that agency budgets, basically outside of the national security agencies, and the Transportation Security Administration (TSA) in particular, agency budgets have stagnated or declined even. I will give you another example, OIRA itself. OIRA staffing has stagnated, declined to a certain degree.

If we are going to impose mandates on both the agencies in terms of additional procedural steps for guidance documents, and at OIRA in terms of review—I have to say the recent track record of OIRA regulatory review is not very good when it comes to delay. We have had unprecedented delays under this Administration. They have gotten a little bit better under Administrator Shelanski but we have had unprecedented delays. We are going to need to—Congress will need to provide the resources to make sure that we have good government. You only get the government that you pay for, and so good government really requires good resources.

Senator LANKFORD. Just as an observation on that: We get calls all the time from businesses and from individuals that say, we have this overwhelming number of guidance documents and new regs that are coming down on us; we have limited resources as well.

And so while I do hear often from government officials saying, if you will just give us more money we will be able to do better this or that, that is the same thing we hear from individuals out in the country, saying, wow, we cannot keep up with—as was mentioned before about Dodd-Frank.

A community bank that has 14 total employees and the number of things that are coming at them from three different agencies, that are indeed conflicted, is overwhelming them. And they say the

same thing: We do not have the staff to manage this. Nor should they have to be able to have the staff to manage that, based on the number of regs that are coming on them.

I want to mention a couple of things, just to be able to—I really appreciate the open dialogue on this. And I want this to be an open dialogue. And so, Senator Heitkamp, anytime you want to jump in, you can jump in this conversation. Let's open this up.

Mr. Narang, I want to be able to bring something up. You brought up three different times the No Action Letters. The one caveat I would have on that—and by the way, I think the No Action Letters are helpful, and I do think that is a document that comes out that everyone can say, OK, that looks like it, but you have used the term "safe harbor" a couple of times.

That does concern me, because on the SEC's website, it says on it the staff are not bound to the statements of previous No Action Letters. So it is not really a safe harbor. It is an interesting piece of information to know that if you are in conflict with SEC you can say, hey, I was trying to follow this. But their staff has full ability to be able to say, hey, we are not bound by that; that was for that group; we published it for your information only. But they are not really bound by that. Am I right or wrong on that?

Mr. NARANG. Thank you, Senator. I believe you are right. It is one of the general limitations on guidance documents, that they are not binding.

I am unfamiliar with how often SEC takes enforcement actions against likeminded—situated businesses—situated in the same——

Senator LANKFORD. I have no idea on that. We can try to find that, but——

Mr. NARANG. So I would hope that it would not be that often, though.

Senator LANKFORD. I would hope so too. But you used the term it is a "safe harbor" at one point, and I want to just put a check on that to say it is not really a safe harbor, because even they say they are not bound by No Action Letters because the facts are going to be different in every single business, every single location. But it does give you a general sense.

To me that is somewhat what guidance should be, is a general sense of this is a direction of where we think things are going to go. But the problem is, is that when we had Education here before——

Mr. NARANG. Right.

Senator LANKFORD [continuing]. We asked basically, if you are a new person at a university and you want to be able to pull all the previous guidance that has come down, where would you go to get that? There is no place to go to get that.

I was interested—you made a comment at one point—what did you say, 580? What was your number?

Mr. CREWS. That is what I tallied up. And to get the Education Department guidance, rather than being right there on the website you click and then you go to a Word document.

Senator LANKFORD. Right.

Mr. CREWS. So the kinds of reporting are all over the map.

Senator LANKFORD. So but you called it, if I remember, a "partial list."

Mr. CREWS. Yes because, see, we have the memo in place, and there is varying degrees of compliance with it. Like, HHS says it does not have any economically significant guidance to report, but on FDA's site it has this great search engine, it has all these procedures to present information.

HUD does not own up to significant guidance, but other agencies do. Sometimes you will see the main umbrella department with zero in numbers of significant guidance but some of the subagencies will acknowledge some significant guidance, which is great.

So in the preliminary inventory I put together, I put those zeroes in there because it is interesting to know which subagencies say they do not have significant guidance and which they do. That is important information as well, but then we can check with those agencies later and find out if that is really the case. If they say they have zero guidance, you can find out from the public maybe the answer is different.

Senator LANKFORD. But that is just significant guidance you are highlighting. Is that correct?

Mr. CREWS. Right, and then you get—this is another reason why we need a lot more disclosure than we have, because to get other kinds of guidances that are sub-significant or secondary, whatever—there needs to be a name for it. One name is "notices" but they are—but notices published in the Federal Register are everything from meeting announcements to something potentially significant.

John Graham, who had been the former head of OIRA, had said what OIRA considers to be a significant notice, it is not quite clear. So what counts as a guidance? What counts as a notice? Once you get below the significant, it gets pretty iffy.

I had mentioned some financial guidance in which the St. Louis Federal Reserve had tallied up what they considered to be significant guidance and posted it. But you see, if you multiply that all across the sectors of the economy, there is a lot of stuff out there that is not easy to find. It is not even easy to find the significant guidance——

Senator LANKFORD. Right.

Mr. CREWS [continuing]. Because I had to do that exercise, but the other, it is extremely difficult.

Senator LANKFORD. And it is the challenge that I have that I bring the illustration up: If you have a new employee at a university, you have a new employee at a manufacturing location, the previous employer retired, died, fired, whatever it may be; new person sits down in the chair and they ask the question, where do I go to get the rules of the road from the Federal Government?

Mr. CREWS. Right.

Senator LANKFORD. They know where to go to get the regulations, but all the interpretive guidance pieces and everything else, there is nowhere they can go to get it.

Mr. CREWS. I am here to say nobody can tell——

Senator LANKFORD. And they are all going to be bound by that.

Mr. CREWS. No one can tell you.

One thing I would say—and I hope there is some common ground here—I had looked at the Public Citizen report, and I understand about the delays in some of the regulations that you are concerned

about. My answer to things like that is, well, when that occurs and it is that severe, that becomes a question where Congress ought to step in and make things happen.

But beyond that, one thing that fell out of that new Public Citizen report is that regulations that are not significant actually come through on a pretty ordinary pace. So that tells me that if you were to—and Public Citizen would be in favor of disclosure and the public having the right to comment. That tells me, for the typical guidances, it should not be too much of a burden for them to go through some kind of alert or notice of some degree.

So I think that disclosure can go a long way toward getting a handle on the significant guidance and then the sub-significant.

Senator HEITKAMP. I think one of the issues that we have is that—probably an unfair kind of analogy, but let's say you have five sisters and you all have photo albums, and one just throws them in a box and the other person, you know, has them indexed, you know, 500 different ways on a spreadsheet, right?

Mr. CREWS. That is pretty good.

Senator HEITKAMP. So we have not set any guidelines for how this information is presented. Now we have a whole body of work out there that is in the shoebox that is not necessarily accessible. And so it is going to take, maybe some direct analysis on, this is the expectation on transparency. You should not have to dig around. You should not have to just wonder if you are missing something. There should be one place where you can go where you can sort it.

And the problem that you have is, I think, this has been ignored, kind of like we are just doing it and we are just doing it, because people are busy and they are not thinking about communication. They are just thinking about today, not what this body of work means kind of in the long run. And so I think there is some work that needs to be done in terms of not just one size fits all, but in terms of setting some standards for how you present the material.

Our frustration here has been every time we talk about—whether it is Taxpayer Bill of Rights, whatever it is, post this information—well, that would just take so much time. Well, I think, number one, we have the tools to do this fairly quickly, but people do not have a framework. And when they say, well, we cannot post it, you wonder why they do not want to post it, not that—everybody can post it.

And so I think there is a need here to maybe set some standards on how the information is presented. We can argue about what is significant and what is not, but, all of this information should be completely transparent and accessible to the public.

Mr. CREWS. A quick one on that. I love the shoebox analogy. And I will tell you, the shoebox is called "notices" at the Federal Register. If you look at the proposed rules coming out every year, right now there are 2,500 in the pipeline. The number of rules finalized last year were 3,410 but the notices were 23,000. And so just "notices" is what it is called, but it contains memoranda, directives and guidances, bulletins, letters, all the—a word salad of things that it includes and it is just in that shoebox now.

One of the things you can start to do is to tease that out, becomes some things, like the FDA notices that Amit mentioned that

are just alerting the public about things—about Zika—those are not guidances that concern anybody. Those are notices coming out of the Federal Government. But the ones where it is going to change behavior or require businesses to react, or some businesses may act differently than others or be affected differently by others, I think those can be pulled out of the notices shoebox in the Federal Register reporting that comes out every year.

So I think that kind of disclosure in presenting the significant guidance and the material sub-significant guidance straight on the webpage, along with elevating the guidance principles, like Paul says, I think will go a long way toward getting a handle on this issue.

Senator LANKFORD. Right. And part of our issue is not just that it is in a shoebox; it is that it is in a shoebox in a closet that no one knows where it is. And so that exists but I cannot get to it and I cannot find it, and I do not even know that it exists on that.

Mr. Noe, you had mentioned something earlier that I want to be able to come back to and it was this thought of people at OIRA finding out about a rule by reading it in the Washington Post when it suddenly shows up.

In our conversations with agency individuals, it is one of the frustrations that an agency does not know what another agency is doing, and so a business or a manufacturing location, whatever it may be, suddenly has two conflicting guidances from two different agencies that, if I do this it is going to break this agency's rule, and if I do this it breaks this one.

OIRA, I would assume, is the one that has to be able to help navigate between the two to be able to raise the red flag. But if not OIRA, who helps form that deconfliction? And how do we get to a point where, if it is a significant rule that is coming out, OIRA at least gets a shot to be able to take a look at that?

Mr. NOE. Mr. Chairman, you are absolutely right that OIRA is the proper place to coordinate with the other agencies on any rule that is important, whether it is a binding legislative rule or regulation, or an interpretive rule or policy statement.

And sometimes it is—I say it myself, but I have to remember it is kind of a misnomer to call it OMB review, because OMB is just an intermediary. It is interagency review. So if EPA, for example, is going to issue a regulation or an important guidance on something related to agriculture, the desk officer who works on those issues at OIRA is going to alert the Department of Agriculture so that they are coordinated on what the policy for the president is on that issue. The same thing if it is energy. They will reach out to the Department of Energy (DOE). If it is about food, it will be Ag plus FDA.

And that is exactly why it is important to have clarity that, one, OMB has authority to have interagency review on the most consequential guidance. For the vast majority, they will not do this. They have very limited resources, as Amit said. And they are focused mostly on the mega rules.

But there are some guidance that are so consequential, they ought to be able to have interagency review on that, and there ought to be a procedure so they actually have a heads up to know

they actually should have interagency review instead of reading about it in the Washington Post.

Senator LANKFORD. OK, so how does that happen?

Mr. NOE. It is very simple. It is just a few steps, which is kind of a streamlined version of what you do for regulations that could be done for guidance.

So, one, the agencies would provide a list to OIRA of their upcoming significant guidance, only the most important ones. Then OIRA could choose—based on its own limited resources and the President's own priorities, pick off that list which ones it wants to review. And then it would alert the other agencies that are affected so that there is a coherence among the agencies that, yes, this is the proper policy; this reflects the President's priorities; we want to go forward with this guidance.

And I can assure you, OMB would not review an enormous number of guidance because, again, they have very limited resources and they have to pay attention to the big regulations. But there are some that they absolutely would want to review, and they should, and the other agencies ought to know about them.

Senator HEITKAMP. One of the problems that we have when we look at this is a lot of the significant guidance, a lot of the significant regulations, are coming out of independent agencies. And we are really challenged in how we do that independent agency review. We had a bill—I mean, it has been really a tough issue for us to kind of navigate in terms of our oversight.

But I want to make a point about guidance, because I used to be one of those regulators back in the day, both as Attorney General (AG) and as tax commissioner, and I got criticized for not promulgating rules and not issuing guidance because of how critical it was for business certainty. You may not like the answer, but you got an answer so you can rely on it.

Again, I do not know that we can say "safe harbor," but certainly during the term, that we would have a court that would say, look, you said something; they relied on it; it is binding. And so we do not want to lose that.

And, Mr. Narang, I think that one of the things that we need to look at is we need to think in the context of if the person in the White House did not share common values, and started issuing guidances that were contrary to rules that had been promulgated over the last 8 years, I mean, how would we then want to see the process operate so that we would at least have notice that there is some erosion from what you thought the principles were or what the rules were?

I think sometimes we look at this in the lens of what the political landscape is today, and we desperately need to look at it from what is the level playing field that we need to be operating on, so regardless of the political affiliations or the tendencies on either side we have rules that we all know?

I mean, couldn't you see a need, in a case like that, to actually have greater notice, have greater scrutiny over guidance that might change rules?

Mr. NARANG. I think that you are absolutely right to point out that this—the procedural issues when it comes to the regulatory

process can cut both ways, depending on who is in the White House.

I do not think that that diminishes the need for our government to operate efficiently. I agree that they should operate in a transparent manner, regardless of who is running the show. But I do think—and certainly that may cut against Public Citizen's interest sometimes, but I do think that government efficiency as a principle is also a bipartisan principle that needs to be honored across administrations.

And we do not have that with the rulemaking process. We are very concerned that adding the same types of procedures for guidance documents will simply make the dysfunction in efficiencies and the rulemaking process then apply to guidance documents.

Senator HEITKAMP. Well, i have a concern, if guidance truly is nonbinding, whether we are putting another layer on that would prevent us from moving efficiently to give business certainty to do the kinds of one-on-ones that can be very helpful. But I have seen it go the other way too, where broad, sweeping changes are done in guidance when they should have been done in rules.

Mr. NARANG. If I could just add to the OIRA discussion really quickly, we talk a lot about transparency around here. One of the major sources of a lack of transparency when it comes to the regulatory process is OIRA.

The GAO has issued multiple reports now, making about 12 recommendations when it comes to OIRA actually following the Executive Order 12866 transparency requirements. Every time the GAO finds that OIRA really is not interested in instituting their recommendations. I think they have only done about one out of 12.

We really feel that, if we are going to give OIRA more authority over more types of agency actions, that they need to right the ship when it comes to reviewing regulations first before we give them guidance document review authority.

Senator LANKFORD. So can I drop the bomb into the middle of this conversation, then? [Laughter.]

So if OIRA does not follow the process, or if a regulator does not follow the process, should there be judicial review? Not on the decision—but did they do the process?

You are welcome. [Laughter.]

Mr. NARANG. Thank you, Chairman. So that is a very thorny question.

Senator LANKFORD. Because I am not asking, did they make the right decision? I am asking, did they do the process, and should there be an ability to have judicial review if they did not complete the process?

Mr. NARANG. I think that maybe it would be interesting to ask an administration witness what they thought of that. Executive Orders——

Senator LANKFORD. I already know what they think. [Laughter.]

Senator HEITKAMP. We do.

Mr. NARANG. Executive Orders are not judicially enforceable. They do not create any legal rights.

You make a very good point that when OIRA—or other agencies, but especially OIRA, since agencies are held to judicial review and judicial review's scrutiny, essentially, when they do not comply

with APA procedural requirements. OIRA does not have that element of judicial review. And, when it comes to, I guess delays, they are not complying with the Executive Order. Of course, it is their Executive Order.

Senator LANKFORD. Right, and that is the problem. But it is every President for the last 20-some-odd years has done 12866. And the question is, if we have a bipartisan agreement, this is a good process. It has been tested. It has been evaluated. Let's just make it statutory and to make sure that is what we actually do.

And again, that is a broader conversation and we are getting past guidance in this. But it does help, when you deal with something like the Congressional Review Act, if you have a significant guidance. A significant guidance is open to the Congressional Review Act. If you do not do the process and actually deem it as significant guidance, you actually pulled it out of that statute to where it is not eligible to be dealt with in that way. And so it does affect how the law functions and how Congress interacts with guidance as well.

Senator HEITKAMP. I think one of the concerns are the nitpicking versus truly significant breaches of process. And I think that people on the one side of this debate in terms of following these rules, following the procedure, would argue, look, if we missed it by a day or if we did something that was not material to the public or really to the end result of the rule, we should not be subject to scrutiny for a nonmaterial breach of process.

But again, if you fail to provide notice and comment on the front end, that is something the courts are going to review——

Senator LANKFORD. Right.

Senator HEITKAMP [continuing]. I think, under APA.

And so, we have this debate going back and forth about judicial review, and I think it challenges us all, kind of going forward, on how do we make everybody comfortable that there is not an "I gotcha" here?

There is an attempt to analyze and to know the rulemaking process so that everybody is playing from a level playing field that the regulated community knows that this is the process, this is the rule of law that I am operating under, and I can count on those steps being taken to protect my rights. And when those steps are not taken, that creates a disharmony and, I think, a sense that the government has run amok.

Senator LANKFORD. Can I ask Mr. Noe to make a comment? It looks like you are about to jump out of your skin, so—— [Laughter.]

Mr. NOE. Well, I just wanted to comment, Mr. Chairman, that I think there is a basic misunderstanding about this issue of delay. And I know Amit is concerned about that. I respect the concern about that, but it is very important to mention this because it is fundamental in the FDA Good Guidance Practices, in the recommendations of ACUS and the ABA that—basically what they said is, for significant guidance documents, the agency ought to ordinarily voluntarily comply with notice and comment, unless they determine it is not feasible or appropriate.

And when Congress passed FDAMA, it is right there in the statute. So there is an out. This is very different than saying this is

a legislative rule subject to APA notice and comment requirements and judicial review. It is very different because the agency can, on its discretion, determine, look, this one was not significant or it was not feasible to do it.

What Congress said is if you do not provide pre-adoption notice and comment for the most consequential guidance and you go ahead and issue it, you ought to still allow the public to comment on it even though it is out there already.

And that is perfectly reasonable. That is what the Administrative Conference of the United States has said. That is what the ABA has said. That is what is in the FDA Good Guidance Practices. And it works perfectly well. The agency has not crashed and burned. In fact, the regulated community, to my understanding—I am not an FDA expert—but they are pretty happy with how that works, and that to do it otherwise would be a major problem.

So here you have an agency where human life is at stake in the decisions it makes, the guidance it provides, and this idea of having a presumption of public notice and an opportunity to say something about this before it goes final works perfectly well. And where they decide, look, it is not feasible, this is an emergency or it is not appropriate, there is an out for that. And so I think that is the same kind of thing you could do if you elevate these Good Guidance Practices to legislation for the agencies in general.

To your point earlier, Senator Heitkamp, I think you could and should do it for the independent agencies too. Their guidance is no different in its impact. You have absolute authority to do that. Of course, I frankly think the President has absolute authority to do it on his own. And I think there is——

Senator HEITKAMP. The independent agencies do not think that.

Mr. NOE. They do not think that, but I think if you consulted legal scholars, they would line up and say that is correct. But the point is it is you. You are a legislator. You have that authority.

As far as judicial review goes, I do not think there is a whole lot for a court to review here other than if it is simply "check the box." Again, we do not want to be embarrassed of our government. Do you have approval procedures for your most important guidance? Do you have standard elements in the guidance, and do you say it is nonbinding? Do you provide access to the public by actually posting them on your website in the 21st Century? Yes or no?

If they did not do that, you could provide limited judicial review to compel agency action lawfully withheld or unreasonably delayed, under the Administrative Procedure Act, Section 706(1). And all that anyone could do, if they are willing to spend the money, is get a court to say, yes, you have got to do what Congress told you to do. Nothing is going to crash and burn if you have that limited judicial review. I personally think you could do that.

Mr. NARANG. So Paul makes a really good point. Congress has the authority and has mandated that certain agencies conduct guidance processes in a different way, in a much more robust way, as they did with FDA.

I think the proper way of congressional intervention in this area is to go, agency by agency, where the problems exist, to the extent that they do exist, rather than a one-size-fits-all approach. I think

this is a broader recommendation when it comes to regulatory reform legislation, generally speaking.

Senator LANKFORD. But here is the challenge when you are dealing with a—I will go back to a manufacturing location as well. They have EPA regulations, they have OSHA regulations, they may have FDA regulations, they have USDA regulations, Department of Labor regulations. If all of them have different standards and different ways to do it—I understand it is very helpful for the agency to say, we are different, but when you are the business, actually, and for the 340 million Americans that are trying to process these regs, it makes it more complicated for them.

And so there is somewhat a balance between making it simpler for the government or making it simpler for the American people. Our default is to try to make it simpler for the American people.

And so while I understand one size does not fit all, there is a need for some kind of standardization so that a compliance person in that business that deals with nine different agencies can have some level of predictability of what to be able to do.

Senator HEITKAMP. And we have established a one size fits all by passing the Administrative Agencies Practice Act. So the question is, should that be expanded into other areas? Should we look at that and say there is a need for a broad-based rule of the road that could apply? I agree with you that there needs to be flexibility. I mean, the last thing you want is the Internal Revenue Service (IRS) not to be issuing letter rulings.

Senator LANKFORD. Right.

Senator HEITKAMP. And no one here wants that. And so I think you and I would agree it probably should be narrower than maybe what these guys would think, but I think at some point having the certainty of knowing, I know what is going to come down because this is the process, and I look for it, and if it does not show up I know there is not new guidance out there that I need to worry about.

And so I think there is some advantage that we could have to standardizing some kind of guidance principles, and making those—I think Paul's point about, what would that review look like? It is not substantive. It is really an objective review is what you are talking about, not a substantive review, right?

Mr. NOE. Yes, Senator, just the process. Did they do it? Did they do what Congress told them to do? That simple.

Senator HEITKAMP. So, I mean, that offers an opportunity to give the certainty that you might need—sorry.

Mr. NARANG. I do want to make clear that I am not making any claims that, significant guidance documents, economic—the creation of these categories across agencies is going to lead to the same length of rulemakings as economically significant rules. That is not the case. It is not going to be as long as that.

But even on the guidance end, delay is not an abstraction. It costs lives. The CDC Opioid Guidance is a great example. They wanted to issue it late last year. When they first came out with it they got backlash from the pharmaceutical industry and they had to delay the guidance for several months. The CDC points out that 40 people across the country die every day from opioid addiction and overdose.

Senator LANKFORD. Mr. Crews.

Mr. CREWS. Just quickly too on the discussion about OIRA and the transparency that you brought up, it is the case that OIRA—we always look at OIRA's reviews of regulations but not the independent agencies since those are left out. And in the past year you have 13 rules that had a cost-benefit analysis done on them, but it turns out that OIRA does review some notices and we can get to the bottom of what that data is actually telling us.

I mentioned that John Graham, who was the former head, said, "The OIRA website"—this is a quote—"is vague about what constitutes a notice." "More clarity about what constitutes guidance notices worthy of review" "would be valuable." But I went back and looked and it turns out there were a few dozen notices that OIRA reviews every year. The nature of what all of those are we do not know yet. And even some of those are considered significant.

So there is some activity at OIRA that would be enhanced by doing this—by enhancing those principles into legislation.

Senator LANKFORD. We have a couple of minutes left here. I want to be able to honor everyone's time on it, so let me kind of go in a couple of lightening round things that should not be lightening round things. That will be faster.

One of them is—and it is for all of us on this, if you have a particular comment. One of the things that we dealt with last year was OSHA put out three new process safety management rules as the result of a quick action from the fertilizer plant explosion in West, Texas.

We have now learned from the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) that that was not an accident after all. That was actually an intentionally set fire. And all of the basis for how they set out these quick emergency guidance to be able to get there—it is an emergency when you put out these new process safety management rules—the foundation of that was incorrect. It was not an industrial accident. It was an intentionally set fire.

They promulgated three different sets of rules. We challenged those three guidance documents—I said rules, but three guidance pieces they put out—and said, this should go through the rulemaking process on all three of these. One of them they have now responded back to us and said, you are right; we are going to repromulgate this as a rule. The other two are now in litigation, where they have stepped aside and settled it.

My concern is it looks like this is—going back to, Mr. Narang, what you were saying—a faster way to be able to create a reg by creating a guidance, stepping aside into a quick settlement with the affected parties and then putting it back out and saying, here is the result of that, that still excludes a lot of people, if it was going to be a true reg, from giving input. The only people that got input were the people that were actually in the settlement. And then everyone else was cut out of that.

I am very concerned about that being a new process that is being birthed out of the length of time and the difficulty it is to do a regulation or a significant guidance, that agencies are exploring, how can we get this done in a faster way with a smaller group of people? That is a separate issue. I just wanted to be able to raise it.

I am very concerned about that. We are going to continue to press on that.

The issue that I wanted to be able to raise is who has—and we cannot get into all of it—who has given good, clear definition of what is guidance, significant guidance, and regulation? It is one of the great struggles that we have.

Every time a new regulation comes out—and, Mr. Narang, you mentioned it, for instance the sexual assault rule on campuses, that campuses across the country have said: That is not a "Dear Colleague" letter. That is a new guidance. That forces us to create this whole new legal system. There is all kinds of issues, all kinds of attorneys. And legal scholars on universities have said, this definitely should be a regulation, not a "Dear Colleague" guidance letter.

Where do we go to be able to get good, clear definition that we can put in statute to clarify, in the days ahead, here are the clear boundaries?

Mr. NOE. Mr. Chairman, I will take a stab at that.

I think that this is pretty fundamental. If it creates or alters legal rights or obligations as a foundational matter, that is a legislative rule, which we call a regulation. If it merely interprets a preexisting legal requirement, whether it is in a statute or a legislative rule, a regulation, that is an interpretive rule. If it simply sets forth agency policy but it is not binding, that is a policy statement.

These are the three kinds of rules under the APA. And if people are fair-minded, I think, when they read what the agency is writing, it is not that mysterious as to which of those three is going on. If there is a proper review process and the agency really intends to follow the rules of the road, that should be pretty clear.

One benefit of having notice and comment as a presumption for guidance is if they feel like there is an emergency and we have to put out an emergency interpretation, they can go ahead and do that, but then the notion is, but we will still take some comment in case we got it wrong and we will think about that comment. And that allows them, if they made an error to—if they quickly made a mistake, they can quickly correct the mistake under that kind of a system.

Mr. CREWS. It is often claimed that there ought to be a law, and sometimes maybe there ought not be a law. I think one of the issues we have here is when Congress has been debating reforms and is looked at the REINS Act, where if a particularly regulation was extremely significant and Congress thought it ought to have a say and would come in and vote up or down on it, I had always thought that should be extended to controversial regulations, not just major ones, because often when you look at the data coming through OMB, there are not any cost-benefit analyses. There are very few that actually even happen.

Senator LANKFORD. Especially in the independents.

Mr. CREWS. Exactly. And so now, given the tendency to turn to guidance now, and given the nature of the economy we have now where we are moving into the information sector and to high-tech sectors, where it is very easy to issue a drone rule and financial rules and telecommunications rules but then not issue any rules after that, just make declarations and guidances and memoranda,

I think you have to bring controversy into it. It is not just that it is economically significant, but if it has alarmed enough people—like it was very controversial, what you described about the explosion and then finding out that there was a sabotage; it was not even a failure of process—you have to have something to flag when there has been a major change in law implemented or a major change in the way that regulated parties have to behave, based on what the Federal Government is doing, whether it is coming out of Congress, an agency, or if through a regulation or through a guidance.

Mr. NARANG. So this is not a direct answer. I will go back to what I said in my oral remarks, which is that one way to deal with concerns about guidance is to make notice-and-comment rulemaking easier.

And this Committee has a good model, actually, just from this Congress in terms of streamlining and making more efficient regulatory processes to address delay. So the delay I am talking about here is energy and infrastructure permitting. And the solution to that delay, which became law last year, passed out of this Committee initially, was essentially to cap public comment periods at 60 days, scale back judicial review, make the standing a little bit more narrower for parties to bring judicial actions on permit denials or approvals, and to reduce cost-benefit analysis, not expand cost-benefit analysis when it comes to environmental impact statements.

So that is an interesting model. I think it potentially is a very effective model. Unfortunately, it is not the model that Congress has generally been following when putting out proposals for reforming the regulatory process. And so I think that hopefully our report makes clear that the delays, when it comes to regulations, are substantial, just as substantial as in the energy and infrastructure permitting world, and so we need similar types of solutions.

Senator LANKFORD. No, I do not think there would be a question from this Committee, either side of the aisle, on dealing with clear deadlines and boundaries and clear definition. No one wants a regulation to take 12.5 years. No one wants that process to be so burdensome and so time-consuming that you actually cannot respond to a statute.

The challenge is if people are not engaged in it—what a lot of folks on this dais have heard me say: We are still a government of the people, by the people, and for the people. And if people do not get input into the regulatory process and to a guidance, then we are no longer a nation of the people, by the people, for the people. This is somebody else that is imposing.

So I think affected parties should have an opportunity to be able to raise their hand and say, have you thought about that, before something goes in. And it should not just be wealthy affected parties, that could do a lawsuit and could step aside and could do that, but it should be anyone that would be allowed to do that. But they cannot do that if they do not get the opportunity to present comment. And they cannot do that if their comments are not heard and actually put into action.

So clear moments where they can do that, where they can engage, is extremely helpful to us, I think, just as a Nation, just as

a transparent government as well. I wish it was as clear as what you just described. There has been uncountable lawsuits that have happened in the past several years over, that is a reg, or, that is a guidance; that guidance has now become something else.

But apparently there are some in government that wish to be able to promulgate something that sure looks a lot like a regulation as a guidance, and no one seems to be stopping them in the process. And I think that should be an OIRA position, but often OIRA does not get the opportunity to see it. And now it just happens and gets out there.

And I think my issue is, how do we actually put this in position with regardless of who is in the White House, that everyone knows regulations come from law and guidance comes from regulation, and everyone can point back to law, not just the preferences of the White House, because if everything is based on, we are going to put out this guidance based on White House preferences, at some point we have lost, it has to be connected to statute over here, not just White House policies.

And so we have to figure that out regardless of who is in the White House. Otherwise, we have no predictability and the next White House can just flip the guidances and say, we are going to go the other direction now; because the last one did, because if this passes a guidance this way, then it can certainly be taken away this way, and now no one knows how to do capital investment in the country.

Mr. NOE. I can tell you, Mr. Chairman, when I was at OIRA we caught a number of what I call spurious rules. They were supposedly guidance that were going to be legally binding, and we were able to stop them.

So I think it can be done if there is OIRA review and there is a desire to make sure people are following the law. It is tempting to go by guidance because it is easier to do, as Amit was saying, but it does not fit with due process to do it.

And I think it is not an accident you have seen this vein of cases from the D.C. Circuit, the spurious rules cases, that actually started growing a lot in the 1990s. And I think that is because the Clinton order took OIRA out of the job of reviewing guidance.

Senator LANKFORD. Well, it is simple. We have to be able to reestablish that and to be able to find a clear way to be able to do it, because at this point we are—my belief, we are clearly out of balance. There is too much latitude to be able to create guidance and too much instability that is created with that, and we are not getting back to the basics of promulgating it based on statute.

And it seems to be a focus on the Chevron deference-type issue that I come back to all the time: We can get away with it. We can call this permissible construction. And so because it is permissible, we are just going to go ahead and do it and wait until a court at some point tries to stop us in the process.

And that is really expensive and really long, and it may be simpler for the agencies but it is much tougher for the American people.

Any other quick comment from anyone?

[No response.]

Gentlemen, I thank you very much again for all the contributions that you made, the study that you do already, and the different reports that you already put out. That is very valuable to us in the national conversation on it. And we want to continue the dialogue both on the staff level and with myself and other Members of this Committee. But let's keep the work going. This is not unsolvable. This is one of those solvable issues, but we have to get some good-quality resolutions, and it has to be able to pass the House, the Senate, and be signed by the White House.

I have heard several of your comments today saying Congress could fix this, and I have smiled only as I thought that, and say, when Congress fixes things, that is law. That also requires the White House to be engaged and to say yes, because most of these issues require a reduction of Executive power, and of late there does not seem to be much conversation about limiting the power of the executive branch. So, yes, while Congress has the power to write that law, the Executive has to sign a law that says, no, the executive branch has to live by law, not Executive Orders. And that will be a different day and a different conversation.

So I appreciate very much the conversation and the input for this. Thank you.

Mr. NOE. Thank you.

Senator LANKFORD. With that, let me see if there is any closing statement I need to make, or announcement.

The hearing record remains open for 15 days, until the close of business on July 14, for the submission of statements and questions for the record.

The hearing is adjourned.

[Whereupon, at 10:29 a.m., the Subcommittee was adjourned.]

APPENDIX

Opening Statement of Senator Heidi Heitkamp

Thank you, Chairman Lankford.

Guidance is the vehicle by which the agency may communicate with businesses and other stakeholders in an official capacity, but outside the more rigid confines of the traditional notice-and-comment rulemaking process.

Guidance helps the public get the clarity and answers they need. Guidance removes ambiguity and confusion, and clarifies obligations. Guidance is a conduit for exchanging information and can assist in outlining the relationship between the government and stakeholders.

In March of last year, the SEC published guidance on Regulation A+. This document was praised by the President and CEO of the Biotechnology Industry Organization, Jim Greenwood, who said, "We applaud the SEC for taking this important and critical step toward encouraging continued innovation within the biotech industry to help spur the development of treatments and cures."[1]

However, sometimes agencies get it wrong. In these cases it is important that the agency is held accountable.

This does not mean that we need full scale changes to the guidance process. We have a judicial system in place that routinely polices agency actions. For example, in *Catholic Health Initiatives v. Sibelius*,[2] the D.C. Circuit threw out an interpretation of the agency because, "there is no way an interpretation of 'reasonable costs' can produce the sort of detailed – and rigid – investment code…"[3]

We must ensure that we do not throw out the baby with the bathwater, and chill this option for information exchange.

I look forward to hearing from our witnesses.

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[1] "BIO Applauds SEC for Publishing Final Guidance on Regulation A." *Press Release Distribution, EDGAR Filing, XBRL, Regulatory Filings*. N.p., 26 Mar. 2015. Web. 30 June 2016.
[2] 617 F.3d 490 (D.C. Cir. 2010)
[3] Id. at 496.

Statement of Paul R. Noe
Vice President, Public Policy
American Forest & Paper Association
American Wood Council

Before

Senate Committee on Homeland Security and Governmental Affairs
Subcommittee on Regulatory Affairs and Federal Management
"Examining the Use of Agency Regulatory Guidance, Part II"
June 30, 2016

Chairman Lankford, Ranking Member Heitkamp, and Members of the Subcommittee, my name is Paul Noe, and I am the Vice President for Public Policy for the American Forest & Paper Association and the American Wood Council. Thank you for the honor to testify before you on agency use of guidance documents. This is an important and timely issue, and we applaud the Subcommittee for doing the hard work of addressing the challenges this issue presents.

I have been involved in regulatory policy in Washington for over 30 years, including the privilege of having served as counsel to this Committee under Chairmen Fred Thompson, Ted Stevens and Bill Roth, and as a drafter of agency good guidance practices when I served as Counselor to Administrator John Graham at the Office of Information and Regulatory Affairs (OIRA) in the White House Office of Management and Budget (OMB). My experience working for the heavily regulated forest products industry for the last seven years further reinforces my appreciation of the importance of guidance and the benefit of due process and good management practices. We strongly believe that effective good guidance practices are an important step towards a more transparent, fair and effective regulatory system.

The American Forest & Paper Association (AF&PA) serves to advance a sustainable U.S. pulp, paper, packaging, tissue and wood products manufacturing industry through fact-based public policy and marketplace advocacy. AF&PA member companies make products essential for everyday life from renewable and recyclable resources and are committed to continuous improvement through the industry's sustainability initiative - *Better Practices, Better Planet 2020*. The forest products industry accounts for approximately 4 percent of the total U.S. manufacturing GDP, manufactures over $200 billion in products annually, and employs approximately 900,000 men and women. The

industry meets a payroll of approximately $50 billion annually and is among the top 10 manufacturing sector employers in 47 states.

The American Wood Council (AWC) is the voice of North American wood products manufacturing, representing over 75 percent of an industry that provides approximately 400,000 men and women in the United States with family-wage jobs. AWC members make products that are essential to everyday life from a renewable resource that absorbs and sequesters carbon. Staff experts develop state-of-the-art engineering data, technology, and standards for wood products to assure their safe and efficient design, as well as provide information on wood design, green building, and environmental regulations. AWC also advocates for balanced government policies that affect wood products.

AF&PA and AWC work together to advance policies of issues of mutual concern, including regulatory reform. The forest products industry has seen both sides of the coin on agency guidance. In some instances, questions of implementation can be appropriately and effectively resolved through guidance. In others, the use of agency guidance may lack appropriate transparency and due process, even to the point of inappropriately substituting for regulation. Accordingly, AF&PA and AWC support legislative and administrative efforts that ensure transparency, due process and effective management for significant agency guidance.

I. Background

A. The Need for Good Guidance Practices

President Reagan's Executive Order 12291, which firmly established OMB review of rules, was quite broad in scope and applied to virtually all "rules" – including both regulations (legally binding legislative rules) and agency guidance (non-binding interpretive rules and policy statements). When President Clinton replaced the Reagan Order in 1993 with Executive Order 12866, it honed in on "significant" regulatory actions. Given the vastness of federal regulatory activity, and the limited resources of OIRA, it was eminently sensible to try to sort the significant agency activity from the insignificant. The problem is that while the Clinton Order applied to significant regulations, it neglected guidance documents – covering only rules that "the agency intends to have the force and effect of law." But there is no doubt that guidance documents can be quite significant. In fact, agencies issue over 3400 regulations annually, but the volume of guidance documents is orders of magnitude larger,[1] and nobody actually knows how many there are.

[1] *See, e.g.,* Peter L. Strauss, *The Rulemaking Continuum*, 41 Duke L.J. 1463, 1469 (1992) (noting that the formally adopted rules of the Federal Aviation Administration are two inches thick, but the corresponding guidance materials, over forty feet; Part 50 of the Nuclear Regulatory Commission's regulations on nuclear plant safety, in loose-leaf edition, is 3/16 of an inch, but the supplemental technical guidance is 9 3/4 inches; and the formally adopted regulations of the IRS occupy one foot of shelf space, but Revenue rulings and similar publications, about twenty feet); *see also* H. Comm. on Gov't. Reform, "Non-Binding Legal Effect of Agency Guidance Documents," H.R.

Starting in 2002, as part of its obligation to provide recommendations for reform under the "Regulatory Right-to-Know Act," OIRA requested public comment on problematic agency guidance and regulations, and received public nominations of 49 problematic guidance documents in need of reform.[2] OIRA received further public comments on problematic guidance in response to its request for public comment on its draft *Report to Congress on the Costs and Benefits of Federal Regulation* in 2004 and 2005[3] and on the proposed Bulletin.[4] The public response was striking – hundreds of comments from a wide array of groups raised concerns – small businesses, farmers, state and local governments, homebuilders, colleges and universities, large businesses, hospitals, trade associations, funeral directors, public interest groups, think tanks, bird watchers, and others. A cursory review of the Preamble to the OMB Bulletin, the comments that OMB received and posted on its website, and the scholarly literature[5] provide many examples.

Although guidance documents may not properly carry the force of law, they are a key component of regulatory programs. As the scope and complexity of regulatory programs has grown, agencies increasingly have relied on guidance documents to provide direction to their staff and to the public. That generally is to the good, and I want to clearly acknowledge that agency guidance often is both very important and very helpful to the regulated community and others. As OMB put it:

> "Agencies may properly provide guidance to interpret existing law through an interpretative rule, or to clarify how they will treat or enforce a governing legal norm through a policy statement. . . . Guidance documents, properly used, can channel the discretion of agency employees, increase efficiency by simplifying and expediting agency enforcement efforts, and enhance fairness by providing the public clear

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Rep. No. 106-1009 (2000) (noting that between March 1996 through 1999, NHTSA had issued 1225 guidance documents, EPA 2653, and OSHA 1641).

[2] OMB, Key to Public Comments, https://www.whitehouse.gov/omb/inforeg_key_comments (last visited June 24, 2016); *see also*, OMB, *Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local and Tribal Entities*, at pp. 75-85 https://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/2002_report_to_congress.pdf (last visited June 24, 2016).

[3] OMB, *Peer Review and Public Comments on the 2005 Draft Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, http://www.whitehouse.gov/omb/inforeg/2005_cb/toc.html (last visited June 24, 2016); OMB, *Public Comments on 2004 Draft Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, https://www.whitehouse.gov/omb/inforeg_2004_cb_list_2004cb/ (last visited June 24, 2016).

[4] OMB, *Comments on Proposed Bulletin on Good Guidance Practices*, https://www.whitehouse.gov/omb/regpol_good_guid_c-index/ (last visited June 24, 2016).

[5] *See, e.g.*, Robert A. Anthony, *"Interpretive Rules, Policy Statements, Guidances, Manuals and the Like –Should Federal Agencies Use Them to Bind the Public?"* 41 Duke L.J. 1311 (1992); Robert A. Anthony, *"Interpretive" Rules, "Legislative" Rules and "Spurious" Rules: Lifting the Smog*, 8 Admin. L.J. (Spring 1994).

> notice of the line between permissible and impermissible conduct while ensuring equal treatment of similarly situated parties."[6]

Unfortunately, many concerns have been raised that agency guidance practices should be better managed and be more consistent, transparent and accountable. These concerns are reinforced by the GAO report that Congress requested on implementation of the OMB Bulletin by four cabinet departments.[7] Moreover, there is growing concern that, in some cases, guidance documents essentially are being used in lieu of regulations -- without observing the procedural safeguards for regulations. As the D.C. Circuit put it:

> The phenomenon we see in this case is familiar. Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in regulations. One guidance document may yield another and then another and so on. Several words in a regulation may spawn hundreds of pages of text as the agency offers more and more detail regarding what its regulations demand of regulated entities. Law is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations.[8]

The concern about the need for better management, transparency and due process for the development and use of guidance documents inspired OIRA to develop the OMB Bulletin for Agency Good Guidance provisions, supplemented by a provision in Executive Order 13422 for OMB review of agency guidance. In pertinent part, E.O. 13422 provided:

> "Significant Guidance Documents
> Each agency shall provide OIRA, at such times and in the manner specified by the Administrator of OIRA, with advance notice of any significant guidance documents. . . . Upon the request of the Administrator, for each matter identified as, or determined by the Administrator to be, a significant guidance document, the issuing agency shall provide to OIRA the content of the draft guidance document, together with a brief explanation of the need for the guidance document and how it will meet that need. The OIRA Administrator shall notify the agency when

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[6] OMB, *Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, at p. 72 https://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/2002_report_to_congress.pdf

[7] U.S. Government Accountability Office, *Regulatory Guidance Processes: Selected Departments Could Strengthen Internal Control and Dissemination Practices*, GAO-15-368 (April 2015) (reviewing implementation of OMB Bulletin for Agency Good Guidance Practices by the departments of Health and Human Services, Labor, Education and Agriculture and finding significant deficiencies).

[8] *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1019 (D.C. Cir. 2000) (striking down emissions monitoring guidance as requiring notice and comment through legislative rulemaking procedures).

> additional consultation will be required before the issuance of the significant guidance document."

Together, Executive Order 13422 and the OMB Bulletin established the first government-wide "rules of the road" to manage the development and use of guidance documents. The E.O. 13422 gave clear authority to OMB to review significant agency guidance documents, a streamlined version of how OMB reviews significant agency regulations. The agencies, in turn, were required to give OMB advance notice of their upcoming significant guidance documents. OMB would be responsible for ensuring that other interested agencies in the federal family received notice, and occasionally, an opportunity to provide input into the most important guidance documents.

The OMB Bulletin on Good Guidance Practices fit hand in glove with E.O. 13422. First, agencies must implement written procedures for the approval of significant guidance documents by appropriate senior officials. Agency employees should not depart from significant guidance documents without appropriate justification and supervisory concurrence. Second, significant guidance documents must have standard elements, such as information identifying the document as guidance, the issuing office, the activity and persons to whom it applies, the date of issuance, title and docket number.

Most notably, agencies are directed to avoid inappropriate mandatory language. This provision was intended to help curb the problem of "regulation by guidance document" criticized in the *Appalachian Power* decision and others. It also will obviate wasteful litigation and increase fairness and accountability in the exercise of regulatory power.

The Bulletin also establishes public access and feedback procedures. For example, agencies are required to maintain on their Web sites a current list of their significant guidance documents, and to provide a means for the public to electronically submit comments on significant guidance documents, or to request that they be created, reconsidered or modified. Finally, the Bulletin establishes pre-adoption notice and comment requirements for guidance documents that rise to the level of being "economically" significant.

When President Obama took office, he retained the OMB Bulletin, but he rescinded E.O. 13422. To substitute for the good guidance provisions of E.O. 13422, the OMB Director issued a memo to restore the regulatory review process to what it had been under Executive Order 12866 between 1993 and 2007. The memo stated: "During this period, OIRA reviewed all significant proposed or final agency actions, including significant policy and guidance documents. Such agency actions and documents remain subject to OIRA's review under Executive Order 12866."

My understanding is that, under that approach, OIRA reviewed little guidance, and when it did, the practice was ad hoc and disorganized. This comes as no surprise since there was no written authority for the practice -- and no procedures governing it. The problem is that:

- OIRA desk officers had to <u>*already know*</u> the guidance existed, and

- They had to get permission to call in a guidance.

That is not the best way to run a railroad. Simply put, you can't review what you don't know exists. The review process has broken down when the first time OIRA desk officers know about an important guidance document is when they read about it in the Washington Post. How many significant guidances do you think an OIRA desk officer might not know about before it was issued? Plenty, I can assure you. And would it be clearly unreasonable for agencies to feel that OMB had no business looking at their draft guidance without any explicit authorization? It was no accident that the provision for OIRA review of guidance was elevated into an Executive Order rather than simply being added to the Bulletin.

Indeed, ignoring guidance inadvertently can undermine OMB's authority to review regulations, similar to how it undermines court review, as the D.C. Circuit explained in *Appalachian Power*. The agency could issue broad, open-ended legislative rules that pass through interagency review (and court review, and for that matter, Congressional review). Then the agency could follow with guidance "expanding the commands in the regulations" to a degree that would have raised concerns if those details had appeared in the regulations from the start. In fact, one might wonder how OMB's abstention from managing and coordinating significant guidance documents may have contributed to the growth in "spurious rules" cases in the courts, which increasingly have criticized agencies for issuing binding rules without observing the public notice and comment procedures that Congress required in the Administrative Procedure Act.[9]

B. The Precedent for Good Guidance Practices

Even before the OMB public comment process, there was a strong foundation for the good guidance practices in E.O. 13422 and the OMB Bulletin that was rooted in the recommendations of leading authorities that stood for decades. This foundation includes the work of many authorities – including the Executive Branch,[10] Congress,[11] the courts,[12] the American Bar Association,[13] and legal scholars.[14]

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[9] The growth in so-called "spurious rule" court cases in the 1990s may not be a coincidence. *See, e.g., Gen. Elec. Co. v. EPA*, 290 F.3d 377 (D.C. Cir. 2002) (striking down PCB risk assessment guidance as a spurious rule requiring notice and comment); *Appalachian Power Co. v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000) (striking down emissions monitoring guidance as spurious rule requiring notice and comment); *U.S. Chamber of Commerce v. Dep't of Labor*, 174 F.3d 206 (D.C. Cir. 1999) (striking down OSHA Directive as a spurious rule requiring notice and comment). *See also,* OMB, *Final Bulletin for Agency Good Guidance Practices*, 72 Fed. Reg. 3432, 3435 (Jan. 25, 2007); OMB, *Key to Public Comments*, https://www.whitehouse.gov/omb/regpol_good_guid_c-index/ (last visited June 24, 2016).

[10] Recommendations of the Administrative Conference of the United States, *Agency Policy Statements*, Rec. 92-2, 1 C.F.R. § 305.92-2 (1992), *available at* http://www.law.fsu.edu/library/admin/acus/305922.html (stating that agencies should not issue statements of general applicability intended to be binding without using legislative rulemaking procedures and that agencies should afford the public a fair opportunity to challenge the legality or wisdom of policy statements and to suggest alternative choices); Recommendations of the Administrative Conference of the United States, *Interpretive Rules of General Applicability and Statements of General Policy*, Rec. 76-5, 1 C.F.R. § 305.76 (1992), *available at* http://www.law.fsu.edu/library/admin/acus/305765.html (stating that agencies should utilize APA notice and comment procedures for interpretive rules of general applicability or statements of general policy likely to have a substantial impact on the public); *The Food and Drug Administration's*

First, the Administrative Conference of the United States (ACUS)[15] issued recommendations for the development and use of agency guidance documents.As far back as the mid-1970s, for example, ACUS recognized the importance of ensuring a notice and comment process for the most significant guidance documents. ACUS Recommendation 76-5 states:

> "Before an agency issues, amends or repeals an interpretive rule of general applicability or statement of general policy which is likely to have a substantial impact on the public, the agency normally should utilize the procedures set forth in the Administrative Procedure Act subsections 553(b) and (c) .... Where there has been no prepromulgation notice and opportunity for comment, the publication of an interpretive rule of general applicability or a statement of general policy... should include ... an invitation to interested persons to submit written comments."[16]

ACUS Recommendation 92-2 later added:

Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. 8961 (Feb 27, 1997) (notice) (establishing FDA's original good guidance practices); OMB, *Draft Report to Congress on the Costs and Benefits of Federal Regulations*, 67 Fed. Reg. 15,014, 15,034-35 (Mar. 28, 2002) (detailing concerns over soliciting public comments on problematic agency guidance practices and specific examples of guidance documents in need of reform). *See also, infra*, note 21.

[11] *See, e.g.*, U.S. Government Accountability Office, *Regulatory Guidance Processes: Selected Departments Could Strengthen Internal Control and Dissemination Practices*, GAO-15-368 (April 2015); Congressional Review Act of 1996, 5 U.S.C. §§ 801-808 (2000) (providing fast-track procedures for Congressional resolutions of disapproval of rules and incorporating the APA definition of "rule" to cover guidance documents); *Food and Drug Administration Modernization Act of 1997*, 21 U.S.C. § 371(h) (2000) (establishing FDA good guidance practices as law); Congressional Accountability for Regulatory Information Act, H.R. 3521, 106th Cong. § 4 (2000) (proposing to require agencies to notify the public of the non-binding effect of guidance documents), H. Comm. on Government Reform, Non-Binding Legal Effect of Agency Guidance Documents, H.R. Rep. No. 106-1009 (2000) (criticizing "backdoor" regulation); *Food and Drug Administration Modernization and Accountability Act of 1997*, S. Rep. No. 105-43, at 26 (1997) (raising concerns about the lack of transparency and consistency in the use of guidance documents).

[12] *See, e.g., supra* note 9.

[13] ABA, *Annual Report Including Proceedings of the Fifty-Eighth Annual Meeting* 57 (1993) (recommending notice and comment for guidance documents likely to have a significant impact on the public); ABA, *Recommendation on Federal Agency Web Pages* 1 (2001), http://www.abanet.org/adminlaw/federa02.pdf (recommending that agencies post on their Websites, *inter alia*, all important policies and interpretations).

[14] *See, e.g.,* Robert A. Anthony, *"Interpretive" Rules, "Legislative" Rules and "Spurious" Rules: Lifting the Smog*, 8 Admin. L.J. I (1994); Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals and the Like-Should Federal Agencies Use Them to Bind the Public?* 41 Duke L.J. 1311 (1992); *see also*, OMB, *Final Bulletin for Agency Good Guidance Practices*, at pp. 2-3 & n. 2, 6.

[15] ACUS is a federal advisory agency charged with providing recommendations on administrative procedure issues. ACUS has made hundreds of recommendations on administrative procedure issues, and most were adopted by agencies or by Congress. *See* Florida State University College of Law, *ABA Administrative Procedure Database*, www.law.fsu.edu/library/admin/acus/acustoc.html (last visited June 24, 2016).

[16] Recommendations of the Administrative Conference of the United States, *Interpretive Rules of General Applicability and Statements of General Policy*, Rec. 76-5, 1 C.F.R. § 305.76-5 (1992), available at http://www.law.fsu.edu/library/admin/acus/305765.html.

> "Agencies should not issue statements of general applicability that are intended to impose binding substantive standards or obligations upon affected persons without using legislative rulemaking procedures.... Policy statements of general applicability should make clear that they are not binding.... Agencies that issue policy statements should examine, and where necessary, change their ... procedures ... to allow as an additional subject requests for modification or reconsideration of such statements."[17]

In 1993, the American Bar Association (ABA) reaffirmed the ACUS recommendations on the use of informal notice and comment procedure for significant guidance documents.[18] In 2001, the ABA further recommended that agencies "explore means to maximize the availability and searchability of existing law and policy on their websites" and include "their governing statutes, all agency rules and regulations, and all important policies, interpretations, and other like matters which members of the public are likely to request."[19]

Moreover, Congress produced what became a model for OMB's Good Guidance Practices.[20] In the Federal Food and Drug Administration Modernization Act of 1997, Congress directed the FDA to issue regulations establishing good guidance practices.[21] Congress was particularly concerned about public knowledge of, and access to, FDA guidance documents; the lack of a systematic process for adopting guidance documents and for allowing public input; and inconsistency in the use of guidance documents.[22] Those same concerns apply to other agencies as well.

II. The Need for Congressional Action

The case for Congressional action is clear. The OMB Bulletin has been in effect since early 2007 in both Republican and Democratic administrations. Over nine years is far more than enough time for the agencies to have fully complied with basic good guidance practices, and clearly they have not. The GAO Report reinforces what

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[17] ACUS, *Agency Policy Statements*, Rec. 92-2, 1 C.F.R. § 305.92-2 (1992), *available at* http://www.law.fsu.edu/library/admin/acus/305922.html

[18] ABA, *Annual Report Including Proceedings of the Fifty-Eighth Annual Meeting* 57 (1993) ("[T]he American Bar Association recommends that: Before an agency adopts a nonlegislative rule that is likely to have a significant impact on the public, the agency provide an opportunity for members of the public to comment on the proposed rule and to recommend alternative policies or interpretations, provided that it is practical to do so; when nonlegislative rules are adopted without prior public participation, immediately following adoption, the agency afford the public an opportunity for post-adoption comment and give notice of this opportunity.").

[19] ABA, *Recommendation on Federal Agency Web Pages* 1 (2001), http://www.abanet.org/adminlaw/federa02.pdf.

[20] As OMB stated in its Preamble (pp. 4-5), FDAMA and FDA's implementing regulations, as well as the recommendations of the former Administrative Conference, informed the development of the Bulletin.

[21] The *Food and Drug Administration Modernization Act of 1997 (FDAMA)*, 21 U.S.C. § 371(h) (establishing FDA good guidance practices as law). Based on FDAMA, the FDA made some changes to its existing procedures to clarify its good guidance practices. *See Administrative Practices and Procedures: Good Guidance Practices*, 21 C.F.R. § 10.115 (2007).

[22] *Food and Drug Administration Modernization and Accountability Act of 1997*, S. Rep. 10543, at 26 (1997).

scholarship, public comments and oversight, have shown. All rulemaking starts with Congress having delegated that authority to the agencies, so it is reasonable and commendable for Congress to improve the rulemaking process as needed.

From my discussions with staff, I understand that the Chairman is considering a legislative proposal to elevate the good guidance provisions of the OMB Bulletin and E.O. 13422 into legislation. We would enthusiastically support this proposal, because it would be a timely good government initiative that is based on the recommendations of leading authorities that have stood for decades. I also think it would be fully consistent with the tradition of bipartisan solutions for improving the regulatory process that has been the hallmark of this Committee for decades. Where a reform has such strong support from non-partisan organizations and experts, and a compelling public need, the desire to improve the transparency and quality of the rulemaking process is more relevant than party affiliation.

To supplement my testimony, I have attached a law review article I wrote on the good guidance practices in the OMB Bulletin and E.O. 13422 which is a foundation for my statement, key recommendations of ACUS, and letters from the ABA Section of Administrative Law and Regulatory Practice supporting those good guidance practices against a rider in 2007 and urging the inclusion of significant guidance in President Obama's Executive order on regulatory review in 2009.

In summary, the failure to implement clear and transparent good guidance practices undermines the quality, fairness, lawfulness and accountability of the regulatory system. Effective good guidance practices could provide much needed transparency, due process, and management for the rulemaking process. These practices are foundational to good government and are long overdue. I would be happy to address any questions you may have. Thank you again for the honor to testify before you.

Attachments

Testimony of
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Vice President for Policy/Director of Technology Studies
Competitive Enterprise Institute

Before the:
United States Senate Homeland Security and Governmental Affairs
Subcommittee on Regulatory Affairs and Federal Management
342 Dirksen Senate Office Building
Washington, D.C. 20510-0250

Examining the Use of Agency Regulatory Guidance, Part II
Thursday, June 30, 2016, 10:00 a.m.

Table of Contents

- Introduction: From Rule of Law to Rule by…Whatever
- The Unknown Number of Federal Agencies Issuing Rules
- How Many Rules Do Federal Agencies Issue That We Know About?
- Even When We Can Measure Ordinary Regulatory Matter, Public Protections Lag
- A Partial Inventory of "Regulatory Dark Matter"
  - *Executive Orders*
  - *Executive Memoranda*
  - *Agency Guidance Documents*
  - *Significant Executive Agency Guidance*
  - *Significant Independent Agency Guidance*
  - *Notices and Other Things That Are Not Quite Regulations that May or May Not Bind the Public*
- The Dark Energy of the Regulatory Process: When Fewer Regulations Mean Less Freedom
- Principles of Reform
  - *All agency decrees matter, not just the "rules"*
  - *Congress must subject guidance to enhanced APA-like procedures and more intense OMB review*
  - *Congress must vote approval of costly or controversial dark matter decrees*
- Conclusion: Congress's To-Do List

The Competitive Enterprise Institute (CEI) is a non-profit public policy research organization dedicated to advancing individual liberty and free enterprise with an emphasis on regulatory policy. We appreciate the opportunity to discuss issues surrounding agency guidance, and thank Mr. Chairman Lankford, Ranking Member Heitkamp, and Members of the Subcommittee.

Executive Summary

Congress passes and the president signs a few dozen laws every year. Meanwhile, federal departments and agencies issue well over 3,000 "legislative rules" and regulations of varying significance. A weekday never passes without new regulation. Yet beyond those rules, Congress lacks and must acquire a clear grasp on the amount and cost of the many thousands of executive branch and federal agency proclamations and issuances, including guidance documents, memoranda, bulletins, circulars, and letters with practical if not always technically legally binding regulatory effect. There are hundreds of "significant" agency guidance documents now in effect, plus many thousands of other such documents that are subject to little scrutiny or democratic accountability.

The Administrative Procedure Act (APA) of 1946 established the process of public notice for proposed rulemakings, and provided the opportunity for public input and comment before a final rule is published in the *Federal Register*, and a 30-day period before it becomes effective. But the APA's requirement of publishing a notice of proposed rulemaking and allowing public comment does not apply to "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice."

In addition to non-congressional lawmaking, the executive branch sometimes declines to enforce laws passed by Congress. Most prominent recently was the July 2013 Treasury Department's unilateral delay, first by blog post, then by IRS guidance, of the Affordable Care Act's (ACA) employer mandate and its accompanying tax penalty for non-compliance. Then came the November 2013 declaration—first by the president during a news conference and subsequently in Department of Health and Human Services guidance material—that insurers could continue to sell non-ACA compliant health policies.

It has long been the case that there are far more regulations than laws. That is troublesome enough. But with tens of thousands of agency proclamations annually, agencies may articulate interpretations and pressure regulated parties to comply without an actual formal regulation or understanding of costs. No one knows how much the regulatory state "weighs," or even the number of agencies at the center of our own bureaucratic "big bang." But for We, the Regulated, ignorance of the law is no excuse;

The upshot of such "regulatory dark matter" is that, without Congress actually passing a law or an APA-compliant legislative rule or regulation being issued, the federal government increasingly injects itself into our state, our community, and our personal lives. This testimony is a preliminary effort at outlining the scope of this phenomenon.[1] It concludes with steps for Congress to address dark matter and to address the over-delegation of legislative power that has permitted it.

Introduction: From Rule of Law to Rule by...Whatever

> *I've got a pen and I've got a phone. And that's all I need.*[2]
> —President Barack Obama, to applause from the U.S. Conference of Mayors

> *If the ruling power in America possessed both these means of government and enjoyed not only the right to issue orders of all kinds but also the capability and habit of carrying out those orders; if it not only laid down general principles of government but also concerned itself with the details of applying those principles; and if it dealt not only with the country's major interests but also descended to the limit of individual interests, then liberty would soon be banished from the New World.*
> —Alexis de Tocqueville, Democracy In America

Astrophysicists have concluded that ordinary visible matter—the Sun, the Moon, the planets, the Milky Way, the multitudes of galaxies beyond our own, and their trillions of component stars, planets, and gas clouds—make up only a tiny fraction of the universe. How tiny a fraction? Less than 5 percent. Instead, dark matter and dark energy make up most of the universe, rendering the bulk of existence beyond our ability to directly observe.[3]

Here on Earth, in the United States, where the government spends $4 trillion annually and regulatory compliance and economic intervention cost nearly half again that amount, there is also "regulatory dark matter" that is hard to detect, much less measure.

Congress passes a few dozen public laws from every year, but federal agencies issue several thousand "legislative rules" and regulations. The post-New Deal Administrative Procedure Act (APA) of 1946 established the process of public notice for proposed rulemakings, and provided the opportunity for public input and comment before a final rule is published in the *Federal Register*, and a 30-day period before it becomes effective.[4] So, we have ordinary public laws on the one hand, and ordinary allegedly above-board, costed out and commented-upon regulation on the other. But the APA's requirement of publishing a notice of proposed rulemaking and allowing public comment does not apply to "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice."[5] There are varying degrees of both clarity of language and adherence to rule of law for pronouncements that may bind or change behavior:

> **(1)** When issuing rules and regulations, agencies are legally required to adhere to the APA and subsequent strengthening legislation, but many do not. Further, most regulations' costs and benefits are unknown, so even much of the ostensibly APA-compliant body of rulemaking lacks transparency.
> **(2)** "Dark matter" such as agency and presidential memoranda, guidance documents ("non-legislative" or interpretive rules), notices, bulletins, directives, news releases, letters, and even blog posts may enact policy while flouting the APA's public notice and comment requirements for legislative rules.[6] They also can escape judicial review. Agencies and bureaus sometimes regulate without writing down anything. Explicit or veiled[7] threats achieve this, as can adverse publicity, whereby an agency issues unfavorable news releases to force compliance from private parties, who are left with no recourse to the courts.[8]

"Sub rosa" regulation has long been an issue, and scholars have studied it extensively. In his 1989 book, *Regulation and the Reagan Era*, economist Robert A Rogowski explained:[9]

> Regulatory bureaucracies are able to accomplish their goals outside the realm of formal rulemaking....An impressive underground regulatory infrastructure thrives on investigations, inquiries, threatened legal actions, and negotiated settlements. ... Many of the most questionable regulatory actions are imposed in this way, most of which escape the scrutiny of the public, Congress, and even the regulatory watchdogs in the executive branch.

Agency guidance documents and directives do not go through ordinary APA processes and are technically supposed to be non-binding, but one ignores them at peril. As the D.C. Circuit famously noted in the 2000 case, *Appalachian Power Co. v. Environmental Protection Agency*:

> Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in regulations. One guidance document may yield another and then another and so on. ...Law is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations.[10]

The upshot of regulatory dark matter is that, without Congress actually passing a law or a "normal" APA-compliant legislative rule or regulation being issued, the federal government increasingly injects itself into our state, our community, and our personal lives on matters such as health care, retirement, labor policy, education policy and funding, finance, critical infrastructure, land access and usage, resource management, science and research funding, energy policy, and frontier manufacturing and technology.

In addition to non-congressional lawmaking, the executive branch often declines to enforce laws passed by Congress. Most prominent recently was the July 2013 Treasury Department's unilateral delay, first by blog post, then by IRS guidance, of the Affordable Care Act's employer mandate and its accompanying tax penalty for non-compliance.[11] Then came the November 2013 declaration, first by the president during a news conference and subsequently in Department of Health and Human Services guidance material, that insurers could continue to sell non-ACA compliant health policies.[12] Similarly, the Department of Homeland Security's policy, "Exercising Prosecutorial Discretion with Respect to Individuals Who Came to the United States as Children and with Respect to Certain Individuals Who Are the Parents of U.S. Citizens or Permanent Residents," was announced in an internal agency memorandum.[13]

President Obama's apparent disdain for Congress has brought about a dark matter apex of sorts. As he said in 2011:[14]

> I've told my administration to keep looking every single day for actions we can take without Congress. ... And we're going to be announcing these executive actions on a regular basis.

That stance was reiterated during President Obama's 2014 State of the Union Address, when he pledged to implement a "year of action," with or without Congress.[15] Agency officials have largely gone along in this aggressive off-the-books rulemaking. "One of the ways that the White House plays a role is to think forward and challenge the agencies to be proactive in saying, 'What more can we do? And what more can we do that's consistent with certain themes?'" explained Obama adviser Brian Deese to *USA Today*.[16] *USA Today* also tallied an increase in "fact sheets" highlighting new agency initiatives during the course of the administration, of which there were 224 in 2014, more than the administration's first three years combined.[17] While President Obama has experienced some backlash over his exercise of executive power, the current dynamic in Washington is still one of Congress responding to the president's legislative agenda rather than the president responding to Congress.[18]

The president is not wholly to blame, though. Congress' over-delegation of its own authority has undermined checks and balances and the principle of separation of powers. Our government's branches seem not to so much to check-and-balance as to leapfrog one another, to ratchet the growth of government upward rather than constrain it to a constitutionally limited role. Cronyism is one thing, but the annihilation of rule of law and its replacement with officials' whim is the essence of usurpation and ultimately tyranny. When representative lawmaking gets delegated to untethered bureaucrats, the decrees of those autonomous administrators can eventually outweigh normal lawmaking as regulatory dark matter expands. As Congress shirks, the presidential "pen and phone" become easier to deploy.

From federal agency regulations on Internet neutrality[19] to health care overhaul to renewable energy power plans that Congress itself rejected when recorded votes mattered,[20] one gets the distinct impression that some in power see the private sector as optional. The rise of dark matter indicates many see the Constitution as optional as well.

The Unknown Number of Federal Agencies Issuing Rules

As bureaucracy sprawls,[21] no one can say with complete authority exactly how many federal agencies exist. The twice-annual *Unified Agenda of Federal Deregulatory and Regulatory Actions*, which compiles agency regulatory plans in the federal pipeline, listed 60 agencies in the Spring 2015 edition,[22] a count that can vary slightly from report to report. The fall 2014 edition, which also contained many agencies' so-called Regulatory Plan, also listed 60.

However, in recent years, the once-routine *Unified Agenda*'s April-and-October schedule appears to be a thing of the past, as it has been published late or failed to appear at all, as in Spring 2012. Moreover, the Draft 2015 *Report to Congress on the Benefits and Costs of Federal Regulations*, which usually appears by April at the latest, was the latest ever, appearing on October 16.[23] The previous latest various were those straddling the two Bush/Obama transition years.[24] So transparency of the bureaucracy is an issue in more ways than one.

The Administrative Conference of the United States lists 115 agencies in the appendix of its "Sourcebook of United States Executive Agencies,[25] but notes:[26]

> [T]here is no authoritative list of government agencies. For example, FOIA.gov [maintained by the Department of Justice] lists 78 independent executive agencies and 174 components of the executive departments as units that comply with the Freedom of Information Act requirements imposed on every federal agency. This appears to be on the conservative end of the range of possible agency definitions. The United States Government Manual lists 96 independent executive units and 220 components of the executive departments. An even more inclusive listing comes from USA.gov, which lists 137 independent executive agencies and 268 units in the Cabinet.

In a 2015 Senate Judiciary Committee hearing, Chairman Chuck Grassley (R-IA) noted: "The Federal Register indicates there are over 430 departments, agencies, and sub-agencies in the federal government."[27] The Senator apparently was citing the Federal Register Agency List, which depicts 438 agencies as of this writing.[28] The online Federal Register Index depicts 257.[29] Table 1 summarizes various tallies.

Table 1. How Many Federal Agencies Exist?

Unified Agenda:	60
Administrative Conference of the United States	115
FOIA.gov (at Department of Justice)	252
Federal Register Index page	257
Regulations.gov[30]	289
United States Government Manual	316
Federal Register Agency List page	438

If nobody knows how many agencies exist by whose decrees we must abide, that means we do not know how many people work for the government (let alone contractors making a living from taxpayers) nor how many rules there really are. But even when we isolate a given, knowable agency, it may be hard to tell exactly what is and is not a rule. That, plus the growing concern that issuing a rule may not even be necessary to achieve bureaucratic ends, call out for congressional response. But let us start with what we do (think we) know about agency rules.

How Many Rules Do Federal Agencies Issue That We Know About?

Much binding law comes from agencies rather than elected lawmakers. Federal departments, agencies, and commissions issued 3,410 rules in 2015, while Congress passed and the president signed 115 bills into law—a ratio of 30 rules for every law.[31] The average has been 26 rules for every law over the past decade as Table 2 indicates. The rules issued in a given year are typically not substantively related to the current year's laws, since agency output represents ongoing implementation of earlier legislation. So far in 2016, agencies have issued 1,634 rules, as of June 22, 2016. Looking back, there have been 86,680 rules since 1995.

Another 2,342 proposed rules appeared in 2015 and are under agency consideration.
So far in 2016, agencies have issued 1,172 additional proposed rules (as of June 22).

Table 2. Public Laws vs. Agency Rules by Category

Year	Public Laws	Total Rules	Econ. Signif. Rules	Major Rules (GAO)	Signif. Rules
1995	88	4,713			
1996	246	4,973		42	308
1997	153	4,584		46	268
1998	241	4,899	27	76	242
1999	170	4,684	41	51	231
2000	410	4,313	35	77	288
2001	108	4,132	75	70	295
2002	269	4,167	38	51	284
2003	198	4,148	38	50	336
2004	299	4,101	40	66	321
2005	161	3,975	48	56	258
2006	321	3,718	48	56	163
2007	188	3,595	41	61	180
2008	285	3,830	62	95	427
2009	125	3,503	70	84	371
2010	217	3,573	81	100	420
2011	81	3,807	79	80	444
2012	127	3,708	57	68	347
2013	72	3,659	51	81	331
2014	224	3,554	69	81	290
2015	115	3,410	61	76	302
2016*	62	1,634	36	33	130
TOTALS:	**4,160**	**86,680**	**997**	**1400**	**6236**

*As of 6/22/2016

Sources: Public Laws: Government Printing Office; Total Rules and Significant Rules: author search on FederalRegister.gov advanced search function, economically significant rules; Unified Agenda of Federal Regulations search on RegInfo.gov; Major Rules: Government Accountability Office. *Figures updated at www.tenthousandcommandments.com.*

As Table 2 also shows, a few dozen rules are characterized as "major," "economically significant" or "significant." There are differences between these defined in law and executive orders, but the usual characterization is of at least $100 million in annual economic impact.[32] Notably, "significant" regulatory actions regularly exceed the number of duly enacted laws.

Even When We Can Measure Ordinary Regulatory Matter, Public Protections Lag

> *[A]s more goals are pursued through rules and regulations mandating private outlays rather than through direct government expenditures, the Federal budget is an increasingly inadequate measure of the resources directed by government toward social ends.*[33]

—Economic Report of the President (Jimmy Carter), 1980

One problem with simply bringing guidance under the Administrative Procedure Act is that even normal rules aren't getting the treatment they deserve under the APA.

We are supposed to be bound solely by laws enacted by Congress and signed by the president, but things do not quite work out that way. Theoretically, thousands of federal agency rules receive scrutiny under the Administrative Procedure Act. Proposed rules are issued, and the public is supposed to get ample time to comment before final rules are published and become binding. Laws amending the APA have sought to subject complex and expensive rules to additional analysis. These reforms include the Paperwork Reduction Act of 1980,[34] the Regulatory Flexibility Act (to address small business impacts),[35] and the Congressional Review Act (CRA), which enables Congress to vote on a resolution of disapproval to reject agency regulations.[36] In addition, various presidential executive orders govern central review of rules by the Office of Management and Budget (OMB) and address cost-benefit analysis for some rules.[37] Regulatory dark matter can escape these requirements.

To put the dark matter discussion into context, we should note shortcomings in oversight of the ordinary, everyday rules and regulations.

First, the central review process at the Office of Management and Budget set up by President Ronald Reagan's Executive Order 12291[38] (as well as subsequent executive orders from other presidents) to assure rule benefits exceed costs is incomplete.[39] President Bill Clinton's 1993 Executive Order No. 12866 eased off the heavier OMB oversight of the Reagan order in that it sought "to reaffirm the primacy of Federal agencies in the regulatory decision-making process."[40] The process was never thorough—it incorporated only executive agencies, not independent agencies—but today central review captures only a fraction of rulemaking.

During calendar year 2014, when 3,554 rules were finalized by 60 federal departments, agencies, and commissions, OMB's 2015 *Report to Congress* (covering fiscal year 2014) reviewed a few hundred significant rules, and 54 major rules—but presented net-benefit analysis for only 13.[41] Notably, the Draft 2016 report is not yet available. Apart from listing some of their major rules, OMB completely ignores independent agencies, some of which are highly influential, such as the Federal Communications Commission and the several bodies implementing and enforcing the Dodd-Frank law. Table 3 compares OMB reviews with the total final rule count in the *Federal Register* over recent years. Overall, the OMB has reviewed just 160 rules since 2001 that happened to incorporate both cost and benefit analysis, and another 86 with cost analysis. While these thousands of rules are all subject to APA, much is "dark matter" in its own right, in the sense that we know little about costs, benefits, and burdens.

Table 3. Major Executive Agency Rules Reviewed by OMB

Year	Rules with both costs and benefits	Rules with costs only	Grand total, rules with costs	Federal Register final rules

2001	14	13	27	4,132
2002	3	0	3	4,167
2003	6	4	10	4,148
2004	11	7	18	4,101
2005	13	2	15	3,943
2006	7	1	8	3,718
2007	12	4	16	3,995
2008	13	6	19	3,830
2009	16	12	28	3,503
2010	18	8	26	3,573
2011	13	6	19	3,807
2012	14	9	23	3,708
2013	7	11	18	3,659
2014	**13**	**3**	**16**	**3,554**
TOTALS	**160**	**86**	**246**	**53,838**

Sources: Costed rule counts, OMB, *2015 Report to Congress* on regulatory costs, Federal Register Final Rules: author search on FederalRegister.gov advanced search function

Second, the APA process is broken in that agencies fail to issue a Notice of Proposed Rulemaking for a substantial portion of their rules.[42] According to a Government Accountability Office (GAO) report:[43]

> Agencies did not publish a notice of proposed rulemaking (NPRM), enabling the public to comment on a proposed rule, for about 35 percent of major rules and about 44 percent of nonmajor rules published during 2003 through 2010.

Agencies often cite the APA's "good cause" exemption,[44] which in GAO's sample agencies used "for 77 percent of major rules and 61 percent of non-major rules published without an NPRM."[45] Yet, the sky is rarely falling in a way that requires such haste. Rather, agencies too often act as if it is practical, necessary, and in the public interest to bypass Congress and make law unilaterally, compounding the breakdown in accountability embodied in delegation itself.

In their defense, agencies tend to ask for public comments more often than not on final rules for which they had never issued a notice of proposed rulemaking. But that gesture is too little too late since, as GAO notes, "the public does not have an opportunity to comment before the rule's issuance, nor is the agency obligated to respond to comments it has received."[46] Reports like the GAO survey appear, and nothing happens to rectify things.

Third, Congress rarely uses its most powerful accountability tool, the Congressional Review Act, to pass resolutions of disapproval (RODs) of costly or controversial agency rules. With spotty public notice and inadequate accountability, it is imperative that Congress frequently go on record via such resolutions to push back against agency overreach. The Regulations from the Executive In Need of Scrutiny (REINS) Act, which has passed the House of Representatives but not yet the Senate, would build on the CRA by creating a requirement akin to an affirmative CRA-style resolution. Under the REINS Act, no major rule—costing $100 million or more annually—could become effective until Congress explicitly approved it.[47] This is a principle that also should apply to dark matter like agency guidance documents and memoranda.

Fourth, even if Congress were inclined to aggressively impose authority, the CRA itself is further undermined by agency lapses. As Curtis W. Copeland found in a white paper prepared for the Administrative Conference of the United States, many final rules are no longer properly submitted by agencies to the GAO's Comptroller General (CG) and to Congress, as required under the CRA.[48]

That submission is indispensable, since Congress awaits reports to issue a resolution of disapproval in the first place. By failing to submit rules, Copeland notes, "the rulemaking agencies have arguably limited Congress' ability to use the expedited disapproval authority that it granted itself with the enactment of the CRA."[49] Congress in a sense lacks the raw material it needs to even contemplate a resolution of disapproval. Remedies for this include passing REINS or automating RODs on every final rule.

Technically, the CRA already applies to agency actions like guidance that are ostensibly not formal rules. In a 1999 *Administrative Law Review* article, Morton Rosenberg of the Congressional Research Service describes legislative history that shows that the scope of the CRA extends beyond agency rules. Rather, noted Rosenberg, the CRA "intentionally adopted the broadest possible definition of the term 'rule' when it incorporated the APA's definition," and was "meant to encompass all substantive rulemaking documents—such as policy statements, guidances, manuals, circulars, memoranda, bulletins and the like—which as a legal *or* practical matter an agency wishes to make binding on the affected public."[50] The CRA's framers recognized the phenomenon of agency strategic avoidance of APA. As Rosenberg notes:

> The framers of the legislation indicated their awareness of the now widespread practice of agencies avoiding the notification and public participation requirements of APA notice-and-comment rulemaking by utilizing the issuance of other, non-legislative documents as a means of binding the public, either legally or practically, and noted that it was the intent of the legislation to subject just such documents to scrutiny.[51]

The regulatory bureaucracy is not the only place Washington's attitude toward the public is to conceal rather than disclose. Misleading unemployment and GDP statistics are often cited to justify increased government spending.[52] Recent news headlines report on inadequate responses by agencies to Freedom of Information Requests, the use of private email for official business, and loss of government emails.[53] Reporters describe difficulty in accessing federal data.[54] We even find claims in the water-flows-uphill category to justify rulemaking: that switching from fossil energy to more expensive and less reliable "alternative" sources of electricity saves money,[55] that adding regulations creates jobs and growth,[56] that minimum wages do not decrease employment,[57] and that forcing companies to pay expand overtime pay helps to grow the middle class.[58]

Modern government sports a pen and phone but also a cloak and a lock, even as it calls itself the "most transparent administration in history."[59] Administrative regulations that ostensibly are subject to notice and comment already do not get appropriate supervision; that makes dark matter, although most assuredly not a new phenomenon, more of a concern in the modern era.

A Partial Inventory of Regulatory Dark Matter

> *The champions of socialism call themselves progressives, but they recommend a system which is characterized by rigid observance of routine and by a resistance to every kind of improvement. They call themselves liberals, but they are intent upon abolishing liberty. They call themselves democrats, but they yearn for dictatorship. They call themselves revolutionaries, but they want to make the government omnipotent. They promise the blessings of the Garden of Eden, but they plan to transform the world into a gigantic post office. Every man but one a subordinate clerk in a bureau.*
>
> — Ludwig von Mises, Bureaucracy (1944)

We can count agency proposed and final rules, and even executive orders and memos, but agency memos, guidance documents, bulletins, and other dark matter are more difficult to broadly grasp and measure. And there is a *lot* of it.

Over-delegation by Congress and non-compliance with the Administrative Procedure Act by agencies are bad enough. But the inability and disinclination to discipline ordinary regulation via the tools purportedly created specifically to ensure that self-restraint—including APA notice-and-comment and OMB central review—is exacerbated by the presence of regulatory dark matter, which escapes constraint. Regulatory compliance costs are often referred to as a hidden tax, but dark matter occupies a class by itself with its lack of disclosure, supervision, and transparency.[60] Guidance documents, presidential and agency memoranda, and notices and bulletins with legal effect can skirt nearly everything: the constitutional lawmaking process, the APA's notice-and-comment requirements, and federal OMB review. As DePaul University law professor David L. Franklin notes: "The distinction between what is binding regulation and what is exempt from notice and comment has been called 'tenuous,' 'baffling,' and 'enshrouded in considerable smog.'"[61]

What follows represents an initial stab at tallying a snapshot of regulatory dark matter. While not all of these are prescriptive regulations, the cumulative effect of the policy making dark matter is highly significant and burdensome. The bottom line: Our elected Congress needs to reassert its constitutional authority over what rules legitimately affect the public.

Executive Orders

> *And though we sung his fame*
> *We all went hungry just the same*
>
> —Steely Dan
> "Kings," on the album *Can't Buy a Thrill.*
> A song about the transition from Richard the Lionheart
> to King John, prior to the Magna Carta.

> *We'll do audacious executive action throughout the course of the year—I'm confident about that....We're going to lean pretty hard into it.*[62]
>
> —White House Chief of Staff Denis McDonough

The use of executive orders (EOs) is nothing new historically, dating back to George Washington's administration.[63] They are not strictly dark matter, but they contribute to policy being implemented without Congress doing so explicitly, and the anchor the braoder discussion over executive branch power. Executive orders' realm is that of the internal workings and operations of the federal government. While technically orders affect just the current administration and subsequent presidents can overturn them, the complexity of overturning them grows as Washington intervenes into more private spheres of activity. For example, President Obama's executive order for a minimum wage for federal contractors,[64] a Non-Retaliation for Disclosure of Compensation Information decree,[65] and an executive order on paid sick leave for federal contractors will reverberate for years among private firms that deal with the government.[66] The same is true for orders on cybersecurity information sharing[67] and sanctions on individuals allegedly engaged in malicious cyber activity,[68] both of which are controversial not only because of their potential effects on privacy, but also for their not having been passed by Congress.[69] Other Obama EOs have addressed matters internal to executive operations, such as blocking accounts of Russian authorities believed responsible for the Ukrainian crisis.[70]

Pen and phone notwithstanding, Obama is far from an EO record-holder. He is no match for Franklin Delano Roosevelt's 3,467 executive orders, among them the seizure of gold.[71] And unlike Harry Truman, he has not attempted to seize steel mills.[72] As of June 22, 2016, President Obama had issued 259 executive orders in total during his entire administration, and he has issued 17 so far in 2016.[73]

Executive orders numbered in the single digits or teens until Abraham Lincoln and the subsequent reconstruction period. The Ulysses S. Grant administration issued 217, then a record.[74] Beginning in the 20th century, orders topped 100 for each presidential term and sometimes numbered in the thousands (again, FDR). The total since the nation's founding exceeds 15,000.[75] Table 4 lists executive orders issued over the past two decades, showing 800 since 1994 according to the *Federal Register* office; the Obama White House lists significant executive orders separately.[76]

Table 4. Number of Executive Orders

Year	Federal Register Database	White House Tally
1995	40	
1996	50	
1997	38	
1998	38	
1999	35	
2000	39	
2001	67	
2002	32	
2003	41	
2004	46	
2005	27	

2006	25	
2007	32	
2008	29	
2009	44	39
2010	41	38
2011	33	36
2012	39	39
2013	24	19
2014	34	29
2015	29	24
2016*	17	15
TOTALS:	**800**	**239**

As of 6/22/2016
Blanks are not available at source or database
Sources: Author search on FederalRegister.gov advanced search function; Presidential Documents; White House Press Office. *Figures updated at www.tenthousandcommandments.com.*

Whether lengthy or brief, orders and memoranda can have significant impacts for or against liberty—a smaller number does not necessarily mean small effects. Like the *Federal Register*, or the numbers of final rules, tallies are interesting but do not tell the whole story in and of themselves. The pertinent question is what executive orders and memoranda—and the ones to come now that the pen and phone are unleashed—are used for and what they *do*. Executive actions can expand governmental power, or they can liberalize and enhance freedom (think Lincoln's Emancipation Proclamation). Obama's Executive Order No. 13563 concerning "Improving Regulation and Regulatory Review" was a pledge to streamline regulation; however it has so far amounted to a few billion dollars in cuts that were swamped by other rules issued.[77] In all, four of Obama's executive orders address regulatory liberalization and reform, but their effectiveness has been limited.[78]

Notable recently on the regulatory front was the executive order "Steps to Increase Competition and Better Inform Consumers and Workers to Support Continued Growth of the American Economy."[79] This action proposes interventionist policies and seemed an attempt to blame anti-competitive practices, not on the regulatory state and the executive branch's own overreach with the "pen and phone," but on private sector actors.[80] The order was inappropriately positive toward telecommunications and antitrust regulation.

Some executive activity that transpires today appears without precedent. *The Washington Post* characterized Obama's unilateral executive action on immigration as one that "flies in the face of congressional intent—no matter how indefensible that intent looks."[81] More notable from the "dark matter" perspective is that the president never actually signed such an executive order, and the Department of Homeland Security never published a rule in the *Federal Register*. Rather, a memorandum was issued by Homeland Security Secretary Jeh Johnson.[82]

Executive Memoranda

USA Today calls presidential memoranda "[e]xecutive orders by another name" that are "not numbered" and "not indexed."[83] Memoranda are hard to count, because they may or may not be

published, depending on the administration's own determination of "general applicability and legal effect."[84]

While presidential memoranda are not new, their quantity has grown significantly in recent years. President Obama's pace tops that of George W. Bush's presidency. Bush issued 131 memos that were published in the *Federal Register* over his entire presidency,[85] while Obama issued 232 as of June 22, 2016, with another year to go.[86] As noted, not all memoranda get published in the *Federal Register*. Some may appear on the White House press office's Web page.[87] Indeed, the Obama White House tally is significantly higher than what gets published in the *Federal Register*. Table 5 shows both tallies.

Table 5. Number of Presidential Memoranda

Year	Federal Register Database	White House Tally	Rules with Both Costs and Benefits	Economically Significant Rules
2000	13			35
2001	12		14	75
2002	10		3	38
2003	14		6	38
2004	21		11	40
2005	23		13	48
2006	18		7	48
2007	16		12	41
2008	15		13	62
2009	38	68	16	70
2010	42	70	18	81
2011	19	85	13	79
2012	32	85	14	57
2013	32	52	7	51
2014	25	45	13	69
2015	31	72		61
2016*	16	52		36
TOTALS:	**377**	**529**		

*As of 6/22 2016; Blanks are not available at source or database
Sources: Author search on FederalRegister.gov advanced search function, Presidential Documents; White House Press Office; Presidential Memoranda. *Figures updated at www.tenthousandcommandments.com.*

Not all memoranda have regulatory impact, but many do. In 2014, Obama memoranda did such things as create a new financial investment instrument and impose new requirements on government contractors regarding work hours and employment preferences. Note again that these are not laws passed by Congress. They are not regulations. They are not even executive orders. They are memos. Presidential memoranda "hereby direct" someone in the federal hierarchy to do something that often leads to new controls and larger government. They are also often aimed at government contractors, which spill over on the private sector or affect private

sector planning, and they remain in place unless a future president revokes them. Here are some recent examples among the count above that were documented in the *Federal Register*:

- Mitigating Impacts on Natural Resources from Development and Encouraging Related Private Investment 11/03/2015.[88] According to a February 2016 House Natural Resources Subcommittee on Oversight and Investigations hearing memo, this directive, issued to five federal agencies and governing mitigation of resource impacts from permitting for projects and activities, "appears to create sweeping new statutory authority through unilateral executive action, and represents a substantial re-write of public land use and water policy....Many of the terms used in the Memorandum to describe resources requiring mitigation from projects—including 'important,' 'scarce,' 'sensitive,' and 'irreplaceable,' are not found in existing statutes and are largely undefined in the Memorandum. The vague and overbroad terms will likely lead to legal uncertainty for many currently permitted projects."[89]
- Promoting Smart Gun Technology 01/04/2016
- Promoting Rehabilitation and Reintegration of Formerly Incarcerated Individuals 04/29/2016
- Unexpected Urgent Refugee and Migration Needs 01/13/2016
- Building National Capabilities for Long-Term Drought Resilience 03/21/2016
- Limiting the Use of Restrictive Housing by the Federal Government 03/01/2016
- Creating a Preference for Meat and Poultry Produced According to Responsible Antibiotic-Use Policies 06/01/2015
- Re-establishing Diplomatic Relations and Permanent Diplomatic Missions [with Cuba] 07/01/2015
- Expanding Broadband Deployment and Adoption by Addressing Regulatory Barriers and Encouraging Investment and Training 03/23/2015
- Student Aid Bill of Rights to Help Assure Affordable Loan Repayment 03/10/2015
- Establishment of the Cyber Threat Intelligence Integration Center 02/25/2015
- Promoting Economic Competitiveness while Safeguarding Privacy, Civil Rights, and Civil Liberties in Domestic Use of Unmanned Aircraft Systems 02/20/2015
- Expanding Federal Support for Predevelopment Activities for Nonfederal Domestic Infrastructure Assets 01/16/2015
- Modernizing Federal Leave Policies for Childbirth, Adoption, and Foster Care to Recruit and Retain Talent and Improve Productivity 01/15/2015
- Enhancing Workplace Flexibilities and Work-Life Programs 06/27/2014
- Helping Struggling Federal Student Loan Borrowers Manage Their Debt 06/12/2014
- Advancing Pay Equality through Compensation Data Collection 04/11/2014
- Updating and Modernizing Overtime Regulations 03/18/2014
- Creating and Expanding Ladders of Opportunity for Boys and Young Men of Color 03/07/2014
- Job-Driven Training for Workers 2/05/2014
- Enhancing Safeguards to Prevent the Undue Denial of Federal Employment Opportunities to the Unemployed and Those Facing Financial Difficulty through No Fault of Their Own 02/05/2014
- Retirement Savings Security 02/04/2014

- Establishing a White House Task Force to Protect Students From Sexual Assault 01/27/2014
- Establishing a Quadrennial Energy Review 01/14/2014

There are 3,500-plus rules and regulations annually, while OMB presents cost-benefit analyses for just a handful each year of the few hundred it reviews. OMB has reviewed just 160 rules with both cost and benefit analysis since 2001, and another 86 with cost analysis (Tables 3 and 5),

Interestingly, the number of presidential memoranda each year exceeds the numbers of "ordinary matter" rules with OMB-reviewed cost-benefit analyses (Tables 3 and 5). In other words, while administrations often emphasize the alleged "net benefits" of major rules,[90] those few are topped by the number of "mere" memoranda, many of which would appear to have significant impacts. Also interesting is that the number of memoranda, per the White House tally, can sometimes approach or even exceed that of completed economically significant rules ($100 million in annual economic impact) published in the *Unified Agenda* (Tables 2 and 5).

Agency Guidance Documents

> *Too often, however, agencies opt for short-cuts. Rather than bothering with the burdensome rule-making process, they use faster and more flexible means of imposing mandates. To avoid running afoul of the letter of the Administrative Procedure Act, these mandates are often couched in tentative, temporary or voluntary terms. Regardless of the language and the format, the effect is the same for regulated entities. The agency suggests that you do something — even if it says that it might suggest something different later — and you do it.*[91]
>
> —Hester Peirce, Mercatus Center

If we do not measure agency rules well, we most assuredly do not measure agency guidance with anything approaching precision. As noted, the Administrative Procedure Act's publishing requirement for proposed rulemaking does not apply to "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice."[92] Such memos, bulletins, and letters can take up considerable space in the *Federal Register* and on agency websites. The problem is that agencies may issue instructions or new interpretations of existing regulations and pressure regulated parties into complying without issuing an actual formal regulation, much less an estimate of costs or burdens.

While purportedly not legally binding, guidance may be binding "as a practical matter," as the late George Mason University law professor and chairman of the Administrative Conference of the United States Robert A. Anthony noted in a 1992 *Duke Law Journal* article, given that "failure to conform will bring adverse consequences, such as an enforcement action or denial of an application."[93] Guidance documents may help agencies circumvent oversight, similar to the "good cause" exemption that already results in notices of proposed rulemaking not being issued for some formal rules. Agencies can also place conditions on their guidance in ways that make it hard to punish them—such as for example, the "contains nonbinding recommendations" caveat that appears throughout the Food and Drug Administration's (FDA) guidance on "Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices."[94]

As a July 2012 House Oversight and Government Reform Committee report explained:

> Guidance documents, while not legally binding or technically enforceable, are supposed to be issued only to clarify regulations already on the books. However … they are increasingly used to effect policy changes, and they often are as effective as regulations in changing behavior due to the weight agencies and the courts give them. Accordingly, job creators feel forced to comply.[95]

John Graham, former head of OMB's Office of Information and Regulatory Affairs (OIRA), and James Broughel of the Mercatus Center at George Mason University call this phenomenon "stealth regulation." They note:

> [Guidance documents] Can have the same effects as a regulation adopted under the APA if regulated entities have no realistic choice but to comply with these agency directives. Moreover, agencies can change these directives without notice-and-comment, and because these documents are generally not published in the Code of Federal Regulations, compliance is more costly for firms that must survey an array of sources to determine how to maintain compliance.[96]

Guidance is pervasive. As University of Washington School of Law reference librarian Mary Wisner notes: "[T]he body of guidance documents (or non-legislative rules) is growing, both in volume and in importance."[97] This paper is an attempt to quantify this mass of sub-rosa regulation. Columbia University law professor Peter Strauss noted (in the same issue of *Duke Law Journal* as Anthony): "Federal Aviation Administration rules are two inches thick while corresponding guidance totals 40 feet; similarly, IRS rules consume a foot of space while supporting guidance documents total over 20 feet."[98]

Noting that the Congressional Review Act is applicable to guidance and other documents, not merely rules (but alas, has yet to be applied to them), Morton Rosenberg characterized high volume back in 1999. Since most of the material submitted to the Comptroller General per the CRA has been ordinary notice-and-comment regulation, Rosenberg maintained:

> It is likely that virtually all the 15,000-plus non-major rules thus far reported to the [Comptroller General] have been either notice-and-comment rules or agency documents required to be published in the Federal Register. This would mean that perhaps thousands of covered rules have not been submitted for review. Pinning down a concrete number is difficult since such covered documents are rarely, if ever, published in the *Federal Register*, and thus will come to the attention of committees or members only serendipitously.[99]

Even in the face of such volume, some dispute the notion that recent guidance is meant to circumvent Congress. Connor N. Raso in the *Yale Law Journal* contends that "agencies do not frequently use guidance documents to avoid the rulemaking process."[100] Raso argues that concerns over guidance are overblown, because the amount of significant guidance documents issued is low compared to APA rules, and agency heads rarely reverse predecessors' guidance.

However, the expansive modern regulatory state is a bipartisan phenomenon and there is no good reason to believe that either party would remove very much guidance upon a change in administration.

Moreover, officially "significant" guidance documents may not capture the extent of guidance that is, in fact, significant. Ohio State law professor Peter Shane defends Raso's article and the guidance-propelled regulatory state itself by asking, "Might the Motivation for Agency Guidance be the Public's Need for Guidance?"[101] But that gets it backward. If thousands of regulations and directives were not a fact of life, there would exist less of a "need." As the economics writer Henry Hazlitt noted: "[I]f the government confined itself to enacting a code of laws simply intended to prevent mutual aggression and to maintain peace and order, it is hard to see how such a code would run into any great number of laws."[102]

Congress has taken an interest in getting clarity on how agencies use guidance and whether agencies regard it as binding, and if so, securing public comment as is done for formal rules.[103] In May 2015, Sens. Lamar Alexander (R-Tenn.) and James Lankford (R-Okla.) sent letters to the Departments of Labor, Education, and Health and Human Services, and the Equal Employment Opportunity Commission, stating, "We are concerned that agencies may be issuing guidance to avoid regulatory requirements," and requesting:[104]

> 1) A list of all guidance issued on or after July 24, 2007, that have been the subject of a complaint that DOL is not following the procedures outlined in OMB's Final Bulletin for Agency Good Guidance Practices.
> 2) A list of all guidance issued on or after July 24, 2007, that have been the subject of a complaint that DOL is improperly treating a guidance document as a binding requirement.
> 3) A list of all guidance, including guidance not deemed significant, issued on or after July 24, 2007, that have been the subject of a complaint or written comments that DOL should have engaged in APA notice and comment rulemaking instead of issuing guidance.
> 4) Provide the complaints or written comments and all documents and communications referring or relating to the complaints or written comments referenced in requests one through three.
> 5) A list of guidance issued on or after July 24, 2007, that has been overturned by a court of law, including guidance that has been overturned in which an appeal is pending.
> 6) From July 24, 2007, to present, all documents and communications referring or relating to a decision to issue guidance on a topic instead of proceeding with notice and comment rulemaking under the APA.
> 7) The number of guidance documents issued on or after July 24, 2007, broken down by year, sub-agency, and whether or not the guidance is significant.
> 8) A list of all guidance currently in draft form and the date the draft was issued.
> 9) A list of all guidance that has been withdrawn on or after July 24, 2007.

Concern over bypassing the rulemaking process continues, and similar detail from all agencies would be useful. A September 29, 2015 letter by these and other Senators to the Department of Labor requested withdrawal of three costly recent guidance documents from the Occupational

Safety and Health Administration and asked that the Department pursue the changes "only through the rulemaking process."[105] In the interim, the Homeland Security and Government Affairs Committee held a hearing on September 23, 2015, "Examining the Use of Agency Regulatory Guidance" featuring representatives from the Departments of Labor and Education.[106] The Government Accountability Office was also on hand to provide testimony on how agencies can strengthen internal controls on guidance documents.[107] Members expressed concern that agencies short-circuit the ordinary rulemaking process and issue guidance when they ought to be issuing formal rulemaking per the Administrative Procedure Act, and that the means by which an agency initiative becomes a rule on the one hand or a guidance on the other is a "black box" that evades Congressional scrutiny.[108]

Guidance documents are subject to CRA review and resolutions of disapproval, but have not been deeply scrutinized in this manner—a clear instance of Congress failing to live up to its oversight duties. Granted, there are instances of agencies performing retrospective review of some of their own guidance documents, but there is little OMB review of how agencies certify those results.[109] Moreover, what constitutes "notice" is unclear. For example, Richard Williams and James Broughel of the Mercatus Center note that of 444 FDA guidance documents issued since 2007, only one notice was reviewed by OMB, and that OMB "is vague as to what documents are included in its 'notice' category, saying only that these are documents that announce new programs or agency policies, which presumably includes guidance documents."[110]

Alongside the aforementioned waivers of provisions of the Patient Protection and Affordable Care Act, prominent recent executive and independent agency guidance documents include:

- **Housing and Urban Development** guidance decreeing landlord and home seller denial of those with criminal records a potential violation of the Fair Housing Act;[111]

- The **Environmental Protection Agency's** (EPA's) Clean Water Act interpretive guidance on "Waters of the United States."[112] This directive took the step of soliciting notice and comment per the APA, though with significant controversy over manufactured endorsement;[113]

- The **Securities and Exchange Commission's** interpretive "Commission Guidance Regarding Disclosure Related to Climate Change," on disclosing potential disruption from "significant physical effects of climate change" on "a registrant's operations and results," and disclosing international community actions that "can have a material impact on companies that report with the Commission."[114] The guidance observes that "Many companies are providing information to their peers and to the public about their carbon footprints and their efforts to reduce them" that hints at where matters are headed as likely emphasis moves from actions affecting a company to how a company allegedly affects others.

- **Commodity Futures Trading Commission** "Staff Advisory" guidance on international financial transactions between overseas party "arranged, negotiated or executed" by a U.S. based individual,[115] that was delayed several times (indicating it perhaps should be a

commented-upon rule, instead) and said to jeopardize thousands of jobs by potentially sending them offshore.[116]

- A flow of **Education Department** guidance, at the rate of one issuance per business day, imposing new mandates on colleges and schools without going through the notice-and-comment process required by the APA.[117] According to the bipartisan Senate-appointed Task Force on Federal Regulation of Higher Education, "In 2012 alone, the [Education] Department released approximately 270 'Dear Colleague' letters and other electronic announcements."[118] "Recalibrating regulation of colleges and universities. Exceedingly high-profile, controversial recent guidance has included:

    - Guidance (a 2011 "Dear Colleague") to colleges and universities on sexual assault and harassment.[119] Noteworthy is that the civil rights laws' applicability to the institutions, not the students, but altered by guidance.[120]
    - Guidance letter (a 2010 "Dear Colleague") on bullying and harassment.[121]
    - Guidance (a 2016 "Dear Colleague") co-produced with the **Department of Justice's Civil Rights Division** requiring inclusion of "gender identity" in the definition of "sex" and requiring schools to allow transgender students to choose which bathroom or locker room to use.[122]
    - 2016 Policy Statement from the Education Department and the **Department of Health and Human Services** "preventing and severely limiting expulsion and suspension practices in early childhood settings"[123] without basis in law or notice and comment.[124]

- The **U.S. Department of Agriculture's Forest Service's** "Notice of Final Directive" permanent Ecosystem Restoration policy to replace Interim Directive, "Ecological Restoration and Resilience Policy," in Forest Service Manual (FSM) 2020, providing broad guidance for restoring ecosystems.[125]

- **Department of Homeland Security** guidance to retailers on spotting home-grown terrorists.[126] As DHS Secretary Jeh Johnson put it, "To address the home-grown terrorist who may be lurking in our midst, we must also emphasize the need for help from the public. 'If You See Something, Say Something' is more than a slogan. For example, last week we sent a private sector advisory identifying for retail businesses a long list of materials that could be used as explosive precursors, and the types of suspicious behavior that a retailer should look for from someone who buys a lot of these materials."[127]

- The **Department of Labor Wage and Hour Division's** blog post and "Administrative Interpretation No. 2015-1" informing the public that most independent contractors are now employees.[128]

- The **Department of Labor Wage and Hour Division's** "Administrative Interpretation No. 2016-1" asserting a WHD-defined possibility of "joint employment" under the Fair Labor Standards Act on case-by-case basis in horizontal and vertical contracting situations "to ensure that all responsible employers are aware of their obligations."[129] With this interpretation, the DoL "will hold more employers liable for wage violations

against employees they do not directly employ. The enforcement effort will focus on the construction, hospitality, janitorial, staffing agencies, and warehousing and logistics"[130] and potentially "penalize any industry that utilizes contractors and labor suppliers."[131]

- Three **Department of Labor** guidance documents regarding the Process Safety Management (PSM) standards for hazardous chemicals have been highlighted by Sen. James Lankford (R-Oklahoma) as bringing a range of manufacturers and retailers within the scope of regulation without the opportunity for public comment.[132] A letter to the Labor Department noted: "These three guidance documents are expected to dramatically expand the universe of regulated parties, create extreme logistical and financial burdens on regulated parties, and convert flexible recommended practices into mandatory requirements—all without the opportunity for public comment. We therefore ask that OSHA immediately withdraw these memoranda." Subject matter of the three guidance documents concerned engineering practices, retail exemptions, and chemical concentrations subject to PSM.

- In addition to Department of Labor guidance, greater use by the **National Labor Relations Board** of memoranda that affect non-union employers.[133]

- The **Equal Employment Opportunity Commission** has issued a series of guidance documents on pregnancy discrimination and accommodation in the workplace, credit checks on potential employees, and criminal background checks.[134]

- Guidance from the **Consumer Financial Protection Bureau** in the form of a "Bulletin" on "Indirect Auto Lending and Compliance with the Equal Credit Opportunity Act" limits the ability of automobile dealers to offer discounts to customers allegedly in the name of credit fairness and eliminating racial bias ("When such disparities exist within an indirect auto lender's portfolio, lenders may be liable under the legal doctrines of both disparate treatment and disparate impact").[135] Given the size of the auto lending marketplace this is clearly an economically significant measure that at the very least required a rulemaking rather than guidance, as well as concerns that even the CFPB recognized internally that it was overestimating bias[136] led to bipartisan House of Representatives passage of H.R. 1737 the "Reforming CFPB Indirect Auto Financing Guidance Act" (a Senate version S. 2663 awaits action) to revoke the guidance.[137] The bill would force CFPB "to withdraw the flawed guidance that attempts to eliminate a dealer's ability to discount auto financing for consumers. The bill also requires the minimal safeguards the agency failed to follow, such as public participation and transparency."[138]

- A claim in the German press, repeated by Reuters, that the **Environmental Protection Agency**, in response to automaker Volkswagen's deploying "defeat device" software to circumvent EPA emissions standards for nitrogen oxides,[139] is influencing that company to build electric cars and electric car charging stations in the United States.[140] One concern for policymakers is to decide how to talk about and treat judgments as regulatory matters, and to recognize when such decrees, penalties aside, will have the effect of improperly influencing the market trajectory of an entire sector.

- The **Council on Environmental Quality's** Revised Draft Guidance for Greenhouse Gas Emissions and Climate Change Impacts[141] that makes the National Environmental Policy Act a global warming instrument, particularly through federal land management decisions. The guidance is under seemingly perpetual review, but "describes how Federal departments and agencies should consider the effects of greenhouse gas emissions and climate change in their NEPA reviews," holding that "agencies should consider both the potential effects of a proposed action on climate change, as indicated by its estimated greenhouse gas emissions, and the implications of climate change for the environmental effects of a proposed action," and expanding upon 2010 draft guidance, "applies to all proposed Federal agency actions, including land and resource management actions." Elizabeth Lake on the site Law360 assets that the new draft "appears to push federal agencies to use NEPA to take a more activist stance in reducing GHG emissions":[142]

> [W]hile courts have held that NEPA is a procedural statute, requiring only a "hard look" at environmental impacts (NRDC v. Morton, 458 F.2d 827, 838 (D.C.Cir., 1972)), this CEQ proposed guidance goes well-beyond this doctrine by instructing agencies to use the NEPA process to force the substantive reduction of GHG emissions.

- The **Department of Transportation's Federal Aviation Administration** June 2016 final rule on drones, "Operation and Certification of Small Unmanned Aircraft Systems,"[143] is highly restrictive,[144] requiring line-of-sight and no night-time operations among much else, ignoring the ability of technological and contractual solutions to address risk, and refusing to stand down to local law enforcement solutions. But it also contains declarations from the agency regarding case-by-case waivers, as well as a large quantity of forthcoming guidance, much of which would seem to be economically significant, on issues like: industry best practices; risk assessment; potential guidance on external load operations; guidance associated with not dropping objects in ways that damage persons or property; advisories on training and direction to air traffic control facilities; preflight checks for safe operation; vehicle conditions for safe operations; and guidance "on topics such as aeromedical factors and visual scanning techniques."

- Prior to the guidance-heralding final rule, there had been a **Federal Aviation Administration** rule interpretation on drones via a "Notice of Policy"[145] that temporarily outlawed commercial activity in violation of the APA, before a reversal by the National Transportation Safety Board.[146]

An Inventory of Significant Executive Agency Guidance

With respect to "significant guidance," some executive, though not independent, agencies comply or make nods toward compliance with a 2007 OMB memo on "Good Guidance Principles"—in effect, guidance for guidance.[147] "Significant" guidance often means that having an economic effect of $100 million annually, similar to the definition for significant and major rules.[148] In fact, President George W. Bush's executive order 13422 subjected significant guidance to OMB review.[149] President Obama's EO 13497 revoked that requirement early in his

presidency, but in March 2009, then-OMB Director Peter Orszag issued a memo to "clarify" that "documents remain subject to OIRA's [the] review under [longstanding Clinton] Executive Order 12866."[150]

With conspicuous exceptions such as the Departments of Energy, Housing and Urban Development, and Health and Human Services (HHS), some agencies not only continue to invoke the 2007 OMB memo, but follow its directive of maintaining Web pages devoted specifically to their "significant guidance," even though it is a suggestion rather than a command. Indeed the FDA confesses no "significant guidance," even though there are 1,184 pieces of acknowledged final guidance from FDA.[151]

Table 6 lists a running inventory of significant guidance documents based largely upon these scattered executive department and agency websites.[152] There are 580 significant guidance documents in total in this compilation (as of August 2015).[153] The EPA's 206 significant guidance documents dominate the tally.

Table 6. Significant Guidance Documents in Effect: A Partial Inventory
Executive Departments and Agencies
(As of August 2015)
(Full chart with links maintained at www.tenthousandcommandments.com)

Department of Agriculture	
Agricultural Marketing Service	0
Animal and Plant Health Inspection Service	0
Economic Research Service	4
Food and Nutrition Service	4
U.S. Forest Service	7
Food Safety and Inspection Service	17
Grain Inspection, Packers & Stockyards Admin	0
National Agricultural Statistics Service	0
Risk Management Agency	0
USDA Total	***32***
Department of Commerce	
National Oceanic and Atmospheric Administration	0
Patent and Trademark Office	3
Department of Defense	1
Department of Education	
Adult Education	2
American Recovery & Reinvestment Act of 2009	12
Career and Technical Education	11
Civil Rights	28
Elementary and Secondary Education	61
Grants and Contracts	1

Higher Education	4
Special Education	21
Department of Education Total	***140***
Department of Health and Human Services	
Centers for Disease Control and Prevention	1
Centers for Medicare and Medicaid Services	0
Food and Drug Administration	0
Office of the Inspector General	0
Department of Homeland Security	
National Infrastructure Protection Plan	1
U.S. Citizenship and Immigration Services	26
U.S. Coast Guard	7
U.S. Customs and Border Protection	0
Federal Emergency Management Agency	12
Immigration & Customs Enforcement	0
Transportation Security Administration	12
DHS Total	***58***
Department of the Interior	
Bureau of Indian Affairs	0
Bureau of Land Management	0
Bureau of Reclamation	0
Bureau of Ocean Energy Mgmt, Reg & Enf.	0
National Park Service	0
Surface Mining Reclamation and Enforcement	2
Fish and Wildlife Service	2
DoI Total	***4***
Department of Justice	
Antitrust Division	2
Civil Rights Division	10
Federal Bureau of Investigation	0
Drug Enforcement Administration	8
Office of Justice Programs	10
U.S. Trustee Program	3
DoJ Total	***33***
Department of Labor	
Employee Benefits Security Administration	0
Office of Federal Contract Compliance Programs	0
Employment and Training Administration	34
Mine Safety and Health Administration	2
Wage and Hour Division	0
DoL Total	***36***

Department of State	0
Department of Transportation	
Office of the Secretary	11
Federal Aviation Administration	38
Federal Highway Administration	0
Federal Motor Carrier Administration	0
Federal Railroad Administration	0
Federal Transit Administration	7
Maritime Administration	7
National Highway Traffic Safety Administration	1
Pipeline and Hazardous Materials Safety Admin.	0
Trans. Total	***64***
Department of the Treasury	2
Department of Veterans' Affairs	0
Environmental Protection Agency	
Office of Air and Radiation	60
Office of Chemical Safety and Pollution Prevention	39
Office of Environmental Information	3
Office of Solid Waste and Emergency Waste	50
Office of the Science Advisor	19
Office of Water	20
Regional Offices	15
EPA Total	***206***
TOTAL	**580**

The preceding table is not purported to be comprehensive. The approach was to follow Unified Agenda agency listing, supplemented with the Federal Register Index of agencies to capture sub-units; some information was gathered via searching "significant guidance" at agencies and examining results. This compilation amounts to the subset web-posted in fulfilment of OMB's 2007 "Agency Good Guidance Practices"; not necessarily posted in obvious manner, but at least posted.

Where a "0" (zero) appears for an agency count, it is because a dedicated page for significant guidance was provided, even if no guidance appeared or had been issued. That is useful information in itself, to demonstrate inactivity, or to underscore improbable claims of no significant guidance in play such as at the Food and Drug Administration, the Department of Homeland Security's U.S. Customs and Border Protection and its Immigration and Customs, Interior Department bureaus, or the Department of Labor's Wage and Hour Division.

Reporting quality from executive agencies varies, as does the length of documents and the number and nature of mandates contained within guidance. Where things are is sometimes a mystery to the agencies (HUD, unhelpfully: "To find a specific publication, you can search our entire web site."[154] Some agencies, such as several U.S. Department of Agriculture (USDA) and HHS sub-units, maintain online landing pages dedicated to significant guidance, but claim none to report. Sometimes an agency subunit, like the Office of Diversion Control at the Department of Justice, will present own set of guidance documents not noted by the parent agency.[155] Similarly, the Federal Emergency Management Agency within the Department of Homeland Security lists guidance documents under several sub-agencies. Some, like the FDA's Office of the Inspector General, report no guidance that rises to the level of significance,[156] yet it hosts other Web pages presenting certain public guidance.[157] Some agencies feature sophisticated search engines (FDA, although it fails to flag any significance); some present detailed itemizations (EPA, Interior); some host descriptive Web pages and list guidance documents on a separate pdf or Word file (Education). Other times, guidance may rise to the level of significance, but it is up to the reader to figure it out. For example, at the Centers for Medicare and Medicaid (CMS) services, we are told of thousands of pieces of guidance:

> CMS issues thousands of new or revised guidance documents annually and cannot make individual decisions on each as to whether it is "significant" as defined under the Executive Order (e.g., annual effect of $100 million or more on the economy). At present, there are approximately 37,000 documents on the CMS Web site and many, perhaps most of these, include guidance.[158]

Indeed, the agency "seems unable to keep pace with its own frenetic lawmaking."[159] While an agency may choose not trouble itself determining significance, those affected do not have that luxury. While Table 5 understates significant guidance counts, since some agencies do not report at all, and those that do self-report, it still serves as an inventory of some of what we know, and as an exercise in showing policy makers and interested parties *what we do not know*. For example, while the Centers for Medicare and Medicaid Services acknowledges thousands of directives of indeterminate impact, GAO noted in 2015 that four agencies issue between 10 and 100 guidance documents per year.[160] The Department of the Interior, which issued 94 rules in 2014, boasts that the Fish and Wildlife Service, one of its several agencies, usually publishes more than 500 *Federal Register* documents annually."[161] Given all the agency disclaimers and qualifications, no representations of completeness are made here.[162] Indeed, the notorious EPA offers no warranties of completeness: "Please be aware that the lists do not include every guidance document issued by EPA. They only encompass those documents that are 'significant' as defined by the GGP Bulletin." The OMB order is not strictly binding, yet the EPA does solicit public comment, and that is a stance policy makers can build upon.[163]

During the 10-year period 2005-2014, OMB reported: "Federal agencies published 36,457 final rules in the *Federal Register*." OMB reviewed 2,851 of these, among which 549 were considered major.[164] While guidance specifically deemed "significant" seems comparable to the number of major rules, agencies like Interior and CMS maintain document flows that rival or outpace rulemaking, so Congress needs to pay more attention to guidance documents, whether they are deemed significant or not.

Even a small number of guidance documents can have a significant impact. The Justice Department's Antitrust Division has only two documents classified as significant guidance documents, but other important DOJ policy statements, guidance documents, and notices affect such matters as cybersecurity, joint ventures, intellectual property, health care, and mergers.[165] Many of these are economically significant for those affected. Until Congress requires consistency in guidance reporting, the haphazard nature of what agencies publicly disclose as guidance in response to the 2007 OMB memo will remain striking.

For present purposes, our concern is guidance affecting the private sector, but guidance directed at agency procedures gets lumped in by those complying with the 2007 memo, such as the National Archives compilation of guidance pertaining to the release of classified information.[166] Other guidance affecting agencies can be noteworthy, such as numerous OMB privacy guidances to federal agencies over the years.[167] Sound future reporting will need to make distinctions.

Significant Independent Agency Guidance

Independent agencies sometimes compile guidance on landing page websites, though they are not required to list their guidance documents under the 2007 OMB directive. The U.S. Equal Employment Opportunity Commission (EEOC) maintains a Web page where it lists its significant guidance documents (23 entries as of this writing).[168] Other EEOC guidance not among these includes guidance to employers on the accommodation of pregnancy.[169] Among other agencies, there is the Federal Trade Commission's page of "Advisory Opinions" issued "to help clarify FTC rules and decisions,"[170] as well as its page detailing "Guidance,"[171] a recent example of which was advertising guidance on disclosure of paid search engine results.[172] The Consumer Financial Protection Bureau has published numerous guidance documents and further ominously invites the regulated public to contact the Office of Regulations "to receive informal guidance from a staff attorney."[173]

While not formal rules, guidance from independent agencies often carries veiled warnings that you best pay attention. The Federal Housing Finance Agency (FHFA), for example, issues guidance with the standard caveat: "Although an Advisory Bulletin does not have the force of a regulation or an order, it does reflect the position of FHFA on the particular issue and is followed by supervisory staff."[174]

In the wake of the Dodd-Frank financial law, banking agency guidance in particular is on the rise. One industry newsletter noted:

> The pace in which banking agencies are issuing guidance appears to have increased considerably since the economic downturn. There have been well over 20 significant pieces of interagency guidance issued just since 2010, including those covering appraisal and evaluations, concentration risk, interest rate risk management and troubled debt restructurings. This does not even include the stand-alone guidance that agencies unilaterally issue in the form of financial institution letters (FDIC), bulletins (Office of the Comptroller of the Currency) and supervision and regulation letters (Federal Reserve Board).[175]

The Federal Reserve Bank of St. Louis compiles itemized lists of federal banking guidance it deems "significant" (in addition to lists of standard notice-and-comment regulation).[176] While this characterization of "significant" will not necessarily conform to the 2007 OMB memo nomenclature, the current tally of 69 guidance documents appears summarized nearby in Table 7. Note that some financial sector guidance is multi-agency (The Treasury Department, an executive agency, is listed here for completeness).

Table 7. Independent Agency Significant Guidance: A Partial Inventory (As deemed significant by the St. Louis Fed)

Commodity Futures Trading Commission	2
Consumer Financial Protection Bureau (CFPB)	12
Federal Deposit Insurance Corporation (FDIC)	11
Federal Financial Institutions Examination Council (FFIEC)	2
Federal Housing Finance Agency	2
Office of the Comptroller of the Currency (OCC)	29
Securities and Exchange Commission	5
Treasury Department	1
FDIC/Board of Governors of the Federal Reserve System (FRS)	1
FDIC/FRS/OCC	6
FDIC/FRS/National Credit Union Administration (NCUA)/OCC	1
FDIC/FinCEN/FRS/NCUA/OCC	1
CFPB/FDIC/FFIEC/FRS/NCUA/OCC	1
TOTAL (As of 10/14/2015):	**74**

Note that this compilation represents a handful of pieces of "significant" banking guidance. The Federal Agency Guidance Database from the Conference of State Bank Supervisors contains a far larger number of other financial sector items like directives, manuals, notices, announcements, and more from numerous agencies.[177] Yet there is even more dark matter from both executive and independent agencies.

Notices and Other Things that Are Not Quite Regulations that May or May Not Bind the Public

> *[W]hen I am 100 percent utterly and completely certain that it is an absolute certainty that it is an absolute necessity that I need to recruit a new employee, I go to bed, sleep well and hope that the feeling has gone away by the morning.*
>
> —A British businessman lamenting French labor regulations.[178]

> *And no one seems sure how many more hundreds of thousands (or maybe millions) of pages of less formal or "sub-regulatory" policy manuals, directives, and the like might be found floating around these days.*[179]
>
> —Judge Neil Gorsuch, 10th Circuit,
> *Caring Hearts Personal Home Services, Inc. v. Burwell*

House Majority Leader Kevin McCarthy (R-Calif.) was called out by *The Washington Post*'s fact checker, for claiming in January 2015 that there were 300 federal rules issued in just a week.[180] He quickly corrected and noted a staffer's blooper in counting notices and proposed rules alongside final rules. But that only raises the question: How can we measure, much less bring under control, the effects of tens of thousands of notices, guidance documents, memos, and other regulatory dark matter when it is so difficult just to determine their actual number?

You read right, tens of thousands. The emphasis so far has been on significant guidance, but there is much more agency dark matter beyond significant guidance. It is worth keeping in mind that the denial of significance is a prerogative agencies already exercise liberally for ordinary APA notice-and-comment rules.

"Public Notices" in the *Federal Register* are "non-rulemaking" documents like meeting and hearing notices and agency-related organizational material. They can also serve as a catch-all for dark matter that manages to get published in the *Federal Register*. Notices make up the bulk of the *Federal Register*, and there are tens of thousands of them yearly—23,970 in 2014, over 19,000 so far in 2015. They can include policy statements, manuals, memoranda, circulars, bulletins, and guidance and alerts, many of which could be important to the public.[181] Matter that may or may not rise to the level of guidance document deemed as significant by OMB may appear among notices. Like major rules treated as non-major but that are in fact major in a real-world sense, guidance that actually is significant but not treated as such could be buried among notices. As noted, OMB is not clear on this.

The FDA's search page on Guidance Documents, for example, illuminates much more going on below the surface. While the agency reports no officially "significant" guidance, under the "document type" heading, we find not just ordinary guidance documents for which one may search, but also:

- Agreement
- Bulletin
- Compliance Policy Guide
- Concept Paper
- Industry Letter
- Information Sheet
- Manual
- Memorandum
- Small Entity Compliance Guide
- Special Controls Document

However, this, is just one agency's inventory of Things that Are Not Quite Regulations. On the regulations.gov website, dozens of document sub-types in addition to rules and notices of rulemakings appear:[182]

Denial of Application
Action Memo/Letter
Adjudication
Advisory Opinions
Agreement/Contract
Analysis

Approval
Audit
Brief
Certification
Clarification
Comment Response
Company/Organization Comment
Complaint
Consent Decree
Consent Order
Data
Decision
Decree
Delay of Effective Date
Determinations
Early comment
Economic Analysis
Environmental Assessment
Environmental Impact Statement
Evaluation
Exemption
Extension of Comment Period
Fact/Data Sheet
Findings of Fact
Guidance
Hearings
ICR Supporting Statement
Industry Circular
Information Collection Request
Interagency Review
Letter
Management Directive
Meeting
Meeting Materials
Memorandum
Motion
Notice of Adequacy
Notice of Approval
Notice of Data Availability
Notice of Filing
Notice of Intent
Notice of Receipt of Petition
Order
Permit/Registration
Petition
Policy
Press Release
Public Announcement/Notice
Procedure
Public Comment
Public Hearing
Deposition/Testimony
Public Participation
Publication
Report
Request for Comments
Request for Grant Proposals
Risk Assessment
Settlement Agreement
Significant Guidance
Study
Supplement
Technical Support Document
Waivers
Withdrawal
Work Plan

This rather exhaustive "word cloud" captures the magnitude of the matter. Determining what is binding is a challenge, to put it mildly. Table 8 shows annual counts, which stood at 24,393 in 2015, and have, apart from 2014, topped 24,000 since 1995. The total count for notices since 1994 has been 538,248. That is over half a million in 20 years.

To what extent do notices get review or oversight? While it is unclear what the criteria are, a portion get reviewed at OMB as if they were the same as notice-and-comment rules, and some notices are even deemed "significant" under EO 12866. As Table 8 shows, at least a few dozen notices rise to the level of receiving OMB review during each calendar year, with around half that many deemed "significant." All in all, since 1994, OMB says it has reviewed 983 notices, of which 492 were significant. In addition, 130 have been flagged "economically significant" (entries of this type abruptly halted in October 2014 through at least December 2015, but have

since been resumed).[183] But what criteria may trigger review of notices and the application of these particular categories is not specified. "The OIRA website is vague about what constitutes a notice," former OIRA Administrator John Graham and James Broughel note: "More clarity about what constitutes guidance notices worthy of review would be valuable."[184]

Table 8. Public Notices in the *Federal Register*

	Total Notices	OMB Reviews	Significant Rules Under EO 12866	Economically Significant Notices
1995	23,162	53	18	4
1996	24,367	31	24	3
1997	26,033	51	21	9
1998	26,197	40	22	3
1999	25,505	36	24	4
2000	25,470	40	30	2
2001	24,829	37	24	10
2002	25,743	55	36	9
2003	25,419	59	35	7
2004	25,309	58	23	9
2005	25,353	59	18	8
2006	25,031	46	18	8
2007	24,476	25	12	2
2008	25,279	28	25	6
2009	24,753	49	22	8
2010	26,173	77	34	17
2011	26,161	61	31	4
2012	24,408	40	19	6
2013	24,261	37	22	2
2014	23,970	46	18	5
2015	24,393	35	12	4
2016*	11,956	20	4	0
TOTALS:	**538,248**	**983**	**492**	**130**

*As of 6/23/2015; *Figures updated at www.tenthousandcommandments.com. Sources: Total Notices: from National Archives and Records Administration, Office of the Federal Register and author search on FederalRegister.gov advanced search function; Number of "Significant" Notices under EO 12866: author search on FederalRegister.gov advanced search function; number of OMB Reviews: author search on RegInfo.gov, review counts database search engine under Regulatory Review heading.*

Oversight matters. The number of notices, *Federal Register* pages, and final rules dropped significantly following President Reagan's EO 12291, before starting to rise again.[185] The "other" documents category in the *Federal Register* (which included these notices plus presidential documents) had been as high as 33,670 in 1980.[186] During the late 1980s, the tally hovered at a considerably lower 22,000 annually.[187] Since 1976, there have been well over one million "other" documents or notices.[188] There is no coordinated congressional or executive branch effort to identify the regulatory dark matter embedded within the thousands of agency notices, but that is exactly what is needed.

At the individual agency level, some guidance and notice material gets listed on cabinet agency websites much like OMB-compliant significant guidance does. For example, the USDA's Animal and Plant Health Inspection Service has no online tally of significant guidance, but does post numerous "Manuals and Guidelines."[189] More examples are the "Advisory Opinions" page from the Department of Commerce's Bureau of Industry and Security,[190] the "Agency Guidance" page from the Department of Transportation's Pipeline Safety and Hazardous Materials Safety Administration,[191] the Department of Energy's "Policy and Guidance" page,[192] and the Department of Housing and Urban Development's "Public Guidance Documents" page on real estate settlement regulations.[193]

Beneath agency guidance not officially deemed significant, we descend the great regulatory chain of being to such diktats as "circulars" at the Federal Transit Administration,[194] "policy statements" at Federal Energy Regulatory Commission,[195] and "Warning Letters" to businesses from the FDA.[196] One pointed warning letter can change firms' behavior, such as the FDA's calling out of a company for making health claims about nuts,[197] and its warning to the genetic testing company 23andMe to halt marketing of its Saliva Collection Kit and Personal Genome Service for failure to secure premarket approval.[198] Agencies issue *hundreds* of such letters, such as the Federal Trade Commission's recent letters to five skin care companies over using the claim "natural."[199] (The extent to which the U.S. federal government micromanages individual firms is not examined in depth here but is another thing that sets dark matter apart from ordinary lawmaking.)

And it continues. For independent agencies not obliged to obey even the loose bounds of the OMB Good Guidance Principles memo, there are numerous forms of guidance. These include:

- The Consumer Financial Protection Bureau's "Guidance Documents;"[200]
- The Federal Deposit Insurance Corporation's "Supervisory Guidance" page[201] (as well as a page of numerous "Financial Institution Letters;"[202]
- The Commodity Futures Trading Commission's "Staff Letters"[203] and "Opinions and Adjudicatory Orders;"[204]
- The Federal Housing Finance Administration's "Advisory Bulletins;"[205] and
- The Consumer Product Safety Commission Office of General Counsel's "Advisory Opinions,"[206] "Voluntary Standards,"[207] and "Recall Guidance."[208]

Among dark matter, "Sue and settle" orders expand government's power and size without congressional oversight, or even the APA's weak discipline.[209] These consent and settlement agreements "commit … the agency to actions that haven't been publicly scrutinized," as Senate Judiciary Committee Chairman Grassley remarked in June 2015 upon introducing legislation to "shine light on these tactics and provide much-needed transparency before regulatory decisions are finalized."[210] Tallies of enforcement actions and administrative law rulings are worth further study in the context of the overall regulatory state, especially given the development that substantial recent agency rulemakings have been overturned by courts.[211]

In the previous section, we noted 69 pieces of "significant" financial agency guidance as compiled by the St. Louis Fed, primarily from executive agencies. The Conference of State Bank

Supervisors' federal guidance database lists a greater collection of bulletins, directives, manuals, notices, announcements, and more from several financial agencies such as the Consumer Financial Protection Bureau.[212] Table 9 shows these 1,445 items in effect as of August 2015. Note that the Treasury Department appears here with a hefty count of 175 items, as does its financial crimes unit and the Office of Thrift Supervision, whereas in the executive branch significant guidance inventory above it sported only two items.

Table 9. Financial Agency Directives: A Partial Inventory
Compiled by the Conference of State Bank Supervisors
All guidance published by the Federal Financial Regulatory Agencies

Consumer Financial Protection Bureau (CFPB)	49
Financial Accounting Standards Board (FASB)	56
Federal Deposit Insurance Corporation (FDIC)	225
Federal Reserve Board	370
Federal Financial Institutions Examination Council (FFIEC)	56
Federal Housing Finance Agency (FHFA)	32
Financial Crimes Enforcement Network (FinCEN)	204
Office of the Comptroller of the Currency (OCC)	192
Office of Thrift Supervision (OTS)	48
Securities and Exchange Commission (SEC)	38
Treasury Department	175
TOTAL (As of 10/14/2015):	**1,445**

Many notice-and-comment regulations already lack impact analysis. Notices, memos, bulletins, guidance, and the like number in the thousands and deserve policy makers' attention. We have highlighted over 1,400 affecting the financial sector alone, but there are many tens of thousands of documents in play across the economy.

The Dark Energy of the Regulatory Process: When Fewer Regulations Mean Less Freedom

> *To limit abuse by the rulers, ancient Rome wrote down the law and permitted citizens to read it. Under Dodd-Frank, regulatory authority is now so broad and so vague that this practice is no longer followed in America. The rules are now whatever regulators say they are.*[213]
>
> – Former Texas Senator Phil Gramm

As everything gets cartelized into business government partnerships, they don't need to issue a written regulations anymore or need to far less

Policy makers routinely debate regulatory costs, but regulatory dark matter's consequences can escape measurement, undermining efforts to fully assess the impact or cost of regulatory intervention. No one really knows what the regulatory state "weighs." For example, the federal government's running of Social Security, on top of trust fund sleight of hand, is not counted as a cost of intervention. Yet there is a substantial cost in the extra wealth people could have

accumulated through investing, and in the inability to bequeath an estate to heirs after a lifetime of garnishment. Yet government says it needs more control to deal with the income inequality it has in no small measure helped cause.

In other words, as government grows to encompass more spheres of activity—from health care to finance to the Internet—agencies will be able to issue fewer written rules yet still expand control. They will not need a law from Congress, notice-and-comment rules, or perhaps even the interpretive guidance, memos, and the like depicted herein. In an instant classic example, consider the *Credit Union Times*' warning to the industry about the Dodd-Frank financial law's "unfair, deceptive, or abusive acts and practices" (UDAAP) provisions: [214]

> UDAAP does not have any implementing regulations and it probably never will. In fact, CFPB Director Richard Cordray said the bureau will not issue any regulations that define exactly what actions or practices violate the law. … So how will a bank, credit union or other financial services provider know if it has violated the law?

As modern bureaucracies take this stance, "law" can become even more arbitrary and even more non-democratic than the dark matter itself. The Consumer Financial Protection Bureau tells regulated parties: "You can contact our Office of Regulations to receive informal guidance from a staff attorney about the Bureau's regulations. … Any such informal guidance would not constitute an official interpretation or legal advice."[215] Who will not obey? Sen. Mike Lee addressed the concern with respect to CFPB when announcing 2016 legislation for a "regulatory budget." He stated:[216]

> In 2012, for instance, when testifying before Congress, the director of the CFPB explained that his agency's mandate was "a puzzle" and that CFPB bureaucrats would define "unfair, deceptive, [and] abusive" on a case-by-case basis. This not-uncommon mindset of federal bureaucrats explains why laws passed decades ago are still spawning new regulations today.

In affirmation of that mindset, the CFPB attempted to assert authority over college accrediting agencies and begun probes, a power not given to it by Congress.[217] The D.C. federal district court ruled in 2016 that the agency exceeded its statutory authority when it issued an August 2015 Civil Investigative Demand to the Accrediting Council for Independent Colleges and Schools.[218]

Other examples of the regulatory mindset include federal agency assertions of authority over non-banks like insurance firms in the wake of Dodd-Frank,[219] and "systemically important" financial institution designations by the Financial Stability Oversight Council's secret processes in the wake of Dodd-Frank conform to the "black box" characterization of how some agency rulemaking takes place today, and were rebuked by Government Accountability Office examinations.[220]

Another alarming example of the descent into arbitrary, unwritten lawmaking influencing an entire sector of the economy is the Federal Communications Commission's order on net

neutrality. Here we see the unprecedented use of "advisory opinions" that threaten the industry's autonomy and capacity to innovate:[221]

> We conclude that use of advisory opinions similar to those issued by DOJ's Antitrust Division is in the public interest and would advance the Commission's goal of providing legal certainty. Although the Commission historically has not used advisory opinions to promote compliance with our rules, we conclude that they have the potential to serve as useful tools to provide clarity, guidance, and predictability concerning the open Internet rules. *Advisory opinions will enable companies to seek guidance on the propriety of certain open Internet practices before implementing them*, enabling them to be proactive about compliance and avoid enforcement actions later. The Commission may use advisory opinions to explain how it will evaluate certain types of behavior and the factors that will be considered in determining whether open Internet violations have occurred. [Emphasis added]

In effect, the FCC, now with the D.C. District Court of Appeals' blessing,[222] elected to regulate tomorrow's Internet as if it were yesterday's common carrier utility. Companies will be demeaned and reduced to checking with the commission first before conducting business; no laws need be passed by Congress, and no further APA-compliant rules need be issued by the agency for it to be able to exert control over the Internet industry's future. This regime will start with infrastructure firms, but is guaranteed to eventually encompass the content and app sectors despite the FCC's assurance to the contrary.[223] And the courts are little help so far. As Bret Swanson noted with respect to the D.C. District Court of Appeals June 2016 upholding of FCC's rules, "Decades ago, Congress passed, and the president signed, a law saying the Internet shall remain "unfettered by Federal and State regulation," but the courts now say agencies may in fact do so at will."[224] Further, the FCC maintains its energy in traditional antitrust regulatory intervention, with new twists. The commission approved the recent Charter-Time Warner merger, but with "voluntary" side agreements the agency lacked authority to impose.[225]

In an effort perhaps not to be outdone by CFPB, the Office of the Comptroller of the Currency's "Supporting Responsible Innovation in the Federal Banking System: An OCC Perspective," proposes an Orwellian, "centralized office on innovation";[226] like the preemptory, Mother-may-I "advisory opinion" guidance to apply to telecom before anyone in that sector moves, "The office could serve as a forum to vet ideas before a bank or nonbank makes a formal request or launches an innovative product or service."[227] "To be effective," readers are assured by OCC, "the improved process should clarify agency expectations" regarding partnerships between banks and non-banks in the evolving financial technology marketplace and "assess whether additional guidance is appropriate to address the needs of banks and their customers in the rapidly changing environment."[228]

Still another case of tomorrow's rules being whatever rulers outside Congress say is the Operation Choke Point initiative that originated in President Obama's Financial Fraud Enforcement Task Force within the Department of Justice, an apparent intimidation campaign aimed at pushing banks to cut off services to legal but politically disfavored businesses like pawn shops and gun stores. There was no law or executive order, no written regulations issued—just

lists of targeted types of businesses, threats against those businesses, and pressure on their banks.[229]

Alarming as such developments are, the arbitrariness they embody is not new. Antitrust intervention—or the threat of it—has derailed business deals and redirected economic resources and investment for over a century. The scale, though, is new. Only certain politically connected firms, protected from competitive processes, will be able to thrive in such a system.

Energy is often ill-defined as the ability to do work; the "dark energy" corollary of dark matter might be thought of as that which halts work and productivity. If the universe's dark energy is "a force that repels gravity," in the policy realm it might be regarded as a force that repels liberty.[230] In much the way dark matter is crucial to understanding the universe, understanding and curbing the proliferation of regulatory dark matter is now central to the preservation of economic liberty.

Principles of Reform

> *The accumulation of all powers, legislative, executive, and judiciary, in the same hands, whether of one, a few, or many, and whether hereditary, selfappointed, or elective, may justly be pronounced the very definition of tyranny.*[231]
>
> —James Madison, Federalist No. 47.

> *The Constitution has been discarded and cannot be restored. ... [S]olutions are now beyond the reach of the electoral and legislative processes. The citizenry must therefore create new counterweights.*[232]
>
> —Charles Murray, *By the People, Rebuilding Liberty without Permission*

The Universe weights "100 trillion trillion trillion trillion tonnes, give or take a few kilograms," according to *New Scientist*.[233] Here on Earth, no one knows how much the regulatory state "weighs," or even the number of agencies at the center of our own bureaucratic "big bang." But for We, the Regulated, ignorance of the law is no excuse; our "duty to read" the *Federal Register* was established shortly after the Administrative Procedure Act passed, as one drought-suffering Idaho wheat farmer relying upon a complicated federal crop insurance program found out the hard way. In the 1947 case, *Federal Crop Ins. V. Merrill*, Justice Felix Frankfurter delivered the opinion:

> Just as everyone is charged with knowledge of the United States Statutes at Large, Congress has provided that the appearance of rules and regulations in the *Federal Register* gives legal notice of their contents.[234]

In his dissent, Justice Robert H. Jackson maintained:

> To my mind, it is an absurdity to hold that every farmer who insures his crops knows what the *Federal Register* contains, or even knows that there is such a publication. If he were to peruse this voluminous and dull publication as it is issued from time to time in order to make sure whether anything has been promulgated that affects his rights, he would never need crop insurance, for he would never get time to plant any crops. Nor am

> I convinced that a reading of technically worded regulations would enlighten him much, in any event.[235]

Decades later, Congress has allowed regulations to expand and rendered us increasingly duty-bound, with little or no say in the matter. As attorney and legal scholar Harvey Silverglate notes, we probably break about three laws a day, without even knowing it.[236] The relationship of the individual to the state continues to change, as the growing quantity and relevance of regulatory dark matter takes the potential for abuse to new heights.

The rise of regulatory dark matter has entirely changed the nature of the regulatory reform debate. It has long been the case that there are far more regulations than laws. That is troublesome enough. But with tens of thousands of agency proclamations annually, OMB review of executive agency "significant" or "major" rules cannot suffice. Ordinary executive agency rules and independent agencies have gotten a pass all along. With dark matter added to the mix, agencies may articulate interpretations and pressure regulated parties to comply without an actual formal regulation or understanding of costs. Left unaddressed, regulatory dark matter can gain new ground, as agencies avoid public and congressional scrutiny by issuing memos, letters, guidance documents, bulletins, and other proclamations and decrees that influence the behavior of the public outside normal Administrative Procedure Act processes and OMB oversight, let alone the constitutional lawmaking process.

To address overregulation and dark matter, Congress must act. It will take the nation's elected representatives to stop dark matter and punish officials engaging in arbitrary behavior. Power must be returned to elected lawmakers.

Regulatory reform emphasizes the things we can count, so it usually focuses on steps like better cost-benefit analysis, sunsetting of rules, bipartisan regulatory reduction commissions, new calls for regulatory budgeting, and other measures.[237] These are important, but the persistence of dark matter means it is not enough to just track notice-and-comment regulation. Below are some principles for Congress to consider in address regulatory dark matter. All must be anchored in Congress explicitly going on record as approving all agency decrees.

All agency decrees matter, not just the "rules"

Unless Congress requires consistency in the reporting of dark matter, the haphazard nature of what agencies disclose as guidance will continue to be a problem. The 2007 memo is a useful starting point. It should be expanded to cover (1) non-significant guidance since agencies should not get to decide what is significant, and (2) independent agencies. We need what Paul R. Noe and John Graham have called "due process and management" for guidance.[238] Reforms will require creating an authoritative list of federal agencies—one does not currently exist—and requiring each agency to maintain consistent, uniform Web pages and databases. The guidance documents compiled in this report came from many disparate agency sources.

In the process, Congress can hold investigations and hearings to determine agencies' criteria for classifying guidance documents as significant and the breakdown of the various types of documents issued by agencies each year. Decisions must be made regarding the appropriateness

of some guidance and memoranda not appearing in the *Federal Register*. On disclosure, the All Economic Regulations Are Transparent (ALERT) Act) of 2015 aims at broad clarity regarding regulatory impacts with monthly reports and schedules of completion, estimates of costs and economic burdens, and annual summary reports.[239] Such disclosure and "report cards" for individual agencies can and must be expanded to incorporate dark matter.[240]

Congress must subject guidance to enhanced APA-like procedures and more intense OMB review

To address stealth regulation, John Graham and James Broughel propose options such as reinstating a George W. Bush-era requirement to prepare analysis for significant guidance documents, explicitly labeling guidance documents as nonbinding, and requiring notice and comment for significant guidance documents. They also call for agencies to inform parties "when a communication is only a recommendation and is not legally binding."[241] These should all be done, but more is needed, since even ordinary regulations outflank such constraints.

Attempts to force more informal regulatory dark matter into the notice-and-comment stream may induce agency creativity in skirting review and using "darker" dark matter measures, like threats and warnings, to escape oversight.[242] In response, Congress can codify President Obama's four executive orders on regulation, and extend their provisions to guidance. The Regulatory Accountability Act of 2015, which has passed the House, contains provisions on early notice, public participation, evidence requirements, and formal hearings, which can be applied to dark matter.[243]

Canada[244] and Great Britain have both implemented rule-in, rule-out requirements with some success.[245] In the U.S. Senate, legislation called the Regulations Endanger Democracy (RED) Tape Act (S. 1944) would introduce the same requirement for ordinary regulations, and extend it to guidance and memoranda.[246] Another recent effort at implementing a guidance document reform agenda is the Regulatory Predictability for Business Growth Act (S.1487) would require interpretive rules and guidance documents that would alter previously issued interpretive rules to undergo public notice and comment before they can go into effect.[247]

Moreover, problems presented by the fact that guidance is often not published in the *Federal Register* have not been adequately surveyed. What coherence exists between that which does and does not appear in the *Federal Register*? If it is not published there, how does one learn of guidance? Does Congress even know? What good will be a notice and comment regime for guidance if the final product does not get published in some venue where anyone can readily find it?

Administrative and institutional reforms like those noted above can help bring measureable accountability and moderation to the rulemaking process. Administrative disclosure and scrutiny can also play a role. Consider that the number of federal regulations stood around 7,000 in the late 1970s. After Ronald Reagan's EO 12291 on OMB regulatory review, the count went down to around 6,000 in the early 1980s, then to 4,700 by 1988. The count stayed below 5,000 during the 1990s, and now clocks in each year around the 3,500 mark.

Congress must vote approval of costly or controversial dark matter decrees

Congress' over-delegation of power is at the root of Washington's out-of-control growth—which has resulted in such indecencies as America's wealthiest zip codes consisting of the ones surrounding the Beltway. It is not enough for OMB to try to do its "darndest" on regulatory oversight and review.[248] Congressional accountability is indispensable in offsetting the pro-regulatory bias that prevails across the entire federal bureaucracy, including its independent agencies.

The new effort by Senators to investigate and scrutinize potential efforts by federal agencies to skirt the law via guidance is well past due. Nothing will change until Congress has to affirm all expensive or controversial agency decrees and actions, from ordinary rules to dark matter. The Regulations from the Executive in Need of Scrutiny (REINS) Act of 2015 (H.R.427), which has already passed the House of Representatives, would require this step for regulations.[249] It should be expanded to cover significant and contentious dark matter.

In the meantime, appropriations restrictions can help rein in agencies' use of dark matter. In addition, Congress should recognize that guidance documents and all dark matter decrees are covered by the Congressional Review Act, and thus subject them to resolutions of disapproval.[250]

Conclusion: Congress's To-Do List

Congress has a duty to affirm that every agency decree matters, not just those subject to formal notice-and-comment or deemed economically significant. Past attempts at serious government downsizing in the 1970s, '80s, and '90s brought partial liberalization of some industries, but fell short when it came to shutting down agencies and increasing agency accountability. Today, circumstances have deteriorated to the point where Congress has no idea of what today's thousands of agency proclamations consist.

Regulation and guidance cannot be controlled without downsizing the federal government and strengthening democratic accountability. That requires reining in the colossal bureaucracies that enable rule by unelected experts. Ending regulation by guidance is especially urgent for frontier sectors such as telecommunications and infrastructure expansion, and policy surrounding drones and automated vehicles. Decades-old agencies are already seeking to regulate new technologies, business models, and contractual arrangements with obsolete rules and without congressional authorization. If government regulation is warranted, Congress should legislate directly rather than tolerate open-ended agency regulation or "informal" guidance. Confronting possible obsolescence of decades old statutes is a necessary, fundamental task.

To accomplish these goals, here are actions Congress should take:

- Abolish, downsize, cut the budgets of, and deny appropriations to aggressive agencies, sub-agencies, and programs that routinely pursue regulatory actions not authorized by Congress.
- Repeal or amend enabling statutes that sustain the regulatory enterprise's excesses in the first place.
- Withhold appropriations for specific agency actions not authorized by Congress.

- Require congressional affirmation for guidance and other agency proclamations likely to have significant economic impact.[251]
- Subject regulatory dark matter to more intense OMB review. By exposing the costs of guidance, this can provide a public record for future reform efforts. President Reagan's Executive Order 12291 provides a good model to follow in this regard, in that it put the burden of proof on agencies to demonstrate need for a new rule. Guidance should be held to the same standard.[252]
- Require agencies to present data regarding regulation and guidance to Congress in a form comparable to the federal budget's Historical Tables.[253] The Reagan and first Bush administrations had something along these lines, a document accompanying the Budget titled the *Regulatory Program of the United States Government*, which included a lengthy appendix, "Annual Report on Executive Order 12291."[254] This could provide a template for disclosure, along with requiring that guidance appear the *Federal Register* in an accessible way. Other disclosures needed are as follows.
    - ***Economically significant guidance.*** Require streamlined, one-location online disclosure of economically significant guidance, augmenting what a few executive agencies voluntarily already publish based on the 2007 OMB memorandum to agencies.[255] The chart contained herein, "Table 6: Significant Guidance Documents In Effect: A Partial Inventory," should expand with information better consolidated, and should incorporate independent agency guidance
    - ***Secondary guidance and notices.*** Require centralized disclosure of these proclamations, which currently are scattered under numerous monikers and across various websites, if publicized at all. This is a massive undertaking, since thousands of documents of assorted types and varying affect are issued with intent to govern.
- Apply the Administrative Procedure Act's notice-and-comment requirement to guidance (that some agencies provide an email address to allow input is not sufficient.
- Apply the Congressional Review Act's 60-day resolution of disapproval process to guidance. If guidance grows, the public can know in which instances Congress could have acted to stop or call attention to it, but did not. Congress should also introduce bills to repeal guidance

It has been a generation since Congress last proposed major downsizing of the federal bureaucracy. This year's congressional task forces,[256] along with a distinctive statement of principles in the 2017 House budget proposal, are good first steps in voicing the principle of congressional authority over lawmaking and of restricting the federal government to appropriate boundaries.[257]

Guidance documents are not new, but the recent blatant executive branch assertions of power—including boasts regarding unilateral action without Congress—makes addressing their power to impose rules more salient than ever. The solution for executive overreach is for Congress to say no to it. Likewise, the Washington bureaucracy endures because Congress has yet to say no to it. The public should understand that and hold their elected representatives accountable for this surrender of their authority and shirking of their duties.

Usually, despite the common refrain, there ought *not* be a law. Financial stability, Internet access, cybersecurity, competitiveness, food safety, and other good things that agencies purport to safeguard by regulating are also forms of wealth and prosperity. Those values require

something more than the man-made administrative agency behemoths created long ago to nurture and expand them. The modern administrative regulatory state approach does not work, and is increasingly abusive and unaccountable. Free enterprise never meant companies get to run wild, and the competitive process itself has a vital role to play in "regulation." Real regulation, real discipline, requires something more than the bureaucratic mindset.

NOTES

[1] This testimony updates Clyde Wayne Crews Jr., "Mapping Washington's Lawlessness: A Preliminary Inventory of 'Regulatory Dark Matter'," *Issue Analysis 2015 No. 6*, Competitive Enterprise Institute, December 2015. https://cei.org/sites/default/files/Wayne%20Crews%20-%20Mapping%20Washington%27s%20Lawlessness.pdf; also available on SSRN Social Science Research Network. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2733378.

[2] Remarks by the President and the Vice President at U.S. Conference of Mayors Reception, the White House, January 23, 2014, https://www.whitehouse.gov/the-press-office/2014/01/23/remarks-president-and-vice-president-us-conference-mayors-reception.

[3] From the Planck cosmology probe's 2013 mapping, our universe contains only 4.9 percent ordinary matter. The rest is a quarter dark matter (26.8 percent) and over two-thirds dark energy (68.3 percent). Matthew Francis, "First Planck Results: The Universe is Still Weird and Interesting," Ars Technica, March 21, 2013, http://arstechnica.com/science/2013/03/first-planck-results-the-universe-is-still-weird-and-interesting/.

[4] P.L. 79-404.

[5] P.L. 79-404, Section 553. "Except where notice or hearing is required by statute, this subsection shall not apply to interpretative rules, general statements of policy, rules of agency organization, procedure, or practice, or in any situation in which the agency for good cause finds (and incorporates the finding and a brief statement of the reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest."

[6] Clyde Wayne Crews, Jr., "Despotism-Lite? The Obama Administration's Rule by Memo," *Forbes*, July 1, 2014, http://www.forbes.com/sites/waynecrews/2014/07/01/despotism-lite-the-obama-administrations-rule-by-memo/. A recent exploration of "ways federal regulatory agencies circumvent formal procedures during the rulemaking process" appears as a series of five studies published by Mercatus Center scholars. For links to all of them, see Media Advisory "Mercatus Releases Five Academic Articles in *Harvard Journal of Law and Public Policy*," May 23, 2014, http://mercatus.org/expert_commentary/mercatus-releases-five-academic-articles-harvard-journal-law-and-public-policy.

[7] Jerry Brito, "'Agency Threats' and the Rule of Law: An Offer You Can't Refuse," *Harvard Journal of Law and Public Policy*, Federalist Edition, Vol. 1, No. 1 (2014), http://www.harvard-jlpp.com/wp-content/uploads/2014/05/37_2_553_Brito.pdf.

[8] For example see Nathan Cortez, "Adverse Publicity by Administrative Agencies in the Internet Era," *BYU Law Review*, Vol. 2011, Issue 5, Article 2, December 1, 2011, http://digitalcommons.law.byu.edu/cgi/viewcontent.cgi?article=2832&context=lawreview.

[9] Robert A. Rogowski, Robert A. 1989. "Sub Rosa Regulation: The Iceberg beneath the Surface," in Roger E. Meiners and Bruce Yandle, eds., *Regulation and the Reagan Era: Politics, Bureaucracy and the Public Interest*, (New York: Homes & Meier, 1989), pp. 209-222.

[10] *Appalachian Power Co. v. Environmental Protection Agency* 208 F.3d 1015 (D.C. Cir. 2000), https://law.resource.org/pub/us/case/reporter/F3/208/208.F3d.1015.98-1540.98-1542.98-1538.98-1537.98-1536.html.

[11] Jonathan H. Adler, "Examining the Use of Administrative Actions in the Implementation of the Affordable Care Act," Testimony before the Subcommittee on Oversight of the Committee on Ways and Means, U.S. House of Representatives, May 20, 2015, http://waysandmeans.house.gov/wp-content/uploads/2015/06/2015-05-20-Oversight-Adler-Testimony.pdf. See also John D. Graham and James W. Broughel, "Stealth Regulation: Addressing Agency Evasion of OIRA and the Administrative Procedure Act," *Harvard Journal of Law and Public Policy*: Federalist Edition, Vol. 1, No. 1 (2014), http://www.harvard-jlpp.com/wp-content/uploads/2010/01/Graham_Broughel_final.pdf. In a Mercatus Center analysis, Graham and Broughel elaborate: "The bulletin outlined how businesses could stay in compliance during the transition period before reporting requirements and fines would fully kick in. No public feedback was solicited on the bulletin, nor was the

bulletin accompanied by an economic analysis (known as a regulatory impact analysis or RIA), even though the policy had large economic effects." Graham and Broughel, "Confronting the Problem of Stealth Regulation," *Mercatus on Policy*, Mercatus Center, April 13, 2015, http://mercatus.org/publication/confronting-problem-stealth-regulation.

[12] Adler.

[13] Jeh Johnson, "Exercising Prosecutorial Discretion with Respect to Individuals who Came to the United States as Children and with Respect to Certain Individuals Who Are the Parents of U.S. Citizens or Permanent Residents," Memorandum, November 20, 2014, http://www.dhs.gov/sites/default/files/publications/14_1120_memo_deferred_action.pdf.

[14] Barack Obama, "Remarks by the President on the Economy and Housing," White House Office of the Press Secretary, October 24, 2011, https://www.whitehouse.gov/the-press-office/2011/10/24/remarks-president-economy-and-housing.

[15] Obama, "State of the Union Address," White House, Office of the Press Secretary, January 28, 2014, http://www.whitehouse.gov/the-press-office/2014/01/28/president-barack-obamas-state-union-address.

[16]Gregory Korte, "Obama's Executive Action Rollouts Increasing In Pace," *USA Today*, April 22, 2015, http://www.usatoday.com/story/news/politics/2015/04/22/obama-executive-actions-increasing/25828391/

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[18] Stephanie Simon, "Obama Faces Power Backlash," *Politico*, February 1, 2014, http://www.politico.com/story/2014/02/barack-obama-executive-power-backlash-102966.

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[21] Chris Edwards, "Forget Too Big to Fail ... The Federal Government is too Big to Work," *Washington Examiner*, July 13, 2015, http://www.washingtonexaminer.com/the-federal-government-is-too-big-to-work/article/2567987.

[22]Office of Information and Regulatory Affairs, Office and Management and Budget, RegInfo.gov advanced search, http://www.reginfo.gov/public/do/eAgendaAdvancedSearch;jsessionid=B3A2661D41F347B94BA3F32EFED6E28.

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[24] Crews, "Obama's 2015 Report to Congress on Federal Regulations Is MIA," CEI Blog, July 22, 2015, https://cei.org/blog/obama%E2%80%99s-2015-report-congress-federal-regulations-mia.

[25] David E. Lewis and Jennifer L. Selin, *Sourcebook of United States Executive Agencies*, Administrative Conference of the United States, March 7, 2013. Pp. 138-141, https://www.acus.gov/sites/default/files/documents/Sourcebook%202012%20FINAL_May%202013.pdf.

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[27] Sen. Chuck Grassley, Prepared Statement for Senate Judiciary Committee Hearing, "Examining the Federal Regulatory System to Improve Accountability, Transparency and Integrity," June 10, 2015," http://www.judiciary.senate.gov/imo/media/doc/06-10-15%20Grassley%20Statement.pdf.

[28] *Federal Register* Agency List, accessed October 23, 2015, https://www.federalregister.gov/agencies.

[29] *Federal Register* 2015 Index, accessed July 24, 2015, https://www.federalregister.gov/index/2015. ("The count is omitted for agency publishing less than 2 documents in a given year.")

[30] "Find Documents" advanced search function on Regulations.gov, http://www.regulations.gov/#!advancedSearch.

[31] Crews, *Ten Thousand Commandments: A Policymaker's Snapshot of the Federal Regulatory State*, (various years) Competitive Enterprise Institute: Washington, D.C., http://www.cei.org/10kc.

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[34] Pub. L. No. 96-511, 94 Stat. 2812, codified at 44 U.S.C. §§ 3501–3521.

[35] P.L. 96-354.
[36] 5 U.S.C. § 801-808.
[37] Carey.
[38] Executive Order 12291, "Federal Regulation," February 17, 1981, http://www.archives.gov/federal-register/codification/executive-order/12291.html.
[39] See Crews, "One Nation Ungovernable? Confronting the Modern Regulatory State," in Donald J. Boudreaux, ed., *What America's Decline In Economic Freedom Means for Entrepreneurship and Prosperity*, Fraser Institute and Mercatus Center at George Mason University (2015), pp. 117-181, http://www.fraserinstitute.org/uploadedFiles/fraser-ca/Content/research-news/research/publications/what-americas-decline-in-economic-freedom-means-for-entrepreneurship-and-prosperity.pdf.
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[41] U.S. Office of Management and Budget, Office of Information and Regulatory Affairs, *Report to Congress On the Benefits and Costs of Federal Regulation* (various years available). https://www.whitehouse.gov/omb/inforeg_regpol_reports_congress/.
[42] The Administrative Procedure Act itself signaled a break with traditional democratic accountability. In his book, *Is Administrative Law Unlawful*, Columbia law professor Philip Hamburger sees the modern administration state as a reemergence of the absolute power practiced by pre-modern kings. Philip Hamburger, *Is Administrative Law Unlawful?* (Chicago: University of Chicago Press, 2014). See also Hamburger's discussions of administrative law in a summer 2014 *Washington Post* blog series, http://www.washingtonpost.com/news/volokh-conspiracy/wp/2014/07/14/prof-philip-hamburger-columbia-guest-blogging-on-his-is-administrative-law-unlawful/.
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[45] U.S. GAO 2012, Introduction.
[46] Ibid.
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[48] Curtis W. Copeland, "Congressional Review Act: Many Recent Final Rules Were Not Submitted to GAO and Congress," Administrative Conference of the United States, July 15, 2014, https://www.acus.gov/sites/default/files/documents/CRA%2520Report%25200725%2520%25282%2529.pdf.
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[50] Morton Rosenberg, "Whatever Happened to Congressional Review of Agency Rulemaking?: A Brief Overview, Assessment, and Proposal for Reform," *Administrative Law Review* (American Bar Association), Vol. 51, No. 4 (Fall 1999), pp. 1066-1067, http://www.jstor.org/stable/40710052.
[51] Ibid.
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Written Testimony of

Amit Narang
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before the

The Senate Committee on Homeland Security and Government Affairs
Subcommittee on Regulatory Affairs and Federal Management

on

"Examining the Use of Regulatory Guidance, Part II"

June 30, 2016

Mr. Chairman and Members of the Committee,

Thank you for the opportunity to testify today on regulatory policy issues. I am Amit Narang, Regulatory Policy Advocate at Public Citizen. Public Citizen is a national public interest organization with more than 400,000 members and supporters. For 45 years, we have advocated with some considerable success for stronger health, safety, consumer protection and other rules, as well as for a robust regulatory system that curtails corporate wrongdoing and advances the public interest.

Public Citizen chairs the Coalition for Sensible Safeguards (CSS). CSS is an alliance of more than 75 consumer, small business, labor, scientific, research, good government, faith, community, health and environmental organizations joined in the belief that our country's system of regulatory safeguards provides a stable framework that secures our quality of life and paves the way for a sound economy that benefits us all. Time constraints prevented the Coalition from reviewing my testimony in advance, and today I speak only on behalf of Public Citizen.

Over the last century, and up to the present, regulations have made our country stronger, better, safer, cleaner, healthier and more fair and just. Regulations have made our food supply safer; saved hundreds of thousands of lives by reducing smoking rates; improved air quality, saving hundreds of thousands of lives; protected children's brain development by phasing out leaded gasoline; saved consumers billions by facilitating price-lowering generic competition for pharmaceuticals; reduced toxic emissions into the air and water; empowered disabled persons by giving them improved access to public facilities and workplace opportunities; guaranteed a minimum wage, ended child labor and established limits on the length of the work week; saved the lives of thousands of workers every year; protected the elderly and vulnerable consumers from a wide array of unfair and deceptive advertising techniques; ensured financial system stability (at least when appropriate rules were in place and enforced); made toys safer; saved tens of thousands of lives by making our cars safer; and much, much more.

Guidance documents have played an essential role in ensuring that Americans receive the benefits of these and other regulatory protections. As discussed more fully later in this testimony, agencies have relied on guidance documents to supplement critical public protections in a wide variety of areas by clarifying the technical details of regulations and their applications to particular situations. It is thus important to maintain the efficient and effective use of guidance documents as an essential tool in helping agencies protect the public.

The first section of this testimony gives an overview of the variety of agency actions that come under the umbrella term "guidance documents," points out the many ways in which guidance documents have benefitted the public and particularly regulated entities seeking clarity in areas of regulatory uncertainty, and disputes the notion that agencies are using guidance documents to circumvent the rulemaking process by referencing empirical evidence that tested and determined those allegations to be unfounded. The second section of the

testimony examines attempts to align the guidance process more closely with the notice and comment rulemaking process and finds that such reforms would harm the public by removing the flexibility and efficiency of the guidance process and imposing the delays and inefficiencies of the notice and comment rulemaking process onto guidance documents. This section relies on the findings of a new and ground-breaking report by Public Citizen that studied tens of thousands of rulemakings over the past twenty years and concluded that delays in the rulemaking process are significant and tied to accumulating procedural and analytical requirements imposed by Congress. The delays and inefficiencies are most acute for "economically significant" rules that provide the most benefits in terms of protecting the public. Thus, the report's empirical findings confirm the many and familiar anecdotes of public health and safety, environmental, and financial reform rules that are taking far too long to complete.

I. What Are Guidance Documents?

The term "guidance documents" does not appear anywhere in the Administrative Procedure Act (APA) but has generally come to be understood as encompassing a wide variety of agency actions that are not considered to be binding rules which typically undergo notice and public comment and abide by the requirements of the APA. Examples of such actions include general agency interpretations of existing legislative rules , statements outlining how an agency intends to regulate an evolving policy area, training manuals written for internal agency staff, compliance guides directed to the general public, advisory opinions tailored to individual case facts, and memoranda from agency leaders providing direction to agency staff members. Thus, agencies use guidance documents not just to manage internal operations but also to communicate essential information to outside parties.

In certain circumstances, agencies do have the discretion to implement congressional mandates or clarify ambiguities in rulemakings through the use of guidance documents. In other circumstances, agencies are only authorized to implement congressional mandates through use of notice and comment rulemaking. The distinction between guidance documents and notice and comment rules is cemented in the APA which explicitly exempts interpretive rules, general statements of policy, and other agency actions that comprise guidance documents.[1]

When agencies have the authority to do so, agencies may opt to issue guidance documents rather than notice and comment rules because doing so allows agencies to communicate its views on agency interpretations and policies to both regulated entities and the public in a significantly more efficient and expeditious manner than under notice and comment rulemaking.[2] Thus, guidance documents allow agencies to avoid devoting scarce time and resources to unnecessary rulemaking. On the other hand, guidance documents are not legally binding on the public which then restricts enforcement of potential non-compliance with

[1] 5 U.S.C. § 553.

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guidance documents.[3] Therefore, agencies must weigh the efficiency advantages that are inherent in guidance documents against the lack of legally binding effect when deciding to adopt guidance documents as opposed to notice and comment rules.

A. Guidance Documents Benefit the Public

The enormous variety of guidance documents across agencies makes it difficult to encapsulate the impacts and effects of guidance documents in a broad manner without significant nuance and context. Yet, there is no doubt that guidance documents provide Americans with enormous benefits similar to public health and safety regulations that undergo notice and comment. Below is a small and non-exhaustive sampling of guidance documents from different agencies that make clear how vital guidance documents are to protecting the public:

- **Opioid and Infectious Disease Guidance**: The Centers for Disease Control (CDC) recently issued guidance directing physicians to limit the prescription of opioid pain medication in an effort to combat the serious and growing epidemic of addiction to opioid pain medication that has resulted in fatal overdoses involving pain medication and illegal hard drugs in many parts of the country.[4] The CDC has also recently issued Zika virus guidance that clarifies the dangerous health impacts of the Zika virus, particularly for pregnant women, and provides guidance for how to avoid contracting the virus.[5] The CDC had issued similar guidance for the Ebola virus last year.

- **Lead Guidance**: The Environmental Protection Agency (EPA) has issued numerous guidance documents related to the prevention of lead poisoning among the public and particularly children.[6] These include guidance to homeowners about the dangers of lead in paint and the options for lead abatement and guidance to real estate developers on how to conduct renovations in a safe manner to avoid lead poisoning as well as information on the presence of lead that should be disclosed to prospective homebuyers. EPA has also issued important guidance on the harmful presence of lead in drinking water including information on protecting schools and child care facilities from lead contamination as well as simple and clear fact sheets on the EPA's revisions to its regulations controlling lead in water.

- **Food Safety Guidance**: the Food and Drug Administration (FDA) has used guidance documents extensively to ensure the safety of foods sold in the U.S. and prevent tainted food outbreaks.[7] Specifically, the FDA has provided clarity on what does and does not constitute "adulterated" foods and how to produce and transport food in a

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[3] Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like-Should Federal Agencies Use Them To Bind The Public?*, 41 DUKE L.J. 1311, 13-14 (1992).
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safe manner that avoids contamination. Examples of such guidance include the prevention of salmonella in eggs which leads to food poisoning and best manufacturing practices for infant formula to ensure its safety and quality.[8]

- **Airline Safety**: The Federal Aviation Administration (FAA) has used guidance documents to ensure both the safety of airplanes by clarifying manufacturing and operational requirements as well as the safety of passengers by prohibiting passengers from bringing dangerous items onto airplanes.[9]

- **Oil and Pipeline Safety Guidance**: The Federal Railroad Administration (FRA) and the Pipeline Hazardous Materials and Safety Administration (PHMSA) jointly issued safety alerts in 2014 warning of the dangers of transporting volatile crude oil by rail and clarifying the need for companies transporting crude oil by rail to notify local authorities when crude oil trains were passing through their jurisdictions and the nature of the crude oil cargo being transported.[10] These actions were taken amidst ongoing crude oil train derailments and explosions and came well before the finalization of regulations that imposed new oil train safety standards.

- **Wage and Hour Guidance**: the Department of Labor (DOL) provides guidance for employees regarding their rights under various labor laws and employers regarding their responsibilities under the law. This guidance is specific to industry sectors and includes guidance on prohibited employment for children and employee rights and benefits under the Family Medical Leave Act.[11]

- **Sexual Assault Guidance:** The Department of Education's Office of Civil Rights (OCR) has issued guidance documents to address the growing problem of sexual harassment and assault on college campuses.[12] Title IX of the Education Amendments of 1972 empowers OCR to prohibit sex discrimination in federally funded educational institutions. OCR has routinely issued technical clarification and guidance to provide educational institutions with clarity of their obligations to students under title IX. Those include "equitable" proceedings with respect to allegations of sexual harassment or assault and findings under a clear preponderance of the evidence standard.

Agencies have also relied on guidance documents to protect the right of minorities and other vulnerable populations that have historically been subject to discrimination. The following are examples of guidance documents that have promoted racial, gender, and sexual orientation equality:

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[8] http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm384451.htm
[9] https://www.faa.gov/regulations_policies/
[10] https://www.transportation.gov/briefing-room/emergency-order
[11] https://www.dol.gov/whd/fact-sheets-index.htm
[12] https://www2.ed.gov/about/offices/list/ocr/letters/colleague-201104.html

- **Employment Discrimination Guidance**: the Equal Employment Opportunity Commission (EEOC) issues only guidance interpreting title VII of the Civil Rights Act of 1964 because it is barred by Congress from issuing substantive regulations which implement title VII.[13] Thus, guidance documents are crucial to the EEOC's mission of preventing discrimination in hiring practices and in the workplace.[14]

- **Disability Discrimination Guidance**: The Department of Justice (DOJ) has issued guidance related to the Americans with Disabilities Act (ADA) in order to clarify the rights of persons with disabilities and to prevent discrimination against such persons based on their disabilities. In 2010, DOJ issued comprehensive guidance that provided standards for state and local governments to ensure disabled access to public facilities, such as wheelchair access.[15]

- **Sexual Orientation Discrimination Guidance**: A number of agencies, including the EEOC, the Department of Education (DOE), and the Department of Housing and Urban Development, issue guidance to prevent discrimination in education, housing, and employment based on sexual orientation. Most recently, the DOJ and DOE jointly issued guidance under title IX of the Education Amendments of 1972[16] requesting that public education institutions, including higher education institutions, allow transgendered students to use restroom facilities of their preference in order to protect both the personal safety and the civil rights of transgendered students.[17] DOE has also released guidance that aids educational institutions in combatting bullying on the basis of sexual orientation.[18]

B. Guidance Documents Benefit Business

One of the primary purposes of guidance documents is to address regulatory uncertainty among businesses as to an agency's interpretation and application of a specific law or regulation. Often times, businesses explicitly request such guidance and rely on an agency's ability to quickly and fully provide such guidance. Within this category, there are certain guidance documents that are issued exclusively for the benefit of businesses and other regulated entities. Any "one-size-fits-all" changes to the guidance document process will make it harder for agencies to issue the following types of guidance documents that are designed to benefit business and industry stakeholders:

- **No Action Letters**: Many agencies use No Action Letters (NAL) to clarify for businesses whether a particular activity violates an agency's regulation. In other words, these letters provide a "safe harbor" for businesses by ensuring that businesses

[13] 42 USC § 2000e-12
[14] https://www.eeoc.gov/laws/guidance/enforcement_guidance.cfm
[15] https://www.ada.gov/regs2010/2010ADAStandards/Guidance2010ADAstandards.htm
[16] 20 U.S.C. §§ 1681–1688 (1972).
[17] http://www2.ed.gov/about/offices/list/ocr/letters/colleague-201605-title-ix-transgender.pdf
[18] http://www.ed.gov/news/press-releases/bullying-students-disabilities-addressed-guidance-america%E2%80%99s-schools

will not be punished when engaging in an activity that could potentially run afoul of a regulation. The Securities and Exchange Commission (SEC) issues many NALs and is the prototypical example. NALs are usually directly requested by businesses that have a strong interest in agencies responding to their requests on an expedited basis. Courts have held that SEC NALs are essentially guidance documents that are exempt from notice and comment requirements.[19] While NALs are directed at individual parties or businesses, the SEC and other agencies make the NALs publicly available on their website and thus NALs have the effect of encouraging other businesses to take advantage of the "safe harbor" to engage in the same activity. In this way, NALs are used to set broad policy without notice and comment. Recently, the Consumer Financial Protection Bureau (CFPB) instituted a NAL process in order to allow innovative and consumer-friendly financial products to be marketed without the possibility of an adverse CFPB enforcement action.[20] CFPB decided that NALs would not be subject to notice and comment because that would "unnecessarily discourage NAL applications and delay the NAL process."[21]

- **Small Business Compliance Guides**: Congress has required agencies to issue guidance to reduce compliance costs for businesses, and small businesses in particular.[22] Agencies routinely issue "compliance guides" when finalizing a regulation in order to provide regulated parties with a clear and easy to understand manual for how to comply with the new regulation. While these guides have proven helpful for businesses, there is a lack of awareness that such compliance guides exist in the first place due to a lack of agency resources to promote awareness of compliance guides.

C. Guidance Documents Are Not Being Abused

Allegations of agencies using guidance documents to flout rulemaking are soundly rejected by the available empirical evidence. The leading study is a 2010 study by Connor Raso in the Yale Law Journal[23] examining whether federal agencies improperly issue guidance documents instead of legally binding notice and comment rules on a widespread basis. Raso tested this by identifying situations where agencies would in theory have a strong incentive to issue guidance rather than notice and comment rules such as at the end of presidential terms when agencies do not have enough time to complete notice and comment rulemaking or whether agencies issued more guidance documents under divided government in order to avoid congressional scrutiny. The study found no evidence that suggests agencies use guidance documents strategically to make important policy decisions outside the notice and comment process.

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[19] N.Y.C. Emps.' Ret. Sys. v. SEC, 45 F.3d 7, 13-14 (2d Cir. 1995).
[20] http://files.consumerfinance.gov/f/201602_cfpb_no-action-letter-policy.pdf
[21] *Id.* at 14.
[22] Small Business Regulatory Enforcement Fairness Act of 1996 § 212.
[23] Connor Raso, *Strategic or Sincere? Analyzing Agency Use of Guidance Documents*, 119 Yale L.J. 782 (2010).

II. The Dangers of Guidance Document Reforms

While the available empirical evidence demonstrates that there is no abuse of guidance documents in order to evade the notice and comment rulemaking process, it is impossible to ignore the strong incentive agencies have to avoid what has become an increasingly inefficient and dysfunctional rulemaking process across regulatory sectors and at virtually every agency. If the Committee believes that agencies should be taking action through notice and comment rulemaking rather than through guidance documents, the solution is to make the notice comment process more efficient and streamlined rather than forcing guidance documents into the notice and comment framework reserved for rulemaking. Turning guidance documents essentially into rules subject to notice and comment as well as other procedural requirements will do nothing to cure the delays and inefficiencies inherent in the current regulatory process. It will only expand those delays to a more agency actions that are designed to address regulatory uncertainty in an expedited manner.

A. Rulemaking Delays Are Widespread and Getting Worse

There are certainly no dearth of examples and anecdotes showing how long it takes for federal agencies to issue new rules, particularly those rules that provide the biggest benefits to the public in term of health, safety, and financial security. The anecdotes touch virtually every regulatory sector and every agency. Recent examples of long-delayed rules that failed to protect Americans quickly enough include new oil train safety standards, new safety standards for blowout preventers on offshore oil rigs to prevent the next BP Gulf Oil Spill, major new food safety regulations that overhaul our food safety system to prevent rather than just respond to tainted food outbreaks, Wall Street reforms that have yet to be finalized almost 8 years after the financial crash, new pipeline safety standards to prevent pipeline leaks and spills, new energy efficiency standards that save consumers money, new workplace safety protections against known carcinogens like silica dust, and new measures to put money back in the pockets of Americans like the fiduciary rule and the overtime rule. Yet, there has been a notable lack of empirical analysis to identify both the length of these delays and the extent of the delays across different agencies. This week, Public Citizen unveiled a ground-breaking report aimed at filling this void.

The report, entitled *Unsafe Delays*[24] and attached at the end of this testimony, examines regulatory delays by collecting and analyzing one of the most comprehensive data sets of rulemaking actions to date. Our report gathered data on all rules listed in the Unified Agenda over the last twenty years, from the first Unified Agenda available electronically in 1995 to the most recent Unified Agenda published last month. In total, we studied a total of 24,311 rulemakings, of which 18,146 were actually completed. The picture of delay that emerges from the report is troubling and serves as an important baseline when considering proposals to turn the process for issuing guidance documents into one that has traditionally been reserved exclusively for rulemaking.

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[24] http://www.citizen.org/unsafedelaysreport

Overall, we found that the rules that are most important to protecting the environment as well as the public's health, safety, and financial security were also the rules that took the longest to finalize and encountered the most delays in the regulatory process. On the other hand, routine or technical rules that were not considered "significant," which comprised the clear majority of all rulemakings, encountered few delays and were usually finalized in a fairly efficient manner. In other words, the "economically significant" rules that were subject to the most procedural requirements in the rulemaking process were also the rules with the greatest delays.

It may not be surprising that rules which must go through more steps in the rulemaking process will take longer, but what is striking and worrisome is the extent of the delay we found. Overall, the average length of rulemakings for all economically significant rules is 2.4 years, 41 percent longer than the overall age for all rules (1.7) years. Economically Significant rules that required a Regulatory Flexibility Analysis (RFA) took on average 2.5 years to complete. However, Economically Significant rules that began with an Advanced Notice of Proposed Rulemaking (ANPRM) took on average 4.4 years to complete, almost twice as long as Economically Significant rules without ANPRMs. Finally, Economically Significant rules that included both ANPRMs and RFA analyses took almost five years to complete on average. Hence, the inclusion of major additional procedural requirements leads to substantial additional delay in the rulemaking process.

The report also found that the agencies charged with protecting the health and well-being of the public and our environment are the agencies with the greatest rulemaking delays. For example the DOL takes 5.4 years on average to complete Economically Significant rules and a whopping 9.1 years if those Economically Significant rules include a RFA analysis. The sub-agency within DOL charged with protecting worker safety, the Occupational Safety and Health Administration (OSHA), experienced the worst delays with Economically Significant rulemakings taking an astounding 12.5 years on average and 15 years if a RFA analysis was required.

Other agencies that took the longest to complete Economically Significant rules on average were the Department of Energy (5 years), The Environmental Protection Agency (3.8 years), and the Department of Homeland Security (3.4 years). We also found that important sub-agencies within larger agencies are more prone to substantial rulemaking delays for Economically Significant rules. For example, two EPA sub-agencies, the office of Solid Waste and Emergency response and the Water office, both take longer than 5 years on average to complete Economically Significant rulemakings. Other sub-agencies with noteworthy delays for Economically Significant rules include the DHS Transportation Security Administration (5.7 years), the USDA Food and Nutrition Service (5.4 years), the DOE Energy Efficiency and Renewable Energy (5.1 years), DOL's Employee Benefits Security Administration (4.4 years), and HHS Food and Drug Administration (3.5 years).

The clear takeaway from our comprehensive empirical research is that many agencies are simply unable to complete Economically Significant rulemakings over the course of one presidential term. Unfortunately, the data in our report also shows that the trend is going in

the wrong direction with increasing rather than decreasing delays. We found that the George W. Bush and Obama Administrations experienced similar rulemaking lengths for their first five years. Beginning in the sixth year of the Obama Administration, completed Economically Significant rulemakings became substantially longer than in the corresponding year in the Bush Administration. Over the last three years, the average length of rulemakings has increased steadily from 3.2 years in 2014 to 3.4 years in 2015 and now 3.8 years this year. In short, the rulemaking delays have reached new heights over the last few years. The data for other types of rules also reflects an increase in rulemaking lengths over the last few years. It has become clear that our current problems with regulatory delay are getting worse.

B. Guidance Document Reforms Will Lead To More Delays

The report's findings are directly relevant to proposals which seek to reform the guidance document process to not only include notice and comment but also other procedural requirements that align guidance documents more closely with economically significant rules. For example, the Regulatory Accountability Act (RAA)[25] creates a "one-size-fits-all" approach for "major" guidance documents[26] which would be a newly created category of guidance documents modeled after the Bush Executive Order[27] in 2007 which itself created a "significant" guidance category for the first time before it was repealed by the Obama Administration. The RAA would require agencies to conduct a full-blown cost-benefit analysis for major guidance and subject this guidance to OIRA review, even for independent agencies whose rules are currently not reviewed by OIRA. The now-repealed Bush EO went further by defining "significant" guidance documents in a way that is virtually indistinguishable from Economically Significant rules. The EO then required notice and comment as well as OIRA review for all "significant" guidance documents.

Our study indicates that proposals to make the process for adopting guidance documents much more similar to the process for adopting Economically Significant rules will surely result in a substantial increase in delays when issuing guidance documents. These proposals are unwise and should not be adopted.

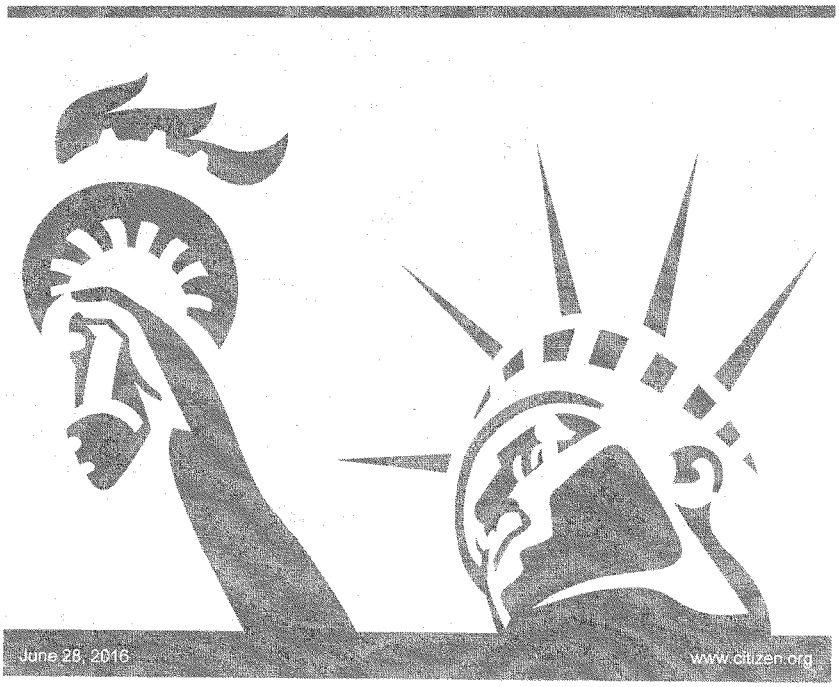
III. Conclusion: Strengthening the System of Regulatory Protections to Strengthen America

There is much to celebrate in our nation's system of regulatory protections. It has tamed marketplace abuses and advanced the values we hold most dear: freedom, safety, security, justice, competition and sustainability. Guidance documents have played an important role in securing these benefits for the public.

Proposals to reform guidance documents threaten to undermine the progress we have made. The clear effect of such reforms would be to add even more delays to a regulatory process that is plagued by inefficiency and dysfunction. Congress should be looking for ways the

[25] Regulatory Accountability Act of 2015, S. 2006 (2015).
[26] Regulatory Accountability Act of 2015, S. 2006 § 5 (2015).
[27] Exec. Order No. 13, 422, 3 C.F.R. 191 (2007).

build upon the successes of our regulatory system, not seeking to weaken the system by introducing more delays.



Unsafe Delays

An Empirical Analysis Shows That Federal Rulemakings To Protect the Public Are Taking Longer Than Ever

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About Public Citizen

Public Citizen is a national non-profit organization with more than 400,000 members and supporters. We represent consumer interests through lobbying, litigation, administrative advocacy, research, and public education on a broad range of issues including consumer rights in the marketplace, product safety, financial regulation, worker safety, safe and affordable health care, campaign finance reform and government ethics, fair trade, climate change, and corporate and government accountability.

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Contents

Introduction **16**

Executive Summary **18**

Methodology **21**

I. Effects of Priority and Statutory Requirements on Rulemaking Length **23**

A. Length of Rulemaking Overview 23
Table 1: Number of Rulemakings and Average Length - All Rulemakings Begun and Finished 1996 - 2016 ..... *23*
B. Effects of Significant Versus Nonsignificant Priority on Rulemaking Length 23
Table 2: Number and Average Rulemaking Length of Completed Rules by Final Priority *24*
C. Case Study on OIRA Delay — A Law to Prevent Backover Deaths by Vehicles 24
D. Effects of a Regulatory Flexibility Analysis on Rulemaking Length 27
Table 3: Length of Completed Rulemakings (RM) With RFA Required *27*
E. Effects of Inclusion of Advance Notice of Proposed Rulemaking (ANPRM) on Rulemaking Length 27
Table 4: Length of Completed Rulemakings (RM) With and Without Inclusion of ANPRM *28*
Table 5: Length of Completed Rulemakings (RM) With and Without Inclusion of ANPRM and RFA *28*
F. Associations Between Legal Deadlines and Rulemaking Length 28
Table 6: Length of Rulemakings (RM) With Legal Deadlines *29*
G. Case Study on Missed Legal Deadlines — The Protracted Creation of a Legally Required Standard on Ozone 30
H. Effects of Changing Priority on Rulemaking Length 33
Table 7: Length of Completed Rulemakings (RM) With No Changed Priority versus Changed Priority *33*

II. Volume of Completed Rules **34**

A. Comparing of the Number of Completed Rules Over the Years 34
Figure 1: Number of Completed Rules Listed in Unified Agenda *34*
Table 8: Average and Number of Rules Completed Under Presidents George W. Bush and Barack Obama (through first seven years) *35*
Figure 2: Number of Completed Economically Significant and Other Significant Rules by Year *35*
Table 9: Yearly Average of Completed Rules *36*
B. Presidents Begin to Enact Most of Their Own Agenda in Their Third Year 36
Figure 3: Number and Percentage of Completed Rules by Year That Began Under the Same President *36*
Figure 4: Number of Completed Economically Significant and Other Significant Rules by Year That Began Under the Same President *37*
Table 10: Yearly Average of Completed Rules Beginning and Ending in One Administration by Priority *37*

III. Rulemaking Length Is Increasing 38

Table 11: Average Rulemaking (RM) Length of Completed Rules 38
Figure 5: Length of Completed Rulemakings 38
Figure 6: Length of Completed Economically Significant Rules 38
Figure 7: Length of Completed Other Significant Rules 39
Table 12: Years in Which the Average Completed Rulemakings Were the Longest 40
Table 13: Years in Which the Average Completed Rulemakings Beginning and Ending Within the Same Administration Were the Longest 41
Figure 8: Difference in Length of Obama Completed Economically Significant Rulemakings Compared to Corresponding Bush Administration Year (Rulemakings that Start and Finish Under Their Administration) 42

IV. Uncompleted Rulemakings 43

Table 14: Number and Average Rulemaking (RM) Length of Uncompleted Rules 43

V. Agency and Sub Agency Analysis 44

A. Agency Completed Significant Rulemakings 44
Table 15: Number and Average Rulemaking (RM) Length of Completed Rules 44
B. Effects of a Regulatory Flexibility Analysis on Completed Significant Rules by Agency 44
Table 16: Number of Rules and Average Rulemaking Length of Economically and Other Significant 45
C. Sub Agency Completed Rulemakings 46
Table 17: Number and Average Rulemaking (RM) Length of Completed Rules by Sub Agency Sub Agencies with Longer Than Average Economically Significant Completed Rulemakings 46
D. Effects of Regulatory Flexibility Analysis on Significant Completed Rules by Sub Agency 47
Table 18: Number and Average Rulemaking (RM) Length of Significant Completed Rules Sub Agencies With Longer Than Average Economically Significant Completed Rulemakings With a RFA Requirement versus No RFA 47
E. Incomplete Rules by Agency 48
Table 19: Number and Average Rulemaking (RM) Length of Incomplete Rulemakings 48
F. Incomplete Rules by Sub Agency 49
Table 20: Number of Rules and Average Rulemaking (RM) Length of Incomplete Rules by Sub Agency (>15 Incomplete Rules) 49
G. Department of Labor (DOL) Case Study — the Long Delayed Silica Rule 50

Conclusion 51

Introduction

When Congress passes a law, it often delegates authority to federal agencies to write rules to carry out the law's intent. For instance, the Occupational Safety and Health Act of 1970 stipulated a purpose "to assure safe and healthful working conditions for working men and women" in part by "authorizing the enforcement of the standards developed under the Act."[28]

The law established the Occupational Safety and Health Administration (OSHA) and delegated to OSHA the responsibility to create standards (also known as rules or regulations) to enforce the law. OSHA has subsequently created hundreds of rules to address specific risks to workers. According to a 2016 AFL-CIO report, more than 532,000 lives have been saved by OSHA's work since the 1970 passage of the Occupational Safety and health Act.[29]

The federal government has taken several steps over the past four decades intended to ensure that the public is alerted to rulemakings early in the process. An executive order issued by President Jimmy Carter in 1978 required agencies to publish agendas at least twice a year outlining regulations under development or review.[30] Since 1983, the government has published a semiannual "Unified Agenda" of federal regulatory and deregulatory actions that compiles individual agencies' ongoing and recently completed rulemakings.[31] Unified Agendas are available online dating back to 1995.[32]

As the Unified Agendas have increased transparency into agencies' intended rulemakings, the time to actually *complete* the rules has grown longer and longer. For instance, in OSHA's early years, it completed numerous important lifesaving rules in less than a year.[33] In a dramatic reversal, since

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[28] The Occupational Safety and Health Act, 29 U.S.C. § 651(2)(b) (1970).
[29] AFL-CIO, DEATH ON THE JOB: A NATIONAL AND STATE-BY-STATE PROFILE OF WORKER SAFETY AND HEALTH IN THE UNITED STATES (April 2016), http://bit.ly/28SjVKQ.
[30] Executive Order 12044 (March 23, 1978), http://bit.ly/1Xd59EM.
[31] CURTIS COPELAND, CONGRESSIONAL RESEARCH SERVICE, THE UNIFIED AGENDA: IMPLICATIONS FOR RULEMAKING TRANSPARENCY AND PARTICIPATION (July 20, 2009), at 14, http://bit.ly/20LQxK1. *See*, http://www.reginfo.gov/public/. Note: In 2012, only one Unified Agenda was published.
[32] *See*, http://www.reginfo.gov/public/. Note: The majority of rulemakings categorized as "routine/frequent" or "informational/administrative" (which may make up as many as 70 percent of all rulemakings) are not included in the Unified Agenda. Examples include the U.S. Coast Guard establishing timetables for operation of drawbridges. *See*, CURTIS COPELAND, ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, CONGRESSIONAL REVIEW ACT: MANY RECENT FINAL RULES WERE NOT SUBMITTED TO GAO AND CONGRESS (July 15, 2014), http://1.usa.gov/28N7bo8.
[33] *See, e.g.*, JUSTIN FELDMAN, PUBLIC CITIZEN, OSHA INACTION: ONEROUS REQUIREMENTS IMPOSED ON OSHA PREVENT THE AGENCY FROM ISSUING LIFESAVING RULES, at 4 (October 2011), http://bit.ly/1RxWIer.

1996, it has taken OSHA an average of 12 years to produce a single Economically Significant rule, according to this report. When OSHA's rulemakings have included a Regulatory Flexibility Analysis, which involves an intensive analysis of the potential effects of rules on small businesses, the average grows to 15 years.[34] These rulemakings are often challenged in court and, thus, can be prolonged even further.

Such delays can carry dire costs. In 2011, Public Citizen analyzed government estimates on the would-be safety benefits of five ongoing OSHA rulemakings that had languished between four and 31 years. Prompt finalization of those rules would have prevented more than 100,000 serious injuries and hundreds of fatalities, according to the analysis.[35]

The obvious reason that the rulemaking process has become so elongated is that many steps have been added to it, due to congressional mandates and other pressures. Despite the ever-growing time it takes to create new rules, critics of regulation continue to allege that regulations are rushed through the process without adequate vetting or scrutiny. To address these alleged concerns, many members of Congress have lately put forth bills to add even more steps to the regulatory process.[36]

The intent of many of these bills is allegedly to produce a more efficient regulatory process. But, until now, there has been a lack empirical data on the effects of steps that have already been added to the process.

This report analyzes data from 20-plus years of the federal government's semi-annual Unified Agendas to determine the consequences of individual variables on the length of rulemakings, trends in the speed of rulemakings, as well as the comparative efficiency of federal agencies in their rulemaking.

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[34] GOVERNMENT ACCOUNTABILITY OFFICE, WORKPLACE SAFETY AND HEALTH: MULTIPLE CHALLENGES LENGTHEN OSHA'S STANDARD SETTING (Introduction) (April 2012), http://1.usa.gov/1sgfrqj.

[35] JUSTIN FELDMAN, PUBLIC CITIZEN, OSHA INACTION ONEROUS REQUIREMENTS IMPOSED ON OSHA PREVENT THE AGENCY FROM ISSUING LIFESAVING RULES (October 2011), http://bit.ly/1RxWIer.

[36] *See e.g.* The Early Participation In Regulations Act of 2015, S. 1820, 114th Cong. (2015), The Regulatory Accountability Act of 2015, Section 3(c), H.R. 185 (2015) and Regulations from the Executive in Need of Scrutiny Act of 2015 H.R.427, 114th Cong. (2015).

Executive Summary

Over the past four decades, numerous steps have been added to the rulemaking process. As these steps have been added, the length of time to create rules has grown. The following are examples of steps or definitions that add substantial delay to the rulemaking process:

- Rules identified as **Economically Significant**, which are determined to have an effect on the economy of $100 million or more in a single year, must undergo cost-benefit analysis and may face multiple reviews by the Office of Information and Regulatory Affairs (OIRA).[37] Rules identified as **Other Significant** do not meet the $100 million threshold but are considered Significant by OIRA and also can be subject to these heightened reviews.

- A **Regulatory Flexibility Analysis (RFA)** requires agencies to conduct an intensive analysis of the potential effects of rules that pose a "significant economic impact on a substantial number of small entities." For a rule that is found to pose a significant economic impact, the agency must quantify the number of small businesses that might be affected, the costs to comply with rule, outline possible alternatives to the rule, and fulfill numerous other requirements.[38]

- Some agencies are required to include an additional phase at the beginning of the rulemaking process called the "advance notice" phase. This includes issuance of an **Advance Notice of Proposed Rulemaking (ANPRM)**.

Addition of Procedural Requirements Lengthens Rulemakings

We found that rules deemed to be of the highest importance (based on the priority assigned and number of requirements attached) take the longest to complete – sometimes longer than one presidential term.

Rules deemed Economically Significant have taken 2.4 years, 41 percent longer than the overall average (1.7 years).

Rules deemed Economically Significant for which a Regulatory Flexibility Analysis was required took 2.5 years.

Inclusion of an Advance Notice of Proposed Rulemaking step in a rulemaking increases the time to finish an Economically Significant rule to 4.4 years – 100 percent longer than rules of the same priority without one.

Economically Significant rulemakings that included both an Advance Notice of Proposed Rulemaking and a Regulatory Flexibility Analysis took almost five years to complete on average.

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[37] Executive Order 12866 (Sept. 30, 1993), http://1.usa.gov/22wdW3D. *See also*, NEGAH MOUZOON, PUBLIC CITIZEN, PUBLIC SAFEGUARDS PAST DUE: MISSED DEADLINES LEAVE PUBLIC UNPROTECTED, at 6 (June 2012), http://bit.ly/22xTf7H.

[38] Public Law 96-354 (1980), http://1.usa.gov/1TVdM2t.

Rulemakings Are at Record Lengths

Until recently, the time it took to complete a rule was similar regardless of presidential administration. But over the past few years, rulemaking lengths have become longer, with completed rules in President Obama's second term experiencing unprecedented rulemaking lengths.

Beginning in the sixth year of the Obama administration, completed Economically Significant rulemakings that began during his presidency took substantially longer than they did the sixth year in the Bush administration. And since then, the difference in the average rulemaking lengths between administrations has increased, with Obama's most recent rulemakings showing the greatest discrepancy.

Economically Significant rules completed in 2015 took an average of 3.4 years, 42 percent longer than average.

Economically significant rules completed in the first half of 2016 have taken the longest on record: an average of 3.8 years, 58 percent longer than average. This means that the time to complete an Economically Significant rule is now taking close to an entire presidential administration.

Rulemaking Lengths Vary Greatly by Agency

Department of Labor (DOL) completed Economically Significant rulemakings have taken 5.4 years – 125 percent longer than the overall average.

The DOL's completed Economically Significant rules involving a Regulatory Flexibility Analysis took 9.1 years – 117 percent longer than DOL rules with no requirement.

The Occupational Safety and Health Administration (OSHA), a sub agency of the DOL that is charged with protecting the nation's 130 million workers, has begun and completed only five Economically Significant rules since 1996.

OSHA's completed Economically Significant rulemakings begun since 1996 have taken an average of 12.5 years – 421 percent longer than the average length of all completed Economically Significant rulemakings. The three Economically Significant rules it has completed in this time period that involved a Regulatory Flexibility Analysis took an average of 15 years.

An OSHA rule to protect workers from excess exposure to silica dust was recently completed after at least 19 years of work. OSHA estimated that the rule will annually prevent at least 579 fatalities and 1,585 cases of moderate-to-severe silicosis.

Completed Economically Significant rules of the Environmental Protection Agency (EPA) had an average rulemaking length of 3.8 years – 58 percent longer than average.

Many Rulemakings Are Long Overdue

Based on our finding that Economically Significant rules take an average of 2.4 years to complete, we have categorized ongoing rulemakings that have taken longer than 2.5 years as Overdue. Overdue rulemakings account for 46 percent of all incomplete rulemakings listed on the spring 2016 Unified Agenda and have an average current rulemaking length of 6.3 years.

Twenty-four percent of overdue rulemakings first appeared on the Unified Agenda prior to President Obama taking office.

Many Overdue rulemakings are being worked on by agencies focused on public health and safety. For example, the Food and Drug Administration has 33 Overdue rules; the National Highway Traffic Safety Administration has 23; the Consumer Product Safety Commission has 20; Air and Radiation, within the EPA, has 20; and OSHA has 17.

Methodology

This study is primarily based on data published in the federal government's Unified Agenda of rulemakings, which has been published twice annually in every year but one since 1996.

Each rule in the Unified Agenda is assigned a Regulatory Identification Number (RIN), which is usually unique to that rulemaking. Some rulemakings are associated with more than one RIN because they are duplicates or were previously reported with another RIN. Duplicate and previously reported rules are not included in this analysis.

This study uses data within the Rule Stage and Action fields in the Unified Agenda to determine the length of a rulemaking.[39]

> **Rule Stage** includes Completed Actions, Final Rule, Prerule, Proposed and Long-Term Actions.
>
> **Actions** are more granular than rule stages. Categories include, but are not limited to, Advance Notice of Proposed Rulemaking (ANPRM), Notice of Proposed Rulemaking (NPRM), Final Action, Final Rule, Interim Final Rule, and Withdrawn. Rules listed as Withdrawn are not included in this study.

Determination of the completion of a rulemaking: A rulemaking is treated as completed when it appears in the Unified Agenda and two conditions are met: 1) The Rule Stage is reported as Completed Actions; and 2) the Action field incorporates the word "Final." The majority of completed rules are described as a Final Action, Final Rule, or Interim Final Rule, but there are a small number of rules that are described slightly differently but still incorporate the word "Final."

Determination of the length of a rulemaking for completed rules: A completed rulemaking is treated as commencing three months prior to when it first appears in the Unified Agenda. For our research, spring Unified Agendas were dated April 1 and fall Unified Agendas were dated October 1. Work on rulemakings appearing on the Unified Agenda for the first time must have commenced sometime in the six months prior to that Unified Agenda's publication if they were reported correctly. Because there is no reported start date for the beginning of a rulemaking, we chose the midpoint of the possible range.

We believe estimating the beginning of a rulemaking to be three months prior to its first publication on the Unified Agenda is a conservative estimate because many rulemakings likely started much earlier. This is supported by a 2009 Government Accountability Office (GAO) report, which found that "agency staff sometimes worked on certain issues related to the rulemaking years before

[39] The Unified Agenda is available at http://www.reginfo.gov/public/.

commencement of the actual rulemaking, either as part of earlier, related rulemakings or policy development for the rule."[40]

A small percentage of completed rules, 6 percent, end up with a negative or zero rulemaking length based on our methodology. Their rulemaking lengths are not included in this analysis. More than 90 percent of the rulemakings with zero or negative rulemaking lengths in this analysis are rulemakings that are not Significant.

We deemed a rulemaking's end date to be the latest date associated with it in the Unified Agenda's Action Date field.

Determination of the length of a rulemaking for uncompleted rules: For uncompleted rules, this study attributes one-half year to each instance in which a rule is listed in the Unified Agenda.

Limitations of dataset on lengths of rules: When analyzing the volume of completed rules (Section II), this report counts all completed rules appearing on the Unified Agenda from spring 1996 through spring 2016, regardless of whether the rules began before 1996.

When analyzing the length of rulemakings, this report only analyzes rulemakings that first appeared on the Unified Agenda in spring 1996 or later to ensure the full extent of the rulemaking process can be measured.

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[40] GOVERNMENT ACCOUNTABILITY OFFICE (GAO), FEDERAL RULEMAKING: IMPROVEMENTS NEEDED TO MONITORING AND EVALUATION OF RULES DEVELOPMENT AS WELL AS TO THE TRANSPARENCY OF OMB REGULATORY REVIEWS, (April, 2009), http://1.usa.gov/28NMaPa.

I. Effects of Priority and Statutory Requirements on Rulemaking Length

A. Length of Rulemaking Overview

The average length of rulemakings that have appeared for the first time on the Unified Agendas between spring 1996 and spring 2016 was 2.1 years. Completed rules, which began and finished between 1996 and 2016, had an average rulemaking length of 1.7 years. Uncompleted rules, which include rules that dropped off of the Unified Agenda prior to 2016 without being completed and rules that appeared on the spring 2016 agenda but not as completed rules, had an average rulemaking length of 3.2 years. [Table 1]

Table 1: Number of Rulemakings and Average Length - All Rulemakings Begun and Finished 1996 - 2016

		Number of Rules	Average Rulemaking Length
All Rulemakings		24,311	2.1
	Uncompleted	6,165	3.2
	Completed	18,146	1.7

As of spring 2016, 75 percent of rules that appeared on the Unified Agenda between spring 1996 and spring 2016 have been completed. As mentioned in the methodology section, these rules meet two conditions: 1) The Rule Stage is reported as Completed Actions and 2) The listing in the Action field incorporates the word Final.

While the average length of all completed rules is 1.7 years, other variables greatly affect the length of rulemakings.

B. Effects of Significant Versus Nonsignificant Priority on Rulemaking Length

Executive Order 12866, signed by President Bill Clinton in 1993, requires non-independent agencies[41] to determine costs and benefits of rules that are expected to impose annual, aggregate costs of $100 million or more. The executive order also stipulates that significant rules must be reviewed by the Office of Information and Regulatory Affairs (OIRA) within the White House's Office of Management and Budget (OMB). Although the Executive Order calls on OIRA to complete its reviews in 90 days – with permission to extend to 120 days in unusual circumstances – OIRA reviews often take far longer in practice.[42]

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[41] Non-independent agencies refer those that are headed by a cabinet secretary and other agencies in the executive branch that are directly accountable to the president. Independent agencies, in contrast, are those that are not headed by a cabinet secretary and over which the president's authority to appoint and dismiss agency leaders is limited. Examples are the Securities and Exchange Commission, Federal Communications Commission and Commodity Futures Trading Commission.

[42] Executive Order 12866 (Sept. 30, 1993), http://1.usa.gov/22wdW3D. *See also*, NEGAH MOUZOON, PUBLIC CITIZEN, PUBLIC SAFEGUARDS PAST DUE: MISSED DEADLINES LEAVE PUBLIC UNPROTECTED, at 6 (June 2012), http://bit.ly/22xTf7H.

The Unified Agenda indicates whether each rule is Significant or not in its Priority field. In order of stringency of associated requirements, options in this field are: Economically Significant, Other Significant, Substantive Nonsignificant, Info/Admin/Other, and Routine and Frequent. Rules deemed Other Significant do not meet the threshold for Economically Significant but are considered Significant by the agency under other criteria, such as if they meet requirements for OIRA review under Executive Order 12866 aside from the $100 million threshold.[43]

Rules categorized as Economically Significant and Other Significant took 41 and 35 percent longer, respectively, to complete than average. [Table 2] Economically Significant and Other Significant rules account for 4 percent and 21 percent, respectively, of completed rules in our dataset.

The Priority categorization of many rules changes in the course of rulemakings. This analysis identifies a rule's Priority as the one that was assigned at completion.

Table 2: Number and Average Rulemaking Length of Completed Rules by Final Priority

Completed Rule Priority	Number of Rules	Average Rulemaking Length	+/- From Average	+/- From Average by %
Economically Significant	736	2.4	+0.7	+41%
Other Significant	3,899	2.3	+0.6	+35%
Substantive, Nonsignificant	11,968	1.5	-0.2	-12%
Routine and Frequent	401	1.3	-0.4	-24%
Info./Admin./Other	1,142	0.9	-0.8	-47%
Total	18,146	1.7	--	--

The majority of completed rules (66 percent) were categorized as Substantive, Nonsignificant. They took an average of 1.5 years to complete. These rulemakings tend to be less controversial, and are less likely to involve extra procedural requirements, such as a need for cost-benefit analysis or OIRA review. However, independent agencies – to which Executive Order 12866 does not apply – appear to categorize rules in the Substantive, Nonsignificant category that would otherwise meet the criteria to be deemed Economically Significant.

C. Case Study on OIRA Delay — A Law to Prevent Backover Deaths by Vehicles

[43] *See, e.g.*, HOWARD SHELANSKI, OFFICE OF INFORMATION AND REGULATORY AFFAIRS, MEMORANDUM FOR REGULATORY POLICY OFFICERS AT EXECUTIVE DEPARTMENTS AND AGENCIES AND MANAGING AND EXECUTIVE DIRECTORS OF CERTAIN AGENCIES AND COMMISSIONS (Feb. 19, 2016), http://1.usa.gov/1TIs3xi and Executive Order 12866 (Sept. 30, 1993), http://1.usa.gov/22wdW3D. (Examples of criteria outlined in Executive Order 12866 for a rule to be deemed significant if it does not meet the threshold of Economically Significant are if it would "[c]reate a serious inconsistency or otherwise interfere with an action taken or planned by another agency; [m]aterially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or "[r]aise novel legal or policy issues arising out of legal mandates.")

One night in 2002, Dr. Greg Gulbransen was backing up his SUV when his two-year-old son, Cameron, darted out into the driveway behind the vehicle. Too small to be seen by his father using any of the vehicle's rearview or sideview mirrors, Cameron was struck by the moving car and killed.[44] This tragedy is not an isolated case; each week, 50 children are injured, two fatally, in "backover" crashes[45] in which a vehicle moving backwards strikes a person behind the vehicle. Each year, backovers kill an average of 210 people and injure 15,000 more. Most victims are children under the age of five, senior citizens over the age of 75, or persons with disabilities, according to the Department of Transportation (DOT).[46] Backovers generally occur when the victim is too small to be seen in the rearview mirror of the vehicle or not mobile enough to move out of the way of the vehicle, even if it is moving slowly.

To prevent the injuries and deaths caused by backovers, in 2008 Congress passed the Cameron Gulbransen Kids Transportation Safety Act.[47] The Gulbransen Act, which was signed into law by President George W. Bush, directed the DOT to revise an existing federal motor vehicle safety standard to expand the area that drivers must be able to see behind their vehicles.[48] (The law stipulated that this could be done through the use of rear-view cameras or other technologies.) The Gulbransen Act mandated that the DOT issue the final rule within three years of the February 2008 enactment of the law.[49] The act also allowed the DOT to establish a new deadline for the rulemaking, but only if the otherwise-applicable deadline "cannot be met."[50]

The DOT issued a proposed rule in 2010 calling for the inclusion of rearview cameras in new cars to ensure that drivers could see a certain area behind their car while in reverse gear. The DOT estimated that the proposal would annually prevent between 95 and 112 deaths and between 7,072 and 8,374 injuries.[51]

Despite this, the DOT failed to meet the February 2011 deadline.[52] Instead, DOT repeatedly set new deadlines, which it failed to meet.

In September 2013, Public Citizen filed a petition with the United States Court of Appeals for the Second Circuit on behalf of Dr. Gulbransen and other stakeholders and nonprofits seeking a writ of

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[44] A full account of this history is available from *In Re* Dr. Greg Gulbransen: Petition for a Writ of Mandamus, September 25, 2013, http://bit.ly/1US1TrE.
[45] *Backover Fact Sheet*, KIDS AND CARS, http://bit.ly/28ZmR8](viewed on June 13, 2016).
[46] *NHTSA Announces Final Rule Requiring Rear Visibility Technology*, NATIONAL HIGHWAY TRANSPORTATION SAFETY ADMINISTRATION, http://1.usa.gov/1fKTYZA, (viewed on June 13, 2016).
[47] Cameron Gulbransen Kids Transportation Safety Act of 2007, (Public Law 110–189, 122 Stat. 639–642), § 4 (February 28, 2008).
[48] *Id.*
[49] *Federal Motor Vehicle Safety Standards; Rear Visibility*, 79 FEDERAL REGISTER 19178, 84 (April 7, 2014)(codified at 49 C.F.R. pt. 571).
[50] *Id.*
[51] *Federal Motor Vehicle Safety Standard, Rearview Mirrors; Federal Motor Vehicle Safety Standard, Low-Speed Vehicles Phase-In Reporting Requirements, National Highway Traffic Safety Administration*, 75 FEDERAL REGISTER 76185 (Dec. 7, 2010), http://1.usa.gov/1totFWn.
[52] *Id.*

mandamus compelling DOT to issue the rule within 90 days.[53] On March 31, 2014, one day before the Second Circuit was scheduled to hear arguments in the case, the DOT issued the rear visibility safety standard that the petitioners sought.[54]

In this case, much remains unknown about the cause of the protracted delay. *Reuters* reported that issuance of the rule was delayed by repeated demands from OIRA officials, who even questioned the need for the law. OIRA was "just having us go back and do things over again," Jim Simons, director of NHTSA's office of regulatory analysis and evaluation, told *Reuters*. "They were coming up with stuff to make us delay the rule."[55]

Whatever the cause, that delay likely led to hundreds of avoidable deaths and tens of thousands of injuries.

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[53] In Re Dr. Greg Gulbransen: Petition for a Writ of Mandamus, (September 25, 2013), http://bit.ly/1US1TrE.
[54] *NHTSA Announces Final Rule Requiring Rear Visibility Technology*, NATIONAL HIGHWAY TRANSPORTATION SAFETY ADMINISTRATION, http://1.usa.gov/1WMVX9D (March 21, 2014).
[55] Scot J. Paltrow, *How a Small White House Agency Stalls Life-Saving Regulations*, REUTERS (Oct. 29, 2015), http://reut.rs/1VVvHZy.

D. Effects of a Regulatory Flexibility Analysis on Rulemaking Length

The Regulatory Flexibility Act (RFA) was adopted in 1980 and was substantially amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) in 1996. It requires federal agencies to first ascertain whether its rules will substantially affect small businesses and, if so, conduct a full analysis of how the rule will affect them and consider any alternatives to the rule that would minimize those impacts. While actual effects could be beneficial or detrimental, the legislation's implementation and interpretation has focused only on detrimental impacts.

A RFA requirement existed in 35 percent of completed rules categorized as Economically Significant, 11 percent of those categorized as Other Significant and 10 percent of those categorized as Substantive, Nonsignificant. Completed Economically Significant and Other Significant rules in which a Regulatory Flexibility Act analysis was required took 9 percent longer than like rulemakings in which a RFA was not required. Substantive, Nonsignificant rulemakings took 7 percent longer when a RFA was required. [Table 3]

Table 3: Length of Completed Rulemakings (RM) With RFA Required

Priority	RFA Required			RFA Not Required	
	#	Average RM Length	% Diff in RM Length RFA Required v. Not Required	#	Average RM Length
Economically Significant	259	2.5	+9%	477	2.3
Other Significant	418	2.5	+9%	3,481	2.3
Substantive, Nonsignificant	1,152	1.6	+7%	10, 816	1.5

E. Effects of Inclusion of Advance Notice of Proposed Rulemaking (ANPRM) on Rulemaking Length

At a general level, the rulemaking process typically consists of two phases: the Proposed Rule and Final Rule phases. The exception to this is when agencies include a third phase at the beginning of the rulemaking process called the "advance notice" phase. This includes issuance of an Advance Notice of Proposed Rulemaking (ANPRM), along with a public comment period.

While some agencies, like the Federal Trade Commission (FTC),[56] are required by statute to issue ANPRMs for many of their rules, most agencies are not obligated to begin their rulemakings with an ANPRM. Nevertheless, agencies may use their discretion to opt for ANPRMs when they believe that it would benefit the rulemaking. For example, if an agency is regulating in a new area or has relatively less expertise, the agency may opt to issue an ANPRM to solicit information from the public and stakeholders. Yet, issuing an ANPRM also results in a tradeoff because including this phase lengthens the rulemaking process significantly and provides more opportunities for opponents of the proposed public protection to object.

[56] Federal Trade Commission Improvements Act of 1980, 15 U.S.C. 57a(B)(2)(A) (1980). The Consumer Product Safety Commission was required to issue ANPRMs for major rules until 2008. *See Rulemaking*, CONSUMER PRODUCT SAFETY COMMISSION (undated; viewed on June 27, 2016), http://1.usa.gov/292QYvm.

Multiple pieces of legislation have been introduced in the 114th Congress that attempt to impose a blanket requirement for agencies to issue ANPRMs for all Economically Significant or major rules regardless of statutory deadlines.[57] If enacted, such bills would guarantee a longer rulemaking process across the federal government.

This study finds that Significant rules for which an ANPRM was conducted have taken 59 to 100 percent longer to complete than rules of the same Priority for which an ANPRM was not conducted. If all agencies were required to issue an ANPRM, the data indicate that Economically Significant completed rulemakings would take 4.4 years on average – 100 percent longer to complete than rules of the same priority without an ANPRM. [Table 4]

Table 4: Length of Completed Rulemakings (RM) With and Without Inclusion of ANPRM

Priority	ANPRM				Non ANPRM			Total	
	#	% of Rules	Average RM Length	% Longer than non-ANPRM	#	% of Rules	Average RM Length	#	Average RM Length
Economically Significant	51	7%	4.4	100%	685	93%	2.2	736	2.4
Other Significant	192	5%	3.5	59%	3,707	95%	2.2	3,899	2.3
Substantive, Nonsignificant	276	2%	3.1	107%	11,692	98%	1.5	11,968	1.5

Significant rules for which *both* an ANPRM and a RFA was conducted have taken more than 100 percent longer than Significant rules with neither requirement. Even the typically uncontroversial Substantive, Nonsignificant rulemakings have taken more than three years to complete when both an ANPRM and RFA analyses are included. [Table 5]

Table 5: Length of Completed Rulemakings (RM) With and Without Inclusion of ANPRM *and* RFA

Priority	ANPRM					Non ANPRM			
	RFA Required			No RFA Required		RFA Required		No RFA Required	
	#	Average RM Length	% Longer than non-ANPRM non-RFA	#	Average RM Length	#	Average RM Length	#	Average RM Length
Economically Significant	24	4.7	114%	27	4.1	235	2.3	450	2.2
Other Significant	30	4.5	105%	162	3.3	388	2.4	3,319	2.2
Substantive, Nonsignificant	37	3.3	120%	239	3.1	1,115	1.5	10,577	1.5

F. Associations Between Legal Deadlines and Rulemaking Length

[57] *See e.g.* The Early Participation In Regulations Act of 2015, S. 1820, 114th Cong. (2015) and The Regulatory Accountability Act of 2015, Section 3(c), H.R. 185 (2015).

Statutory deadlines allow Congress to direct agencies to issue regulations by a certain date. Such deadlines can pertain to the time by which a rule should be finalized, when the Notice of Proposed Rulemaking should be issued, or other actions should take place. Statutory deadlines indicate that Congress wants agencies to prioritize a particular regulatory action, and that it believes that the regulatory action is necessary within an expedited timeframe. Some statutes, such as the Clean Air Act, expressly authorize citizen lawsuits to be brought against the government when rulemaking deadlines are missed. Most statutes, however, do not contain such citizen enforcement mechanisms, and Congress itself does not have legal standing to enforce a missed statutory deadline against an agency.

If a court finds that an agency broke the law by missing a statutory deadline or otherwise unreasonably delaying a regulatory action, it can impose a judicial deadline for completion of a regulatory action. Therefore, statutory deadlines are often converted into judicial deadlines with courts serving as the eventual venue for enforcement of missed statutory deadlines.

In theory, statutory deadlines carry the force of law and should compel agency compliance with deadlines. In practice, agencies often miss these deadlines. A 2015 report by the R Street Institute found that agencies meet statutory deadlines only about half of the time.[58]

We compared the length of rulemakings according to whether they involved a statutory or judicial deadline, or both. Economically Significant rules with statutory deadlines were completed 17 percent faster than those with no deadline. Economically Significant rules with judicial deadlines took 57 percent longer to complete than rules with no legal deadlines. Economically Significant rules with both statutory and judicial deadlines took 178 percent longer than those that lacked either. [Table 6]

Table 6: Length of Rulemakings (RM) With Legal Deadlines

Priority	No Legal Deadline		Statutory Deadline Only			Judicial Deadline Only			Statutory & Judicial		
	#	Average RM Length	#	Average RM Length	% Dif. From No Deadline	#	Average RM Length	% Dif. From No Deadline	#	Average RM Length	% Dif. From No Deadline
Economically Significant	359	2.3	316	1.9	-17%	32	3.6	+57%	29	6.4	+178%
Other Significant	3,080	2.3	616	2.3	0%	164	2.2	-4%	39	3.5	+52%
Substantive, Nonsignificant	10,595	1.5	1,024	1.7	+13%	283	1.9	+27%	66	3.8	+153%

[58] SCOTT ATHERLEY, R STREET, FEDERAL AGENCY COMPLIANCE WITH CONGRESSIONAL REGULATORY DEADLINES, at 1 (August 2015), http://bit.ly/1Q10TWf.

G. Case Study on Missed Legal Deadlines — The Protracted Creation of a Legally Required Standard on Ozone

The greater time to complete rules with judicial deadlines is not likely because of the existence of a judicial deadline. Instead, a judicial deadline is typically imposed in the course of a rulemaking because it is taking so long. This most often occurs with respect to laws that include statutory requirements for standards to be updated.

The Clean Air Act authorizes the public to sue the agency to enforce a missed statutory rulemaking deadline. Legislation currently pending in Congress would restrict the ability of citizens to bring suit against the Environmental Protection Agency (EPA) and other agencies for missing statutory rulemaking deadlines.[59] A 2014 Government Accountability Office report that examined EPA deadline lawsuits paints a sobering picture of delays and reinforces the need for citizen lawsuits to hold EPA accountable for such delays.[60]

The GAO report focused on one particular office within EPA, the Office of Air and Radiation (OAR). Some of the delays detailed in the report are eye-popping: a rule regulating petroleum refineries was not implemented until 26 years after the congressional deadline;[61] a rule regulating emissions from natural gas processing plants missed its deadline by 19 years.[62]

The Clean Air Act requires the EPA to assess the effectiveness of National Ambient Air Quality Standards (NAAQS) every five years and to strengthen those standards if EPA scientists determine they are too weak to adequately protect the public.[63] The protracted update to the standard for ozone (one of the six pollutants that EPA restricts under the NAAQS) is a telling example of the EPA's struggles in fulfilling this obligation. Ozone is one of the primary components of smog, which is harmful to respiratory and cardiovascular health.

This story begins in 2003, when environmental groups and public health groups sued the EPA for failing to issue an updated ozone standard as required by the Clean Air Act.[64] Under a settlement to the lawsuit, the EPA committed to a deadline of December 2006 to finalize a new standard.[65] That deadline was subsequently pushed back to 2008, when the EPA issued a new rule calling for reducing permissible levels from 84 to 75 parts per billion (ppb).[66]

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[59] The Sunshine for Regulatory Decrees and Settlements Act of 2015, H.R. 712, 114th Cong. (2015).
[60] U.S. GOVERNMENT ACCOUNTABILITY OFFICE, GAO-15-34, ENVIRONMENTAL LITIGATION: IMPACT OF DEADLINE SUITS ON EPA'S RULEMAKING IS LIMITED (December 2014), http://1.usa.gov/1V2gh0n.
[61] *Id.*, at 11.
[62] *Id.*
[63] GOVERNMENT ACCOUNTABILITY OFFICE, GAO-15-34, ENVIRONMENTAL LITIGATION: IMPACT OF DEADLINE SUITS ON EPA'S RULEMAKING IS LIMITED, at 14 (December 2014), http://1.usa.gov/1V2gh0n.
[64] *American Lung Association. v. Horinko*, No. 03-778 (D.C. District. Court) (March 31, 2003).
[65] Consent Decree re: *American Lung Assoc. v. Horinko*, D.C. District Court No. 03-778 (D.C. District Court) (July 31, 2003).
[66] National Ambient Air Quality Standards for Ozone, 73 FEDERAL REGISTER 16436 (March 27, 2008).

Public health groups immediately challenged that standard in court as too lenient and industry groups challenged it as too stringent.[67] Those claiming the standard was too lenient pointed to an EPA advisory committee's recommendation to set permissible limits at 60 to 70 ppb. Those arguing that the standard was too stringent claimed the costs of meeting the standard outweighed the benefits. Ultimately, the court deferred resolving the matter because the newly elected Obama administration committed to re-evaluating the 75 ppb that was issued 2008.[68]

The Obama Administration's EPA informed the court in September 2009 that it expected to issue a new proposed standard in December 2009, with the intent of finalizing it by August 2010. The EPA came close to meeting the first part of this goal when it issued a proposed standard in January 2010. The proposed standard recommended lowering exposures to between 60 and 70 ppb.[69] Public health and environmental groups encouraged the EPA to adopt 60 ppb.[70] Industry groups argued that the standard should be left at 75 ppb.[71]

The EPA announced in August 2010 that it would not meet the deadline to issue a final standard that it had set for that month, and that it would need another two months to finalize it. But by December 2010, the EPA still had not finalized the standard. It then announced that it needed until at least July 2011 to create the finalized standard in order to give its scientists additional time to study the basis for its recommendation of 60 to 70 ppb.[72]

On July 26, 2011, the EPA once again announced that it would miss its deadline – this time because the rule was undergoing review at OIRA. Public health groups sued to order the EPA to finalize the ozone standard immediately.[73] Industry groups responded by asking the court to refrain from doing so.[74]

A major development came on September 2, 2011, when the Obama administration ordered the EPA to withdraw the proposed ozone standard.[75] The administration claimed that it would prefer to wait until the next five-year reconsideration of the standard, which was scheduled for 2013.[76]

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[67] The challenges to the standard were consolidated in the D.C. Circuit Court of Appeals as *State of Mississippi v. EPA*, Case No. 08-1200 (D.C. Circuit Dec. 11, 2013).
[68] *Id.* at 9.
[69] National Ambient Air Quality Standards for Ozone, 75 FEDERAL REGISTER 2938 (Jan. 19, 2010).
[70] *See e.g.*, Comments on the U.S. Environmental Protection Agency's Proposed Reconsideration of the National Ambient Air Quality Standards for Ozone, American Lung Association et al, (March 22, 2010), http://bit.ly/1XucVJT.
[71] Economic Implications of EPA's Proposed Ozone Standard, MAPI Manufacturer's Alliance (September 2010), http://bit.ly/1UdZhVq.
[72] Declaration of Regina McCarthy, Assistant Administrator for Air and Radiation, *State of Mississippi v. EPA*, No. 08-1200 (D.C. Circ. Dec. 8, 2010)
[73] *State of Mississippi v. E.P.A.*, Doc. No. 1322086 (D.C. Cir. Aug. 8, 2011).
[74] *State of Mississippi v. E.P.A.*, Doc. No. 1323634 (D.C. Cir. Aug. 10, 2011).
[75] President Barack Obama, *Statement by the President on the National Ambient Air Quality Standards*, THE WHITE HOUSE, (September 2, 2011), http://1.usa.gov/1PyFApf.
[76] *Id.*

The move was widely seen as succumbing to the intense political pressure in opposition to the rule by industry groups and Republicans in Congress.[77]

The EPA's scientific advisory committee completed its review in 2014 and made virtually the same recommendations as it had in 2008, namely that the standard should be set at between 60 and 70 ppb.[78] The EPA moved to finalize the standard at 70 ppb in fall of 2015.[79] Not surprisingly, industry groups have challenged the rule in court in order to block it.[80]

Every year of delay in issuing new NAAQS standards has real consequences for the health of our citizens. The EPA estimated that the new standards, over 10 years, will yield economic benefits of $2.9 billion to $5.9 billion, prevent 320 to 660 premature deaths, and prevent 230,000 asthma attacks in children.[81]

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[77] John M. Broder, *Re-election Strategy Is Tied to a Shift in Smog*, NEW YORK TIMES (Nov. 16, 2011), http://nyti.ms/1rtDL6W.
[78] CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE (CASAC), CASAC REVIEW OF THE EPA'S SECOND DRAFT POLICY ASSESSMENT FOR THE REVIEW OF THE OZONE NATIONAL AMBIENT AIR QUALITY STANDARDS (2014), http://1.usa.gov/1UgtYyN.
[79] *National Ambient Air Quality Standards for Ozone*, 80 FEDERAL REGISTER 65291 (Oct. 26, 2015)
[80] Devin Henry, *Coal Company Sues Over 'Destructive' EPA Ozone Standards*, THE HILL (Oct. 26, 2015), http://bit.ly/1UTdtp1.
[81] *EPA's Final Air Quality Standards for Ground-Level Ozone By The Numbers*, ENVIRONMENTAL PROTECTION AGENCY http://1.usa.gov/1XZKft5, (undated; references final action of Oct. 1, 2015).

H. Effects of Changing Priority on Rulemaking Length

Rulemakings that are categorized under multiple Priorities have taken considerably longer to complete, on average, than those that maintain the same priority.

For example, 61 percent of completed Economically Significant rules were assigned that priority from start to finish. They took an average of 1.7 years to complete. But 33 percent of rules categorized as Economically Significant at completion were previously deemed Other Significant. They took an average of 3.6 years to complete. About 10 percent of rules categorized as Economically Significant at completion were categorized as Substantive, Nonsignificant at some point. Those rulemakings also took an average of 3.6 years to complete.

Thus, rules concluding with an Economically Significant priority that previously were assigned other priorities took 112 percent longer to complete than those that were categorized as Economically Significant from start to finish. [Table 7]

Table 7: Length of Completed Rulemakings (RM) With No Changed Priority versus Changed Priority

Priority at Rule's Completion	# of RM That Only Involved This Priority	% of All RM Ending With This Priority	Avg RM Length	Previous Priority Assigned to Rule*								
				Economically Significant			Other Significant			Substantive, Nonsignificant		
				#	Avg RM Length	% Dif	#	Avg RM Length	% Dif	#	Avg RM Length	% Dif
Economically Significant	446	61%	1.7				245	3.6	+112	72	3.6	+112
Other Significant	2,859	73%	1.9	124	3.1	+63				889	3.4	+79
Substantive, Nonsignificant	11,258	94%	1.4	31	3.1	+121	519	3.2	+129			

* A small number of rules were assigned more than one previous priority in the course of rulemaking and are counted more than once under Previous Priorities, above. For instance, a rule categorized as Economically Significant when finalized might previously have been categorized as Other Significant and Substantive Nonsignificant (or under less substantive categories not shown here).

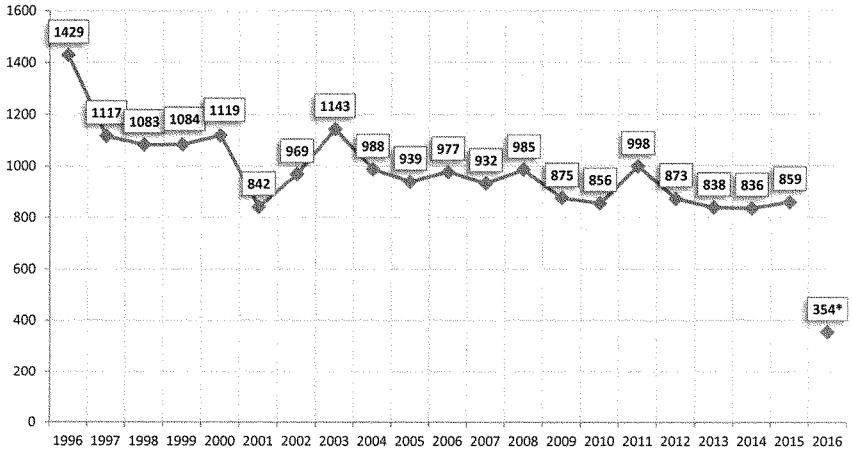
II. Volume of Completed Rules

The number of completed rules has been relatively constant over the time period for which downloadable Unified Agendas are available. However, the number of completed rules categorized as Economically Significant and Other Significant has vacillated significantly year by year. Compared to his predecessor, the total number of completed rules has fallen under President Obama, the number of Economically Significant rules has risen, and the number of Other Significant rules has been about the same.

A. Comparing of the Number of Completed Rules Over the Years

The rate of rulemaking in the federal government has been fairly steady over the past 20 years. The yearly average of completed rules between 1996 and 2015 was 987. The peak year was in 1996, with 1,429 completed rules while the lowest number of completed rules occurred in 2014, with 836. [Figure 1]

Figure 1: Number of Completed Rules Listed in Unified Agenda[82]



* Includes data in spring Unified Agenda only.

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[82]Note that these figures are limited to completed rulemakings that are listed in the Unified Agenda. The majority of rulemakings categorized as "routine/frequent" or "informational/administrative" (which may make up as many as 70 percent of all rulemakings) are not included in the Unified Agenda. Examples of those not submitted to the Unified Agenda include the U.S. Coast Guard establishing timetables for operation of drawbridges. *See*, CURTIS COPELAND, ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, CONGRESSIONAL REVIEW ACT: MANY RECENT FINAL RULES WERE NOT SUBMITTED TO GAO AND CONGRESS, at 53 (July 15, 2014), http://1.usa.gov/28N7bo8.

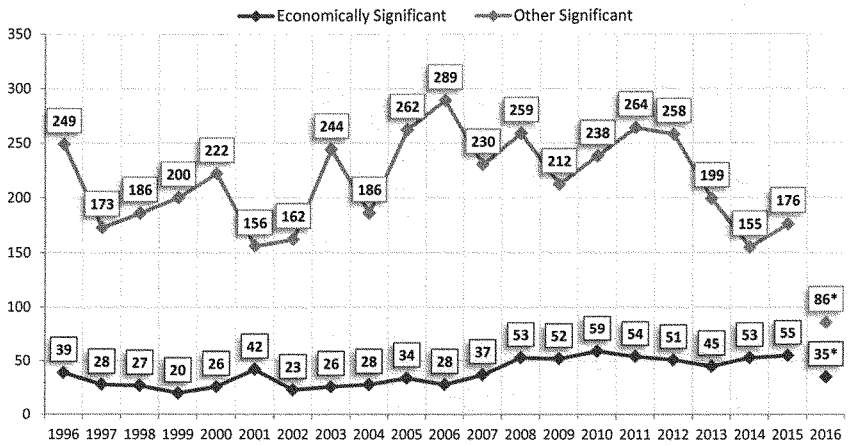
If we restrict our analysis to just the last two administrations, Barack Obama's administration has completed an average of 10 percent less per year, 876 rules, than the administration of George W. Bush, who completed 970 on average per year. [Table 8]

Table 8: Average and Number of Rules Completed Under Presidents George W. Bush and Barack Obama (through first seven years)

Administration	Yearly Average	Total
Bush 2001-2007	970	6,790
Obama 2009-2015	876	6,135

There is more variation within rules categorized as Economically Significant and Other Significant each year. The number of completed Economically Significant rules has ranged from 20 to 59 annually. The number of completed Other Significant rules has ranged from 155 to 289. The $100 million threshold for the categorization of Economically Significant is not adjusted for inflation, making it easier to reach with the passage of time. [Figure 2]

Figure 2: Number of Completed Economically Significant and Other Significant Rules by Year



* Includes data in spring Unified Agenda only.

Looking at the first seven years of their presidencies, President Bush's administration completed an average of 31 Economically Significant and 218 Other Significant rules each year. Under Obama, an average of 53 Economically Significant and 215 Other Significant rules have been completed annually. [Table 9]

Table 9: Yearly Average of Completed Rules

	Economically Significant		Other Significant	
President	Yearly Average	Total	Yearly Average	Total
Bush 2001-2007	31	218	218	1,529
Obama 2009-2015	53	369	215	1,502

B. Presidents Begin to Enact Most of Their Own Agenda in Their Third Year

Most of the completed rules during the first year of a presidency – and especially those reported as completed in the first spring Unified Agenda after a new president is inaugurated – are unlikely to reflect the agenda of the new president.

In order to figure out just how many completed rules begin and finish with a president, we analyzed two separate datasets. The first was data from spring 2001 through fall 2007 (President Bush), the second was data from spring 2009 through fall 2015 (President Obama). A minority of completed rules in the first year of their presidencies had begun under their administrations. Even in the second year of their presidencies, close to 40 percent of all completed rulemakings began before they took office. By year three, both Presidents Bush and Obama were responsible for the vast majority of completed rules. [Figure 3]

Figure 3: Number and Percentage of Completed Rules by Year That Began Under the Same President

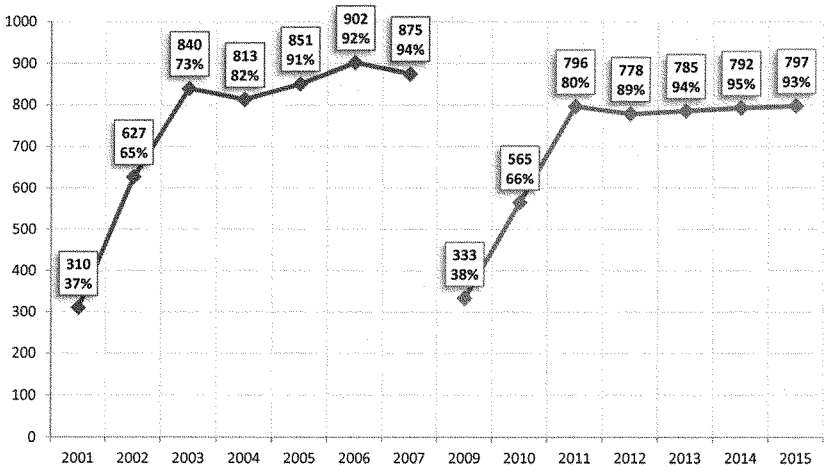
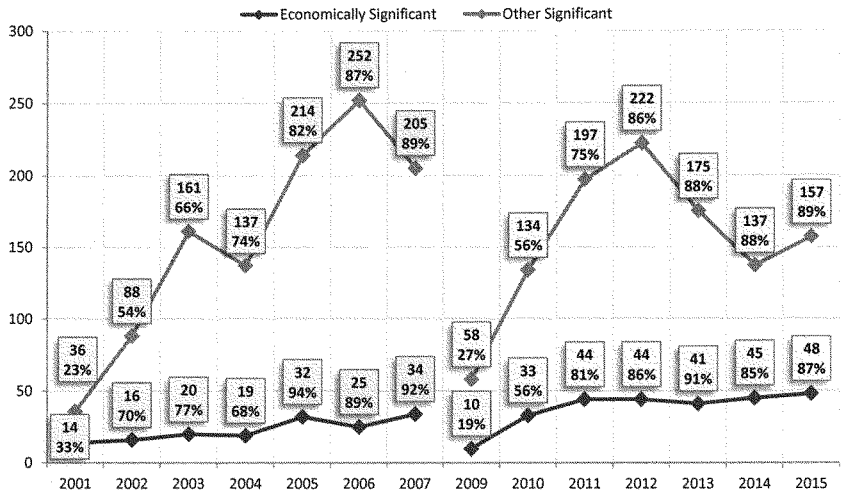


Figure 4, below, uses the same methodology to determine the number of Economically Significant and Other Significant completed rules that began and finished under Presidents Bush or Obama. In the first two years of the Obama presidency, a smaller percentage of completed Economically Significant rules (14 percentage points fewer) had begun during his presidency compared to the corresponding years for Bush.

Figure 4: Number of Completed Economically Significant and Other Significant Rules by Year That Began Under the Same President



President Bush began and completed more aggregate rules and Other Significant rules during the first seven years of his presidency than Obama. But Obama began and completed more Economically Significant rules. [Table 10]

Table 10: Yearly Average of Completed Rules Beginning and Ending in One Administration by Priority

	All Rules		Economically Significant		Other Significant	
President	Yearly Average	Total	Yearly Average	Total	Yearly Average	Total
Bush 2001-2007	745	5,218	23	160	156	1,093
Obama 2009-2015	692	4,846	38	265	154	1,080

III. Rulemaking Length Is Increasing

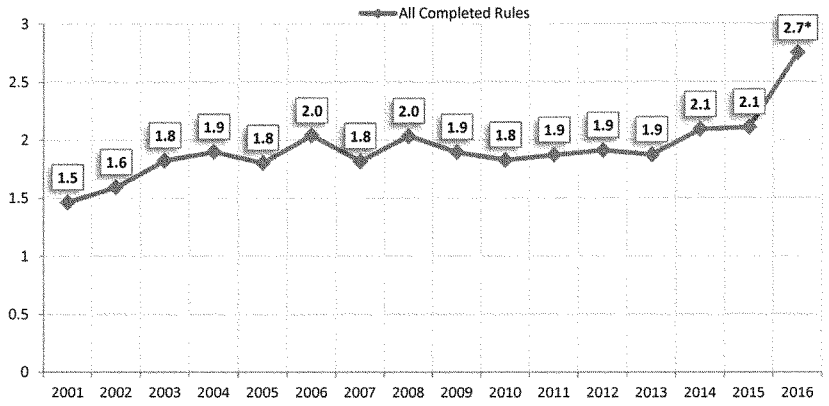
The average time it has taken to finish rules that were completed from 2001 through 2016 has been 1.9 years. The average length of completed rulemakings during the Bush and Obama administrations has been about equal (1.8 years for Bush and 2.0 years for Obama). [Table 11]

Table 11: Average Rulemaking (RM) Length of Completed Rules

President	Average RM Length of Completed Rules
Bush 2001-2008	1.8
Obama 2009-2016	2.0

However, the length of completed rulemakings inched up to 2.7 years in 2016 – 42 percent longer than the yearly average. [Figure 5]

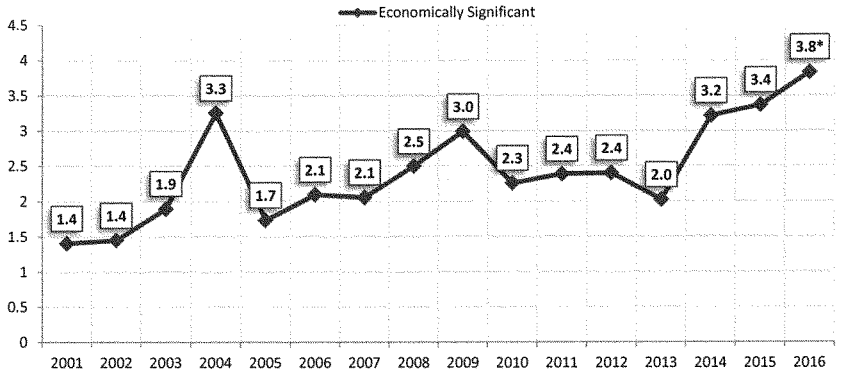
Figure 5: Length of Completed Rulemakings



* Includes data in spring Unified Agenda only.

The trend of increasing lengths of rulemakings is more pronounced when Economically Significant and Other Significant rulemakings are isolated. Economically Significant rules completed under President Bush (2001-2008) took an average of 2.1 years, 16 percent shorter than the 2001-2016 average (2.5). Economically Significant rules completed under President Obama (2009-2016) had an average length of 2.8 years, 12 percent longer than the average. Economically Significant rules completed in 2015 averaged 3.4 years, the longest annual average for completed Economically Significant rules in this analysis. Economically Significant rules completed in 2016 averaged 3.8 years. [Figure 6]

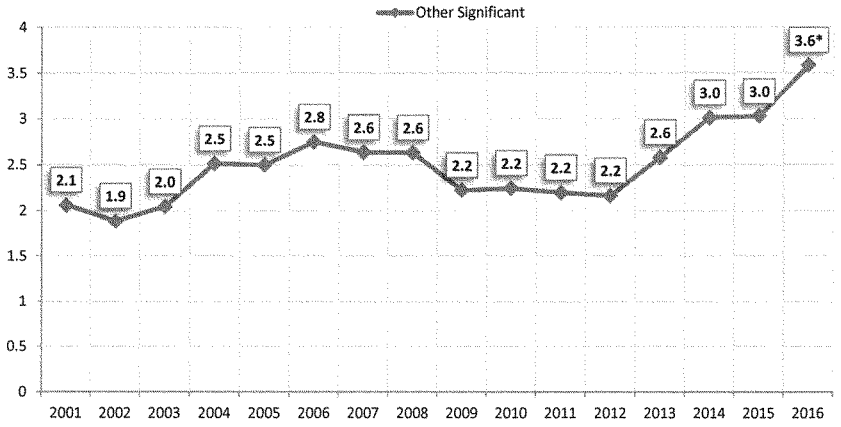
Figure 6: Length of Completed Economically Significant Rules



*Includes data in spring Unified Agenda only.

The average length of Other Significant rulemakings completed in 2014 and 2015 was the longest of any year between 2001 and 2016, at three years – 20 percent longer than the 2001-2016 average (2.5). Similar to the trend for Economically Significant completed rulemakings, Other Significant rulemakings completed in 2016 jumped to 3.6 years in length. [Figure 7]

Figure 7: Length of Completed Other Significant Rules



*Includes data in spring Unified Agenda only.

At this point, completed rules in 2016 are the longest on record, followed by 2015 and 2014.

In theory, it would make sense for Obama-era rules to show slightly longer average lengths because some rulemakings in the Obama era date back further than his predecessor (*i.e.*, in our dataset, the longest potential rulemaking under Bush was about 12 years, 1996 to 2008. The longest potential rulemaking under Obama is about 20 years, 1996 to 2016.) But the extent of increases during the Obama administration indicates something irregular. Table 12 shows the five years with the longest average rulemaking lengths of all completed rulemakings, as well as the longest completed Economically Significant and Other Significant rulemakings. In order to show clear differences in the ranking, the ages had to be rounded to a third decimal point, but the difference is stark in recent years.

Completed Economically Significant rules so far in 2016 took an average of 3.8 years – 58 percent longer than the overall average for Economically Significant completed rules. On average, Significant rules completed in 2016 have taken almost the entire second term of the Obama Administration to complete.

Table 12: Years in Which the Average Completed Rulemakings Were the Longest

A. All Completed Rules		
Year	**President**	**Average Rulemaking Length**
2016*	Obama	2.745
2015	Obama	2.111
2014	Obama	2.089
2006	Bush	2.038
2008	Bush	2.034
B. Economically Significant Completed Rules		
Year	**President**	**Average Rulemaking Length**
2016*	Obama	3.826
2015	Obama	3.363
2004	Bush	3.251
2014	Obama	3.211
2009	Obama	2.990
C. Other Significant Completed Rules		
Year	**President**	**Average Rulemaking Length**
2016*	Obama	3.582
2015	Obama	3.027
2014	Obama	3.014
2006	Bush	2.751
2007	Bush	2.636

*Includes data in spring Unified Agenda only.

As done previously in this analysis, we isolated rulemakings that began and finished under the Bush and Obama administrations. Examining the data this way allows for a more equal comparison.

Table 13 shows that the longer length of rulemakings toward the end of the Obama administration is not due to rulemakings that began prior to his presidency. This finding is most apparent in Economically Significant completed rulemakings. [Table 13B]

When excluding completed rulemakings that began prior to their administrations, the trend of longer rulemaking toward the end of the Obama administration continues to be clear.

Table 13: Years in Which the Average Completed Rulemakings Beginning and Ending Within the Same Administration Were the Longest

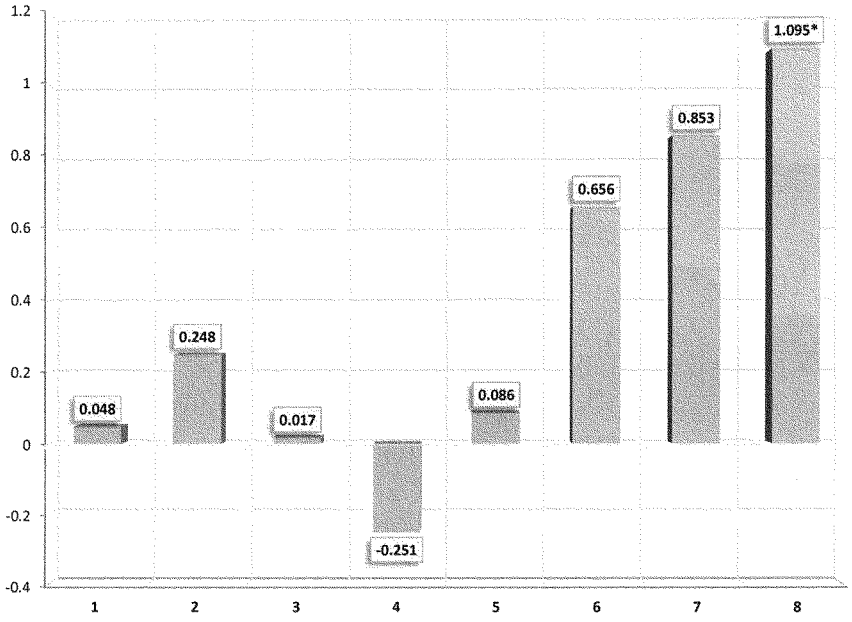
A. All Completed Rules		
Year	**President**	**Average Rulemaking Length**
2016*	Obama	2.253
2008	Bush	1.844
2015	Obama	1.750
2014	Obama	1.683
2006	Bush	1.640
B. Economically Significant Completed Rules		
Year	**President**	**Average Rulemaking Length**
2016*	Obama	3.250
2015	Obama	2.696
2008	Bush	2.155
2014	Obama	2.141
2007	Bush	1.843
C. Other Significant Completed Rules		
Year	**President**	**Average Rulemaking Length**
2016*	Obama	3.077
2008	Bush	2.418
2015	Obama	2.326
2014	Obama	2.223
2007	Bush	2.163

*Includes data in spring Unified Agenda only.

Figure 8 shows the difference in the average rulemaking length between the Obama and Bush administrations by the corresponding year in their administrations. As with Table 14, it only includes rulemakings that began and ended during their administrations.

The Bush and Obama administrations experienced similar rulemaking lengths for their first five years. Beginning in the sixth year of the Obama administration, completed Economically Significant rulemakings became substantially longer than in the corresponding year in the Bush administration. And since then, the difference in the average rulemaking lengths between administrations has increased, with the difference between their average rulemaking lengths in the first half of their final years being the largest – 1.095 years. [Figure 8]

Figure 8: Difference in Length of Obama Completed Economically Significant Rulemakings Compared to Corresponding Bush Administration Year (Rulemakings that Start and Finish Under Their Administration)



*Includes Spring Unified Agenda from Obama Administration only.

IV. Uncompleted Rulemakings

From 1996 to 2016, 25 percent of all rulemakings appearing on the Unified Agenda were uncompleted. Of these, 56 percent, or 3,436 rules, are inactive, meaning the rule was taken off of the Unified Agenda without being completed.

Table 14: Number and Average Rulemaking (RM) Length of Uncompleted Rules

			Number of Rules	Average RM Length
All Uncompleted Rules			6,165	3.2
Inactive		Rule does not appear on the spring 2016 Unified Agenda and never reached the Completed category	3,436	2.8
Incomplete Rulemakings			2,729	3.6
Early Stage*	Incomplete	Rule appears on the spring 2016 Unified Agenda, but first appeared on the Unified Agenda in 2016,2015, or 2014	1,471	1.2
Overdue*	Incomplete	Rule appears on the spring 2016 Unified Agenda, and also first appeared on the Unified Agenda Prior to 2014	1,258	6.3

* Category created by Public Citizen.

The remaining 44 percent, 2,279 rules, appeared on the spring 2016 Unified Agenda but are incomplete. Public Citizen has segregated these rules into two categories: 1) "Early Stage Rules," which appeared on the Unified Agenda for the first time in 2014, 2015, or 2016, meaning that they have not been in progress much longer than the average of the longest category of completed rulemakings in this analysis, Economically Significant rules (2.4 years) and 2) Overdue rules, which are rules that first appeared on the Unified Agenda before 2014, meaning that they have been in process at least 2.5 years – higher than the Economically Significant completed rulemaking average.

Rulemakings we have categorized as overdue account for 46 percent of all incomplete rulemakings listed on the spring 2016 Unified Agenda and have an average current rulemaking length of 6.3 years. Twenty-four percent of overdue rules first appeared on the Unified Agenda prior to President Obama taking office.

V. Agency and Sub Agency Analysis

There is a wide variation in the lengths of time that individual cabinet level agencies take to complete rules. Some agencies, like the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA), must fulfill additional steps to complete rulemakings. This section will focus on how procedural requirements affect the rulemaking length of Significant rulemakings within agencies.

A. Agency Completed Significant Rulemakings

Completed Economically Significant rulemakings from the Department of Justice (DOJ) have been the longest among cabinet level departments, at 5.5 years – 129 percent longer than the overall average. The DOJ is followed by the Department of Labor (DOL), with an average rulemaking length 125 percent longer than average, the Department of Energy (DOE) (108 percent longer) and the (EPA) (58 percent longer). [Table 15]

Table 15: Number and Average Rulemaking (RM) Length of Completed Rules

Agency	Name	Economically Significant		Other Significant	
		#	Average RM Length	#	Average RM Length
DOJ	Department of Justice	6	5.5	173	3.0
DOL	Department of Labor	27	5.4	172	2.7
DOE	Department of Energy	28	5.0	40	2.8
EPA	Environmental Protection Agency	72	3.8	323	2.9
DHS	Department of Homeland Security	22	3.4	91	2.5
TREAS	Department of the Treasury	15	3.3	70	2.0
DOT	Department of Transportation	56	2.9	252	2.9
HUD	Dept. of Housing and Urban Development	8	2.6	166	2.6
USDA	Department of Agriculture	73	2.1	343	2.5
DOC	Department of Commerce	13	1.9	217	1.6
HHS	Department of Health and Human Services	262	1.7	468	2.2
DOD	Department of Defense	12	1.7	163	2.0
DOI	Department of the Interior	24	1.5	214	2.4
ED	Department of Education	27	0.9	89	1.2
Other*		91	1.5	1,118	2.0
Total		**736**	**2.4**	**3,899**	**2.3**

*This category, which includes 67 agencies, regards rulemakings for which the field in the Unified Agenda typically devoted to cabinet level agencies is blank and the agency conducting the rulemaking is listed in the Unified Agenda field normally devoted to sub agencies. Most agencies in this category are independent agencies. Two agencies included in this category – the State Department and Veterans Affairs Department – are cabinet level agencies.

B. Effects of a Regulatory Flexibility Analysis on Completed Significant Rules by Agency

Overall, completed Significant rules undergoing a Regulatory Flexibility Analysis took 9 percent longer than rules without the requirement. Nine of the 14 cabinet agencies experienced longer rulemakings for Economically Significant rules requiring a RFA than for rules that did not.

Department of Labor (DOL) completed Economically Significant rules requiring with a RFA were the longest in that category, at 9.1 years – 117 percent longer than DOL rules with no RFA requirement. Along with the DOL, the Department of Justice (DOJ), the Department of Energy (DOE), the Environmental Protection Agency (EPA), the Department of Homeland Security (DHS), and the Department of Transportation (DOT) all had average rulemaking lengths of more than three years for Economically Significant completed rules that required a RFA. [Table 16]

Table 16: Number of Rules and Average Rulemaking Length of Economically and Other Significant

Agency	Economically Significant				Other Significant			
	RFA Required		No RFA Required		RFA Required		No RFA Required	
	#	Avg RM Years	#	Avg RM Years	#	Avg RM Years	#	Avg RM Years
DOL	7	9.1	20	4.2	24	2.4	148	2.7
DOJ	4	8.0	2	0.5	17	2.0	156	3.0
DOE	15	5.3	13	4.7	5	3.5	35	2.7
EPA	17	3.4	55	3.9	5	1.8	318	2.9
DHS	7	3.2	15	3.5	8	6.1	83	2.1
DOT	15	3.2	41	2.8	31	4.0	221	2.7
DOC	8	2.9	5	0.6	63	2.0	154	1.3
USDA	16	2.7	57	1.9	55	3.0	288	2.4
DOD	2	2.3	10	1.5	15	1.3	148	2.0
TREAS	3	2.2	12	3.7	0		70	2.0
HHS	114	1.8	148	1.6	79	2.6	389	2.1
DOI	7	1.4	17	1.5	12	2.1	202	2.4
HUD	1	1.4	7	2.8	2	2.2	164	2.6
ED	5	1.2	22	0.8	4	2.1	85	1.2
Other*	38	1.3	53	1.7	98	2.1	1,020	2.0
Total	**259**	**2.5**	**477**	**2.3**	**418**	**2.5**	**3,481**	**2.3**

*This category, which includes 67 agencies, regards rulemakings for which the field in the Unified Agenda typically devoted to cabinet level agencies is blank and the agency conducting the rulemaking is listed in the Unified Agenda field normally devoted to sub agencies. Most agencies in this category are independent agencies. Two agencies included in this category – the State Department and Veterans Affairs Department – are cabinet level agencies.

C. Sub Agency Completed Rulemakings

As might be expected due to smaller sample sizes, sub agencies showed significantly greater variation in average rulemaking length than cabinet level agencies.

Economically Significant completed rules by the Occupational Safety and Health Administration (OSHA) have been the longest rulemakings by far, with an average rulemaking length of 12.5 years – 421 percent longer than average.

The five sub agencies with the longest Economically Significant rulemakings are OSHA, Solid Waste and Emergency Response (SWER), the Transportation Security Administration (TSA), Food and Nutrition Service (FNS), and Energy Efficiency and Renewable Energy (EE). [Table 17]

Many of the agencies with the longest Economically Significant rulemakings are focused on public health and safety.

Table 17: Number and Average Rulemaking (RM) Length of Completed Rules by Sub Agency Sub Agencies with Longer Than Average Economically Significant Completed Rulemakings (5 or more Economically Significant Completed Rules)

Sub Agency	Name	Agency	Economically Significant		Other Significant	
			#	Average RM Length	#	Average RM Length
OSHA	Occupational Safety and Health Administration	DOL	5	12.5	21	3.7
SWER	Solid Waste and Emergency Response	EPA	6	5.8	48	3.6
TSA	Transportation Security Administration	DHS	5	5.7	16	2.5
FNS	Food and Nutrition Service	USDA	11	5.4	35	4.6
EE	Energy Efficiency and Renewable Energy	DOE	26	5.1	25	2.4
WATER	Water	EPA	8	5.0	33	3.4
FMCSA	Federal Motor Carrier Safety Administration	DOT	7	4.7	25	3.6
EBSA	Employee Benefits Security Administration	DOL	12	4.4	43	2.6
OCC	Comptroller of the Currency	TREAS	9	3.7	9	2.1
FDA	Food and Drug Administration	HHS	26	3.5	98	3.4
AR	Air and Radiation	EPA	56	3.4	199	2.4
FAA	Federal Aviation Administration	DOT	8	3.3	92	2.8
NOAA	National Oceanic and Atmospheric Administration	DOC	7	2.9	96	2.1
NHTSA	National Highway Traffic Safety Administration	DOT	26	2.6	30	2.6

D. Effects of Regulatory Flexibility Analysis on Significant Completed Rules by Sub Agency

Adding a RFA requirement to Economically Significant rulemakings from OSHA lengthens the rulemaking even more, to 15 years, the longest of all sub agencies with three or more completed Economically Significant rules requiring a RFA. OSHA rules are followed by rules from Energy Efficiency and Renewable Energy (EE), with an average of 5.3 years; the Food Safety and Inspection Service (FSIS), with an average of 5.2 years; and the Employee Benefits Security Administration (EBSA), with an average of 4.6 years. [Table 18]

Table 18: Number and Average Rulemaking (RM) Length of Significant Completed Rules
Sub Agencies With Longer Than Average Economically Significant Completed Rulemakings
With a RFA Requirement versus No RFA
(3 or more RFA Economically Significant Completed)

Sub Agency	Name	Agency	Economically Significant				Other Significant			
			RFA Required		No RFA Required		RFA Required		No RFA Required	
			#	Avg RM Length	#	Avg RM Length	#	Avg RM Length	#	Avg RM Length
OSHA	Occupational Safety and Health Administration	DOL	3	15.0	2	8.8	0	0	21	3.7
EE	Energy Efficiency and Renewable Energy	DOE	15	5.3	11	4.9	5	3.5	20	2.2
FSIS	Food Safety and Inspection Service	USDA	3	5.2	1	4.0	7	2.0	22	3.5
EBSA	Employee Benefits Security Administration	DOL	3	4.6	9	4.3	14	3.1	29	2.4
FAA	Federal Aviation Administration	DOT	4	4.2	4	2.7	10	2.3	82	2.9
FMCSA	Federal Motor Carrier Safety Administration	DOT	5	4.0	2	6.3	6	5.2	19	3.1
AR	Air and Radiation	EPA	15	3.5	41	3.4	2	1.4	197	2.4
NOAA	National Oceanic and Atmospheric Administration	DOC	6	3.5	1	0.2	54	2.3	42	1.8
FDA	Food and Drug Administration	HHS	21	3.4	5	3.9	38	3.6	60	3.3
AMS	Agricultural Marketing Service	USDA	3	2.6	2	0.3	8	2.1	4	0.9

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1995 is likely a contributing factor to OSHA's 15 year rulemaking lengths for completed Economically Significant rules requiring a RFA analysis. SBREFA added to requirements outlined in the Regulatory Flexibility Act (RFA) adopted in 1980. It imposed special requirements on OSHA and the Environmental Protection Agency (EPA) to convene panels of small businesses during the rulemaking process.[83]

[83] Public Law 104-121 (1996), http://1.usa.gov/1sZzV7f. Also *see, e.g., A Guide to the Regulatory Flexibility Act*, U.S. SMALL BUSINESS ADMINISTRATION (May 1996), http://1.usa.gov/1Zbijzo.

E. Incomplete Rules by Agency

In total, 46 percent of incomplete rules are overdue, according to the definition applied in this report. Six of fourteen cabinet level agencies have greater than 46 percent of their incomplete rules categorized as overdue. The Department of Justice (DOJ) has the largest percentage of incomplete rules that were overdue, 73 percent, followed by the Department of Homeland Security (DHS), Treasury (TREAS), the Department of Labor (DOL) and the Department of Interior (DOI).

The agency with the most Overdue rules, 203, is Treasury. Treasury's Overdue rulemakings have an average current rulemaking length of 6.8 years.

The agency with the longest Overdue rulemakings is DHS, with an average current rulemaking length of 8.2 years. DHS is followed by the DOJ (8.1 years), TREAS (6.8 years), the EPA (6.7 years), and the USDA (6.5 years). [Table 19]

Table 19: Number and Average Rulemaking (RM) Length of Incomplete Rulemakings

Agency	Name	Overdue Rules*			Early Stage* (2014-2016) Rules
		#	% of Agency's Incomplete Rules	Average RM Length	#
DOJ	Department of Justice	64	73%	8.1	24
DHS	Department of Homeland Security	78	68%	8.2	36
TREAS	Department of the Treasury	203	56%	6.8	161
DOL	Department of Labor	43	50%	6.0	43
DOI	Department of the Interior	123	50%	4.7	124
DOT	Department of Transportation	90	48%	4.8	99
HHS	Department of Health and Human Services	75	46%	6.2	87
USDA	Department of Agriculture	53	45%	6.5	65
HUD	Department of Housing and Urban Development	17	41%	5.9	24
EPA	Environmental Protection Agency	61	40%	6.7	90
DOE	Department of Energy	32	35%	5.2	59
DOD	Department of Defense	18	26%	4.8	50
DOC	Department of Commerce	43	25%	5.6	127
ED	Department of Education	4	18%	5.3	18
Other**		354	43%	6.5	464
Total		1,258	46%	6.3	1,471

* Category created by Public Citizen.

**This category, which includes 67 agencies, regards rulemakings for which the field in the Unified Agenda typically devoted to cabinet level agencies is blank and the agency conducting the rulemaking is listed in the Unified Agenda field normally devoted to sub agencies. Most agencies in this category are independent agencies. Two agencies included in this category – the State Department and Veterans Affairs Department – are cabinet level agencies.

F. Incomplete Rules by Sub Agency

Many overdue rules are being worked on by agencies focused on public health and safety. The Food and Drug Administration (FDA) has 33 Overdue rules, with an average current rulemaking length of 7.6 years; the Consumer Product Safety Commission (CPSC) has 20, with an average of 7 years; the National Highway Traffic Safety Administration (NHTSA) has 23, with an average of 4.6 years; Air and Radiation (AR) has 20, with an average of 6.3 years; and Occupational Safety and Health Administration (OSHA) has 17, with an average of 6.7 years. [Table 20]

Table 20: Number of Rules and Average Rulemaking (RM) Length of Incomplete Rules by Sub Agency (>15 Incomplete Rules)

Sub Agency	Name	Agency	Overdue Rules*			Early Stage* (2014-2016) Rules
			#	% of Agency's Incomplete Rules	Average RM Length	#
IRS	Internal Revenue Service	TREAS	160	58%	6.9	114
FWS	United States Fish and Wildlife Service	DOI	70	44%	4.6	89
FDA	Food and Drug Administration	HHS	33	58%	7.6	24
NRC	Nuclear Regulatory Commission		31	60%	8.3	21
USCG	U.S. Coast Guard	DHS	30	79%	7.7	8
SEC	Securities and Exchange Commission		30	44%	5.0	38
NOAA	National Oceanic and Atmospheric Administration	DOC	27	24%	5.5	85
SSA	Social Security Administration		23	52%	8.7	21
NHTSA	National Highway Traffic Safety Administration	DOT	23	58%	4.6	17
CPSC	Consumer Product Safety Commission		20	49%	7.0	21
AR	Air and Radiation	EPA	20	29%	6.3	50
EE	Energy Efficiency and Renewable Energy	DOE	19	31%	4.6	43
OSHA	Occupational Safety and Health Administration	DOL	17	49%	6.7	18
USCIS	U.S. Citizenship and Immigration Services	DHS	16	73%	10.0	6
TTB	Alcohol and Tobacco Tax and Trade Bureau	TREAS	16	44%	8.6	20

* Category created by Public Citizen.

G. Department of Labor (DOL) Case Study — the Long Delayed Silica Rule

After about two decades of work, the Occupational Safety and Health Administration (OSHA) in March of this year finally released an updated standard on exposure to silica dust standard.[84]

More than two million workers in the United States are exposed to silica dust, especially construction workers and others who operate jackhammers, cut bricks or use sandblasters. Inhaling the dust causes a variety of harmful effects, including lung cancer, tuberculosis, and silicosis (a potentially fatal respiratory disease.) The rule will reduce the permissible exposure limit for silica to 50 micrograms per cubic meter (from the currently allowed 100) over an eight hour workday. "OSHA estimates that the proposed rule would prevent between 579 and 796 fatalities annually – 375 from non-malignant respiratory disease, 151 from end-stage renal disease, and between 53 and 271 from lung cancer – and an additional 1,585 cases of moderate-to-severe silicosis annually," OSHA wrote in 2013.[85]

Silica-related disease is not evenly distributed across the U.S. population. As a result, the benefits of the new rule will be felt most strongly among working class communities and communities of color. In Michigan, studies show the incidence of silicosis in African Americans is almost six times greater than that of Caucasians.[86]

OSHA has long acknowledged that its silica dust standard, adopted in 1971, was obsolete. It deemed a rulemaking to update the standard a priority in 1997 and listed the rulemaking on its agenda in 1996. In 2011, OSHA submitted to OIRA a draft proposed rule to reduce exposure levels. Although OIRA is supposed to complete reviews in three months, it took 921 days to complete its review on the proposed silica standard.[87] The rule then languished at OSHA for another two-and-a-half years before being finalized.[88]

According to the methodology used in this analysis, the rulemaking took about 19 years. The rule is considered Economically Significant and required a Regulatory Flexibility Analysis. Completed rules with the same priority and procedural requirement have had an average rulemaking length of 2.9 years – making the silica rulemaking 555 percent longer than average. Even at the low end of OSHA's estimates, more than 9,000 fatalities would have been prevented if the rule had been completed within the average timeframe.

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[84] *Occupational Exposure to Respirable Crystalline Silica,* 81 FEDERAL REGISTER 16286 (March 25, 2016), http://1.usa.gov/28W5RPs .

[85] *Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis: Supporting document for the Notice of Proposed Rulemaking for Occupational Exposure to Crystalline Silica*, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (2013). http://1.usa.gov/28TSwx4.

[86] KENNETH ROSENMAN AND MARY JO REILLY, MICHIGAN STATE UNIVERSITY, 2012 ANNUAL REPORT: TRACKING SILICOSIS AND OTHER WORK-RELATED LUNG DISEASES IN MICHIGAN, http://bit.ly/28TSPYC.

[87] *A Timeline of Delay and Disease*, CENTER FOR PUBLIC INTEGRITY (June 29, 2015), http://bit.ly/28YIdmn.

[88] *Occupational Exposure to Respirable Crystalline Silica,* 81 FEDERAL REGISTER 16286 (March 25, 2016), http://1.usa.gov/28W5RPs .

Conclusion

The rulemaking process takes years, and in many cases, newly elected presidents must act quickly to ensure that rules to enact their agenda are completed before their term ends. The current state of the regulatory process is a slow and inefficient one, and unfortunately if some members of Congress get their way, the process will only become longer.

Multiple pieces of legislation have been introduced in the 114th Congress that would not only increase the number of steps agencies must take when developing new rules, but also greatly increase the number of rules requiring these lengthy new steps. For example, the Regulatory Accountability Act of 2015, passed by the House of Representatives at the very beginning of the 114th Congress, would add as many as 74 new rulemaking requirements onto the existing process for most rules, including imposing a blanket requirement for agencies to issue ANPRMs for all Economically Significant or major rules.[89]

If enacted, these expanded procedures and mandates could cause the regulatory process to slow down further or even grind to a halt. Our analysis shows that if an ANPRM and a RFA analysis are required on Economically Significant, rulemakings take close to five years. Proposals to increase the requirements within an ANPRM and RFA analysis would increase rulemaking lengths even more.

Surprisingly, supporters of these bills claim that they will result in a more streamlined regulatory process.[90] While increasing regulatory efficiency may be one of the stated aims of the bills, the outcome will certainly be the exact opposite, making the current delays and inefficiencies in the regulatory process even worse. As this study shows, requiring more rules to include ANPRMs or go through RFA analyses will in no way expedite or streamline the rulemaking process for these rules. It will simply extend the current state of rulemaking delays to even more rules.

On average, Occupational Safety and Health Administration completed rules with an Economically Significant priority and a RFA requirement takes 15 years. The Food Safety and Inspection Service rules with a similar priority take over five, and the Federal Motor Carrier Safety Administration and the Federal Aviation Administration rules take close to four. This is unacceptable.

Each year that public safety rules are delayed costs lives. Legislation to further lengthen rulemakings would put more Americans in danger of serious injury or death.

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[89] *See e.g.* The Early Participation In Regulations Act of 2015, S. 1820, 114th Cong. (2015), The Regulatory Accountability Act of 2015, Section 3(c), H.R. 185 (2015) and Regulations from the Executive in Need of Scrutiny Act of 2015, H.R.427, 114th Cong. (2015).

[90] *See, e.g.*, Rep. Collin Peterson (D-Minn.), Press Release, *Reps. Peterson and Goodlatte Introduce Bill to Rein in Excessive Regulatory Costs* (Jan. 7, 2015), http://1.usa.gov/29hr8ES.

Post-Hearing Questions for the Record
Submitted to Paul Noe
Vice President, Public Policy
American Forest & Paper Association and American Wood Council
From Chairman James Lankford

"Examining the Use of Agency Regulatory Guidance, Part II"
June 30, 2016

United States Senate, Subcommittee on Regulatory Affairs and Federal Management
Committee on Homeland Security and Governmental Affairs

1. In order to function, the Congressional Review Act relies on accurate determinations of economic significance, including those determinations as they relate to guidance. Yet, agencies very rarely ever submit guidance to OIRA as economically significant. Does this effect of this designation shape agency behavior, incentivizing them to avoid the statutory requirements of the Congressional Review Act? If so, what is the effect on the regulatory process and economy at-large?

Congress adopted a very broad definition of "rule" in the Congressional Review Act ("CRA") so that agencies could not avoid its requirements and procedures through "regulation by guidance" and to enhance Congressional authority over rulemaking in general, regardless of whether rulemaking is issued through legislative rules (regulations) or guidance. The term "rule" in the CRA (5 U.S.C. § 804(3)), with limited exceptions, is based on the broad definition of a "rule" in the Administrative Procedure Act ("APA"), 5 U.S.C. § 551(4), which includes "the whole or a part of an agency statement of general . . . applicability and future effect designed to implement, interpret, or prescribe law or policy . . ." Accordingly, the CRA provides expedited procedures for Congressional review and disapproval of not only legislative rules (that ordinarily must be adopted through notice-and-comment procedures), but also guidance (interpretive rules and agency policy statements that are not required by the APA to be adopted through notice-and-comment procedures). These expedited procedures for Congressional review and disapproval of both regulations and guidance apply regardless of whether they are designated as economically significant or not. As stated in the legislative history of the CRA:

> **"The authors intend this chapter to be interpreted broadly with regard to the type and scope of rules that are subject to congressional review. The term "rule" in subsection 804(3) begins with the definition of a "rule" in subsection 551(4) and excludes three subsets of rules that are modeled on APA sections 551 and 553. This definition of a rule does not turn on whether a given agency must normally comply with the notice-and-comment provisions of the APA, or whether the rule at issue is subject to any other notice-and-comment procedures. The definition of "rule" in**

subsection 551(4) covers a wide spectrum of activities. First, there is formal rulemaking under section 553 that must adhere to procedures of sections 556 and 557 of title 5. Second, there is informal rulemaking, which must comply with the notice-and-comment requirements of subsection 553(c). Third, there are rules subject to the requirements of subsection 552(a)(1) and (2). This third category of rules normally either must be published in the Federal Register before they can adversely affect a person, or must be indexed and made available for inspection and copying or purchase before they can be used as precedent by an agency against a non-agency party. Documents covered by subsection 552(a) include statements of general policy, interpretations of general applicability, and administrative staff manuals and instructions to staff that affect a member of the public. Fourth, there is a body of materials that fall within the APA definition of "rule" and are the product of agency process, but that meet none of the procedural specifications of the first three classes. These include guidance documents and the like. For purposes of this section, the term rule also includes any rule, rule change, or rule interpretation by a self regulatory organization that is approved by a Federal agency."

"Congressional Review Title of H.R. 3136," Congressional Record, S3683, S3687 (April 18, 1996) (statement of Senators Nickles, Reid, and Stevens)(Emphasis added.)

2. As the D.C. Circuit noted in a 2000 case, *Appalachian Power Co. v. Environmental Protection Agency*:

> "Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in regulations. One guidance document may yield another and then another and so on. ...Law is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations." 208 F.3d 1015, 1020 (2000).

How do we allow for the flexibility that guidance provides agencies to communicate with regulated entities while ensuring that agencies remain within the bounds of both statutory authority and the regulations they have promulgated?

I believe there are several ways to help ensure that agencies develop and use guidance consistent with the law and basic principles of good government, as follows:

First, agencies should follow good guidance practices in the development and use of guidance. This includes:
(1) Agency Procedures: for the approval and use of significant guidance documents by appropriate senior officials. Agency employees should not depart from the guidance

without appropriate justification and supervisory concurrence.
(2) Standard elements: For example, agency staff should be directed to avoid inappropriate mandatory language.
(3) Public access and feedback procedures: This should include a presumption of pre-adoption notice and comment for the most significant guidance.

Unfortunately, the agencies have not complied with the OMB Bulletin for Agency Good Guidance Practices, as demonstrated by oversight and the report of the U.S. Government Accountability Office, Regulatory Guidance Processes: Selected Departments Could Strengthen Internal Control and Dissemination Practices, GAO-15-368 (April 2015)(reviewing implementation of the OMB Bulletin for Agency Good Guidance Practices by the departments of Health and Human Services, Labor, Education, and Agriculture and finding significant deficiencies). Accordingly, these good guidance practices should be elevated into statute.

Second, there should be a clear process for interagency review of significant guidance through the Office of Information and Regulatory Affairs in the Office of Management and Budget. While OMB currently claims the authority to review guidance through a memorandum issued by Director Orzag, there is no established process for doing so, and the staff at OIRA cannot reasonably be expected to review what they might not know exists. There is a need for a streamlined process for each agency to provide OIRA with advance notification of significant guidances and -- if requested by OIRA -- for the agency to provide a copy of a guidance document to OIRA, with a brief explanation of its need. This guidance review process could be included in the above referenced legislation.

Third, Congress could curb the problem of "regulation by guidance" by ending court deference to agency interpretations of their own rules. After the Supreme Court's decision in Perez v. Mortgage Bankers Association, it is clear that agencies can dramatically change binding regulatory policy simply by issuing interpretive guidance – without public notice and comment. Specifically, an agency can reverse a prior longstanding and definitive interpretive guidance simply by issuing a new interpretive guidance that purports to "clarify" the underlying vaguely-worded regulation. This can occur not only without review by the public, but also without review by the OMB, the courts, or Congress. At the same time, the courts grant substantial deference to agency interpretations of their regulations under the Seminole Rock doctrine, so there is no effective check on "regulation by guidance." Congress should legislatively overrule Seminole Rock deference.

Fourth, Congress should continue its oversight on agency guidance practices, and compliance or non-compliance with the OMB Bulletin for Agency Good Guidance Practices.

3. As we look to best practices governing agency issuance of guidance, what are some recommendations you would give OIRA? For example, would prohibiting the use of mandatory language be an important directive in ensuring that agencies issue guidance documents in a proper manner?

OIRA could do several things to improve the implementation of good guidance practices. First, OIRA could provide stronger oversight over implementation of the Bulletin for Agency Good Guidance Practices, including ensuring that agencies do not inappropriately use mandatory binding language in guidance, as the Bulletin already requires. Second, OIRA could establish a clear process for OMB review of guidance, as described above. OIRA also could work to secure the necessary funding to ensure its effectiveness.

Post-Hearing Questions for the Record
Submitted to Clyde Wayne Crews
Vice President for Policy
Competitive Enterprise Institute
From Chairman James Lankford

"Examining the Use of Agency Regulatory Guidance, Part II"
June 30, 2016

United States Senate, Subcommittee on Regulatory Affairs and Federal Management
Committee on Homeland Security and Governmental Affairs

1. In order to function, the Congressional Review Act relies on accurate determinations of economic significance, including those determinations as they relate to guidance. Yet, agencies very rarely ever submit guidance to OIRA as economically significant. Does this effect of this designation shape agency behavior, incentivizing them to avoid the statutory requirements of the Congressional Review Act? If so, what is the effect on the regulatory process and economy at-large?

Executive Orders, guidance documents, memoranda and other "non-rules" evade notice-and-comment and, with rare exceptions, the federal Office of Management and Budget's review mechanisms.

Yet even when rules do undergo notice and comment procedures it may not be sufficient as far as the Congressional Review Act (CRA) is concerned, making guidance proliferation all the more worrisome. A recent Administrative Conference of the United States white paper finds that final rules increasingly are not being submitted to the Government Accountability Office (GAO) for its database on such rules, and to Congress as is required under the 1996 Congressional Review Act (CRA).

The CRA requires agencies to submit reports to Congress on their major rules—defined roughly as those costing $100 million or more. The neglect of this submission is a significant lapse, adding to the pre-existing issue of independent agencies rules (and presumably guidance) being exempt from OIRA review. The operational problem is that the reports are regarded as essential in case Congress opts to introduce a formal Resolution of Disapproval of an agency rule, or guidance, under the CRA.

The CRA gives Congress a 60 legislative day window in which to review a major rule and, if desired, pass such a resolution of disapproval. The reports are expected for this very reason; given the reality of report lapses, I would submit that the Senate or Congress does not necessarily need to wait for such a report.

The CRA's shortcomings is one of the reasons some support a required affirmation of major rules—and I recommend, guidance—by Congress, not merely the option to disapprove. This step would re-establish congressional accountability for agency actions. In the meantime, if agencies do anticipate Congress taking more interest in the CRA as far as ordinary regulation is concerned, one may expect them to rely even further on guidance.

2. As the D.C. Circuit noted in a 2000 case, *Appalachian Power Co. v. Environmental Protection Agency*:

> "Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in regulations. One guidance document may yield another and then another and so on. ...Law is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations." 208 F.3d 1015, 1020 (2000).

How do we allow for the flexibility that guidance provides agencies to communicate with regulated entities while ensuring that agencies remain within the bounds of both statutory authority and the regulations they have promulgated?

There are a few dozen laws every year, 3,000-plus rules and regulations, and then uncounted guidances numbering in the tens of thousands on top of that. There are several hundred pieces of "significant" guidance in play as far as we know from what agencies have disclosed. If regulatory oversight is the proper approach to coping with some social, safety, economic or environmental concern, it is the case that regulated parties wish for clear guidance and that is understandable and appropriate. But political regulation as opposed to evolving competitive disciplines may be the wrong approach. Furthermore, guidance can inappropriately coerce, and it can overwhelm. A new GAO report this month looked at the Internal Revenue Service's hierarchy of guidance trying to advice on compliance with the tax laws, wherein the Internal Revenue Code itself merely occupies the tip, the apex, while below that in increasingly widening bases and quantities, one finds: "Treasury Regulations," "IRS Bulletins," "Written Determinations," and "Other IRS Publications and Information."

When one sees such proliferation with the IRS, one might surmise the time for tax reform and simplification has arisen. Likewise, when one sees a proliferation with some other walk of life—financial sector, Internet, health care, one might similarly conclude the time has come for Congress to step in and legislate, or rather in particular, to enact regulatory liberalization to remove the regulatory/administrative uncertainty that may be generating the "desire" for guidance. It isn't necessarily the case that guidance is wanted, just that there is no alternative in an inappropriately heavily regulated modern economy. In frontier sectors such as drones and driverless cars, for example, Congress must be especially attuned to guidance inappropriately setting terms at the dawn of such new sectors when

agencies attempt to cling to obsolete regulatory agency models already in place such as the FAA and the NHTSA inappropriately issuing guidance on communications, deployment, fitness and such merely because government's already happen to control airspace and highways. There may be (I submit there are) alternative approaches to the regulatory rule-and-guidance mode.

Ultimately answers to questions of compliance with legitimate guidance are similar to the questions of what to do when Congress wishes to disapprove of an ordinary rule. What matters most is reinvigorated congressional accountability for what agencies do, a reengagement with the lawmaking process, and use of the CRA noted above, as well as passing legislation such as the REINS Act and applying it, not just to "economically significant" rules, but to controversial rules *and guidance*. The recent 2016 House Task Force reports on economic reform and on congressional over-delegation provide numerous suggestions to reinstate the principles of separation of powers and checks and balances. The overuse of guidance is just one of the consequences of lapses in these principles.

3. As we look to best practices governing agency issuance of guidance, what are some recommendations you would give OIRA? For example, would prohibiting the use of mandatory language be an important directive in ensuring that agencies issue guidance documents in a proper manner?

There are numerous discrete actions Congress can take to govern agency issuance of guidance, both for itself to assume and to delegate to central reviewers such as OIRA. The better approach is to be comprehensive, regarding off-the-books rulemaking through the prism of appropriate separation of powers, and congressional accountability.

One coping mechanism recently emerged in Sen. Mike Lee's new Article 1 Regulatory Budget Act, with its promises to "Eliminate the abuse of regulatory 'dark matter'" in part by requiring notice-and-comment for guidance costing $100 million plus, and to allow civil actions for individuals affected by non-compliant guidance.

Congress's To-Do List on agency guidance should go even further. Congress must affirm that every agency decree matters, not just those agencies elect to subject to formal notice and comment or unilaterally deem (or fail to deem) economically significant. Circumstances have deteriorated such that Congress has no idea of what today's thousands of agency proclamations consist.

In the broadest sense, without downsizing the federal government and strengthening democratic accountability, regulation and guidance cannot be controlled. The past century has seen the establishment of colossal bureaucracies and rule by unelected experts, and these bodies do not wish to give up power, and the do not step aside when advances such as the internet and autonomous mobility for all intents and purposes, obsolete them and their reason for being.
Still, those decades-old agencies are already targeting new technologies, business methods and contractual arrangements without congressional authorization. If intervention is

warranted, Congress should directly legislate rather than sit by idly tolerating open-ended agency regulation, or, worse, "informal" guidance.

Limited reversals in the scope of government come only too far apart, such as the 1970-80s partial economic liberalization. Next in the mid-1990s, led by then-Budget Committee Chairman John Kasich (R-Ohio), Congress proposed eliminating entirely the Departments of Commerce, Education and Energy along with 14 agencies, 68 commissions and 283 programs.

Yet, confronting possible obsolescence of decades old statutes is a necessary, fundamental component of addressing inappropriate guidance; one could argue such ongoing confrontation is a primary role of governance. Ending guidance abuse means the primary assignment for Congress is to: (1) Abolish, downsize, cut budgets of and deny appropriations to aggressive, overly regulatory agencies, sub-agencies and programs; and (2) Repeal or amend enabling statutes that sustain the regulatory enterprise's excesses.

Guided by such headlights, there are other, lesser steps Congress can take

- **Costly or controversial guidance and other "regulatory dark matter" should require congressional affirmation (REINS-like standards applied to certain guidance);**
- **The Administrative Procedure Act's controls should be applied to certain guidance, but unfortunately guidance often may not appear in the Federal Register or even feature prominently on an agency website. A great deal of lawmaking happens outside congressional authority, and complications with APA as a solution include the fact that the APA notice and comment often gets neglected even for normal rules.**
- **Regulatory dark matter should be subjected to E.O. 12291-style OMB central review. Like exposing guidance to the APA, however, this is an incomplete solution, but is important in that it will provide a public record and document any lack of cost-benefit analysis or general lack of supervision or accountability. That public record could hasten future reforms.**
- **The legislative history of the Congressional Review Act applies to guidance, but few appear to realize it. The 60-day hold and "resolution of disapproval" provisions of CRA should be taken seriously and emphasized with respect to guidance documents as well as rules of concern. If guidance grows inappropriately, the public should be aware that Congress could have frozen or called attention to it. Withholding appropriations has apparently halted more rules than has the CRA's one success (a Clinton ergonomics rule), so the appropriations process can also be used to limit agency guidance.**
- **Regulation and guidance also need concise official presentation to Congress comparable to the federal budget's Historical Tables. Under President Reagan and the first Bush, there existed a *Regulatory Program of the United States Government* with a detailed appendix titled "Annual Report on Executive Order 12291." Also, guidance could appear the Federal Register in a more clearly labeled and accessible way. With respect to *economically significant guidance* that agencies are already supposed to be reporting based on the 2007 OMB memorandum to agencies on "Good Guidance Practices," policymakers should force streamlined, one-location disclosure. For the *secondary***

guidance and notices **scattered under numerous monikers and across various websites, if publicized at all, these proclamations urgently need centralized disclosure.**

Guidance documents are nothing new, but in our complex economy more salient than ever. Along with a distinctive statement of principles in the 2017 House budget proposal concerning regulatory budgeting, this year's congressional Task Forces prominently articulated the principle of congressional authority over lawmaking and of containing the federal government within appropriate boundaries. The time is ripe to address guidance as part of overall questions of federalism and checks and balances.

Post-Hearing Questions for the Record
Submitted to Amit Narang
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Public Citizen
From Chairman James Lankford

"Examining the Use of Agency Regulatory Guidance, Part II"
June 30, 2016

United States Senate, Subcommittee on Regulatory Affairs and Federal Management
Committee on Homeland Security and Governmental Affairs

1. During your verbal testimony you indicated you do not agree that all agencies should be forced into using the level of internal review used by the FDA. If not universally implementing a higher level of review, what changes would you feel are appropriate to increase the transparency in the guidance process?

   I do not believe that a significant lack of transparency plagues the guidance process currently at agencies in any systemic fashion. Most guidance documents are available to the public through agency websites although are infrequently accessed by the public due to the obscure and technical nature of these guidance documents. To the extent that any proposed reforms to the guidance process allow for increased OIRA oversight similar to the FDA's significant guidance process, I believe that increasing transparency in the rulemaking process should certainly begin with increasing the transparency of OIRA's regulatory review as required by Executive Order 12866. As I mentioned in my oral testimony, the Government Accountability Office has noted repeatedly that OIRA does not follow the vast majority of transparency requirements in its Executive Order 12866. I encourage the committee to pursue such reforms as the most effective way to increase transparency in our current rulemaking process.

2. In your testimony, you cited from the Public Citizen report that economically significant rules that required an ANPRM took 4.4 years to complete across the board, and explained that that is twice as long as rules that do not require an ANPRM. ANPRMs are currently voluntary, and typically used when an agency is unsure what action to take or requires more information prior to drafting a regulation. Could this not explain the prolonged rulemaking process, rather than the ANPRM announcement itself?

   It is not surprising that regulations which underwent an ANPRM took longer than those regulations which did not. Rather, what is surprising is just how much longer those regulations with ANPRMs took on average compared to those regulations without ANPRMs. Given that ANPRMs usually come with just 60 day public comment periods, it is disconcerting to see that economically significant regulations with ANPRMs take more than two years longer on average to finalize than economically significant regulations without this additional step. The clear take-

away from our report is that adding an ANPRM to an economically significant regulation will result in significantly longer rulemakings, more so than has been presumed in the past.

It is true that agencies currently have the discretion to publish an ANPRM and do so regularly for a substantial number of rulemakings. Generally, agencies opt to do so when soliciting such information from the public at the outset of the rulemaking process will be helpful to the agency because, for example, the agency is less familiar with the particular market sector it is authorized to regulate and has limited expertise in regulating such a sector. On the other hand, it makes little sense for agencies to opt for ANPRMs when they have substantial expertise and familiarity with the sector and market participants it is authorized to regulate.

I agree that in situations where agencies have limited expertise and familiarity, it can be appropriate and helpful for agencies to solicit feedback through an ANPRM. Yet, the opposite applies when agencies have substantial expertise and familiarity with the regulatory sector. In that instance, an ANPRM will add needless delay without any benefit to the agency's rulemaking. This is why blanket requirements to apply ANPRMs to all economically significant or major rules will not improve the rulemaking process but rather will only make it less streamlined and efficient.

3. In your testimony, you repeat the notion that a one-size fits-all approach to guidance documents would have unintended consequences and unintentional delay. However, is it not possible, if not plausible, that each agency having their own set of standards would cause unintended consequences and delays, particularly when dealing with topics over which multiple agencies promulgate guidance?

I am not aware of any instances in which multiple agencies issuing joint guidance have been hindered by competing or differing processes for issuing guidance. In the handful of circumstances where I have encountered joint guidance documents, namely in the civil rights context, it appears that the agencies coordinated effectively to issue the guidance in a timely manner. I believe agencies have appropriate processes for harmonizing guidance practices, when such practices are in fact different, to avoid any consequences that variations in guidance processes might present.

I believe the committee should think carefully before adopting reforms to impose a uniform guidance process across agencies, including potentially notice and comment for guidance documents. As I made clear in oral and written testimony, while such a uniform approach may not significantly impact existing guidance processes that already incorporate notice and comment under the agency's discretion, for example at the FDA, it will significantly impact guidance processes such as the SEC's process of issuing No Action Letters that does not currently include an opportunity for notice and comment. Certainly, additional delay in issuing No Action Letters will be a predictable consequence of such a reform, intended or unintended.

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