Post-Hearing Questions for the Record
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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 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"
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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 Amit Narang
Regulatory Policy Advocate
Public Citizen
From Chairman James Lankford

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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.