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Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

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LAWRENCE J. BRADY
STAFF DIRECTOR

January 10, 2012

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington D.C. 20201

Dear Madam Secretary:

Executive Order 12866 assigned the Office of Information and Regulatory Affairs (OIRA) with the responsibility of reviewing regulatory impact analyses (RIAs) from federal agencies before the agency moves forward with the regulation.¹ OIRA is charged with ensuring that agencies consider a variety of alternative solutions and regulate only after determining that the benefits of the regulation justify its cost.² President Obama reaffirmed these principles in Executive Order 13563,³ released on January 18, 2011. According to this executive order:

Our regulatory system . . . must allow for public participation and an open exchange of ideas. It must promote predictability and reduce uncertainty. It must identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends. It must take into account benefits and costs, both quantitative and qualitative. It must ensure that regulations are accessible, consistent, written in plain language, and easy to understand. It must measure, and seek to improve, the actual results of regulatory requirements.⁴

This week, economists Christopher Coyne of Duke University and Jerry Ellig of George Mason University released a series of papers⁵ about the quality of the Administration's RIAs for

¹ Executive Order 12866, *Federal Register* 58, no. 190 (October 14, 1993): 51, 735-44.

² *Id.*

³ Executive Order 13563, *Federal Register* 76, no. 14 (January 21, 2011): 3821-23.

⁴ *Id.*

⁵ Christopher J. Conover and Jerry Ellig, "Beware the Rush to Presumption, Part A: Material Omissions in Regulatory Analyses for the Affordable Care Act's Interim Final Rules," Mercatus Center Working Paper, January 2011; Christopher J. Conover and Jerry Ellig, "Beware the Rush to Presumption, Part B: Substandard Regulatory Analyses for the Affordable Care Act's Interim Final Rules," Mercatus Center Working Paper, January 2011; Christopher J. Conover and Jerry Ellig, "Beware the Rush to Presumption, Part C: A Public Choice Analysis of the Affordable Care Act's Interim Final Rules," Mercatus Center Working Paper, January 2011.

the eight Patient Protection and Affordable Care Act (PPACA) interim final rules⁶ issued in 2010. The studies found significant mistakes and troubling problems with the Administration's RIAs. In fact, the economists gave all eight RIAs an "F".⁷ According to Ellig and Coyne, the analyses of the 2010 PPACA regulations were "seriously incomplete, often omitting significant benefits, costs, or regulatory alternatives.... For these regulations, the quality and use of regulatory analysis fell well below the standards set by other federal agencies and by HHS itself."⁸ The main findings from the Coyne and Ellig's analysis of the PPACA RIAs are:

- The estimated benefits and net benefits of the regulations were systematically biased upward.
- The estimated costs of the regulations were systematically biased downward.
- The distinction between transfers and efficiency benefits was often confused.
- The analyses systematically ignored less expensive regulatory alternatives.⁹

More specifically, the RIAs failed to account for efficiency loss of taxation (the losses to social welfare when individuals engage in less productive behavior in order to minimize their tax burden) although "such losses are very real and well-recognized in the literature on social-welfare economics."¹⁰ The RIAs consistently failed to account for both moral hazard (the risk that individuals will change behavior because of insurance coverage) and additional administrative costs. The RIAs also overlooked the impact of program crowd-out (*e.g.*, subsidies go to health insurance plans that would have existed without the subsidy) and thus significantly overestimated benefits for several of the regulations. In several of the RIAs, Coyne and Ellig found that the agencies "selectively cited literature" that supported the Administration's preconceived regulatory aims. For example, Coyne and Ellig found that your department's RIAs only cited studies showing cost savings from preventive care, even though the preponderance of evidence shows that most preventive care services actually increase costs.¹¹

According to Coyne and Ellig, "All eight regulations appear to have understated the costs. In some cases, costs are understated by billions of dollars. The net effect of this pattern is

⁶ Early Retiree Reinsurance Program (75 FR 24450), Dependent Coverage for Children up to Age 26 (75 FR 27122), Grandfathered Health Plans (75 FR 34538), Preexisting-condition Exclusions, Lifetime and Annual Limits, Prohibition on Discrimination, and Patient Protections (75 FR 37188), Coverage of Preventive Services (75 FR 41726), Internal Claims, Appeals, and External Review Processes (75 FR 43330), Preexisting-condition Insurance Plan (75 FR 45014), Medical Loss Ratio Requirements (75 FR 7464).

⁷ Christopher J. Conover and Jerry Ellig, "Beware the Rush to Presumption, Part B: Substandard Regulatory Analyses for the Affordable Care Act's Interim Final Rules," Mercatus Center Working Paper, January 2011.

⁸ Christopher J. Conover and Jerry Ellig, "Beware the Rush to Presumption, Part C: A Public Choice Analysis of the Affordable Care Act's Interim Final Rules," Mercatus Center Working Paper, January 2011, page 2.

⁹ Christopher J. Conover and Jerry Ellig, "Beware the Rush to Presumption, Part A: Material Omissions in Regulatory Analyses for the Affordable Care Act's Interim Final Rules," Mercatus Center Working Paper, January 2011.

¹⁰ Christopher J. Conover and Jerry Ellig, "Beware the Rush to Presumption, Part A: Material Omissions in Regulatory Analyses for the Affordable Care Act's Interim Final Rules," Mercatus Center Working Paper, January 2011, page 7.

¹¹ Christopher J. Conover and Jerry Ellig, "Beware the Rush to Presumption, Part A: Material Omissions in Regulatory Analyses for the Affordable Care Act's Interim Final Rules," Mercatus Center Working Paper, January 2011, pages 10-11.

to further contribute to the bias favoring regulation.”¹² Coyne and Ellig failed to find that any of the eight PPACA regulations were clearly beneficial, and that the cost of three of the eight regulations¹³ would clearly exceed the associated benefits.¹⁴

Although Executive Order 12866 states RIAs should include “an assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonable alternatives to the planned regulation identified by the agencies or the public, and an explanation of why the planned regulatory action is preferable to the identified potential alternatives”,¹⁵ the Administration’s RIAs of the PPACA regulations failed to do so. Coyne and Ellig found “that the analyses ignored less-expensive alternatives that would be obvious to most health policy analysts.”¹⁶ These systematic failures in the 2010 PPACA RIAs are deeply troubling.

The poor quality of the RIAs might be caused by inadequate time spent doing the analyses or political bias. Despite the long-established requirement for a 60 day notice and comment period under Executive Order 12866, all eight rules were issued via interim final regulations in an apparent effort to avoid a robust comment period. The researchers posit that the tight deadlines in the PPACA prevented the agencies from conducting high-quality analysis before the agencies issued regulations. According to Coyne and Ellig, “[i]f a president or high-ranking White House officials have already made major decisions about favored regulations, then OIRA cannot credibly threaten to return regulations. With major decisions already made, agency economists have little incentive to produce high-quality analysis and likely face pressure to produce analysis that supports prior decisions.”¹⁷

We have several questions about the failure of your department to conduct accurate and careful cost-benefit analyses. We are concerned that the 2010 PPACA regulations failed to meet the criteria of President Obama’s Executive Order 13563. We also have several questions about HHS’ RIAs as well as how HHS is going to improve the regulatory process moving forward for the many future PPACA regulations that have yet to be issued. In preparing your responses, please answer each question individually and include the text of each question along with your response.

¹² Christopher J. Conover and Jerry Ellig, “Beware the Rush to Presumption, Part A: Material Omissions in Regulatory Analyses for the Affordable Care Act’s Interim Final Rules,” Mercatus Center Working Paper, January 2011, page 8.

¹³ These regulations are the Early Retiree Reinsurance Program (75 FR 24450), Dependent Coverage for Children up to Age 26 (75 FR 27122), and Preexisting-condition Insurance Plan (75 FR 45014) regulations.

¹⁴ Christopher J. Conover and Jerry Ellig, “Beware the Rush to Presumption, Part A: Material Omissions in Regulatory Analyses for the Affordable Care Act’s Interim Final Rules,” Mercatus Center Working Paper, January 2011.

¹⁵ Executive Order 12866, *Federal Register* 58, no. 190 (October 14, 1993): 51, 735-44.

¹⁶ Christopher J. Conover and Jerry Ellig, “Beware the Rush to Presumption, Part A: Material Omissions in Regulatory Analyses for the Affordable Care Act’s Interim Final Rules,” Mercatus Center Working Paper, January 2011, page 18.

¹⁷ Christopher J. Conover and Jerry Ellig, “Beware the Rush to Presumption, Part C: A Public Choice Analysis of the Affordable Care Act’s Interim Final Rules,” Mercatus Center Working Paper, January 2011, page 1.

1. Why did each RIA for the eight 2010 PPACA regulations fail to account for real world costs associated with the higher taxes required to finance the regulations or subsidize an activity related to the regulation?
2. Many prior studies show significant efficiency losses from individuals consuming excessive health care (care whose costs exceed its value) when health insurance becomes more heavily subsidized. For example, Finkelstein and McKnight estimated Medicare's excess utilization at 28 percent of program spending.¹⁸ Moreover, moral hazard from the Medicare Part D program has been estimated at 41 percent of program spending.¹⁹ Why did each RIA fail to account for the real world costs associated with moral hazard losses of expanding health insurance coverage?
3. According to the research, the PPACA RIAs failed to consider program crowd-out. For example, Coyne and Ellig found that the RIAs failed to consider crowd-out in the early retiree health insurance program and that failing to do so led to benefits being over-estimated by a factor of three or four. Does HHS typically account for program crowd-out when conducting RIAs? Why was program crowd-out, which is a topic of considerable academic research,²⁰ ignored in the 2010 PPACA RIAs?
4. For the preventive services regulation (75 FR 41726), federal agencies appear to have cherry-picked literature reviews in order to advance the Administration's regulatory goals. Why did you ignore Louise Russell's 2009 article²¹ in *Health Affairs* as well as multitudes of other academic studies²² that shows most preventive services do not lower overall health care costs?
5. Section 1(b) of Executive Order 12866²³ states that agencies should adopt a regulation "only upon a reasoned determination that the benefits of the intended regulation justify the costs." According to the Coyne and Ellig, "In all of the RIAs examined, analysts concluded that the benefits of a regulation outweighed its costs even though there was no instance in which this claim was demonstrated empirically with quantitative estimates of

¹⁸ Amy Finkelstein and Robin McKnight, "What Did Medicare Do (and Was It Worth It)?" NBER Working Paper Series no 11609, Cambridge, MA, 2005.

¹⁹ Mark V. Pauly, "Medicare Drug Coverage and Moral Hazard," *Health Affairs* 23, no. 1 (2004): 113-22.

²⁰ For instance, see Jonathan Gruber and Kosali Simon, "Crowd-Out 10 Years Later: Have Recent Public Insurance Expansions Crowded Out Private Health Insurance?," *Journal of Health Economics*, Vol. 27 (2008), pp. 201-17.

²¹ Louise Russell, "Preventing Chronic Disease: An Important Investment, But Don't Count on Cost Savings," *Health Affairs*, Vol. 28, No. 1, January 2009, pp. 42-45

²² Alan Monheit et al., "State Policies Expanding Dependent Coverage to Young Adults in Private Health Individual Plans," Presented at the Academy Health State Health Research and Policy Interest Group Meeting, Chicago, IL, 2009; Finkelstein and McKnight, "What Did Medicare Do (and Was It Worth It)?"; David Card, Carlos Dobkin, and Nicole Maestas, "The Impact of Nearly Universal Insurance Coverage on Health Care Utilization and Health: Evidence from Medicare," NBER Working Paper Series no. 10365, Cambridge, MA, 2004; and Christopher J. Conover, "How Health Affects the Bottom Line for Businesses and Employers," Presentation at North Carolina Legislative Black Caucus Foundation Health Summit, Raleigh, NC, 2011.

²³ Executive Order 12866, *Federal Register* 58, no. 190 (October 14, 1993): 51, 735-44.

benefits and costs.”²⁴ Can HHS make a “reasoned determination” if the RIA does not clearly and carefully consider how to measure benefits and costs of proposed rules? Why did HHS refrain from following Section 1(b) of Executive Order 12866?

6. In her June 2011 testimony before the House Committee on Energy and Commerce, Sherry Glied, HHS Assistant Secretary for Policy and Evaluation, stated, “We’ve already weighed their benefits and costs for these regulations and issued regulations only when benefits exceeded costs.”²⁵ Ellig and Coyne’s carefully documented research shows that this statement was at best mistaken and potentially purposefully misleading. How did HHS conclude that all eight of the rules had benefits that exceeded their costs when not one of the RIAs sought to quantify expected benefits?
7. Does HHS plan on doing higher quality cost-benefit analyses for future PPACA regulations?
8. According to Coyne and Ellig, the tight deadlines in the PPACA prevented the agencies from conducting high-quality analysis before the agencies issued regulations. Do you believe that the rushed nature of this rule-making process is the reason HHS was deficient in assessing a variety of regulatory alternatives? If this is not the key reason for the poor quality of the RIAs, please explain what is.
9. Does HHS plan on issuing any additional interim final rules for future PPACA regulations?
10. For the Early Retiree Reinsurance Program (75 FR 24450) regulation, what are the specific metrics HHS will use to track its success or failure?
11. For the Dependent Coverage for Children up to Age 26 (75 FR 27122) regulation, what are the specific metrics HHS will use to track its success or failure?
12. For the Grandfathered Health Plans (75 FR 34538) regulation, what are the specific metrics HHS will use to track its success or failure?
13. For the Preexisting-condition Exclusions, Lifetime and Annual Limits, Prohibition on Discrimination, and Patient Protections (75 FR 37188) regulation, what are the specific metrics HHS will use to track its success or failure?
14. For the Coverage of Preventive Services (75 FR 41726) regulation, what are the specific metrics HHS will use to track its success or failure?

²⁴ Christopher J. Conover and Jerry Ellig, “Beware the Rush to Presumption, Part A: Material Omissions in Regulatory Analyses for the Affordable Care Act’s Interim Final Rules,” Mercatus Center Working Paper, January 2011, page 8.

²⁵ House Energy and Commerce Committee, *The Views of the Department of Health and Human Services on Regulatory Reform: An Update*, (testimony by Sherry Glied), 112th Cong., 1st session, 2011.

The Honorable Kathleen Sebelius

January 10, 2012

Page 6

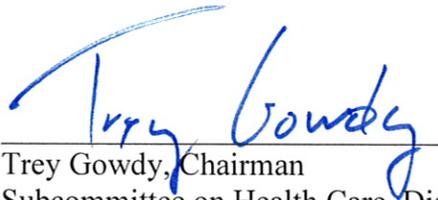
15. For the Internal Claims, Appeals, and External Review Processes (75 FR 43330) regulation, what are the specific metrics HHS will use to track its success or failure?
16. For the Preexisting-condition Insurance Plan (75 FR 45014) regulation, what are the specific metrics HHS will use to track its success or failure?
17. For the Medical Loss Ratio Requirements (75 FR 7464) regulation, what are the specific metrics HHS will use to track its success or failure?

The Committee on Oversight and Government Reform is the principal oversight committee of the House of Representatives and may at “any time” investigate “any matter” as set forth in House Rule X. An attachment to this letter provides additional information about responding to the Committee’s request. Please provide this information to the Committee by January 24, 2012. If you have any questions about this request, please contact Brian Blase with the Committee staff at 202-225-5074. Thank you for your attention to this matter.

Sincerely,



Darrell Issa, Chairman



Trey Gowdy, Chairman
Subcommittee on Health Care, District of
Columbia, Census and the National Archives

Attachment

cc: The Honorable Elijah Cummings, Ranking Minority Member
House Committee on Oversight and Government Reform

The Honorable Danny Davis, Ranking Member
Subcommittee on Health Care, District of Columbia, Census and the National Archives

ONE HUNDRED TWELFTH CONGRESS
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Minority (202) 225-5051

Responding to Committee Document Requests

1. In complying with this request, you should produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. You should also produce documents that you have a legal right to obtain, that you have a right to copy or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party. Requested records, documents, data or information should not be destroyed, modified, removed, transferred or otherwise made inaccessible to the Committee.
2. In the event that any entity, organization or individual denoted in this request has been, or is also known by any other name than that herein denoted, the request shall be read also to include that alternative identification.
3. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, or thumb drive) in lieu of paper productions.
4. Documents produced in electronic format should also be organized, identified, and indexed electronically.
5. Electronic document productions should be prepared according to the following standards:
 - (a) The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.
 - (b) Document numbers in the load file should match document Bates numbers and TIF file names.
 - (c) If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

6. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, box or folder is produced, each CD, hard drive, memory stick, thumb drive, box or folder should contain an index describing its contents.
7. Documents produced in response to this request shall be produced together with copies of file labels, dividers or identifying markers with which they were associated when they were requested.
8. When you produce documents, you should identify the paragraph in the Committee's request to which the documents respond.
9. It shall not be a basis for refusal to produce documents that any other person or entity also possesses non-identical or identical copies of the same documents.
10. If any of the requested information is only reasonably available in machine-readable form (such as on a computer server, hard drive, or computer backup tape), you should consult with the Committee staff to determine the appropriate format in which to produce the information.
11. If compliance with the request cannot be made in full, compliance shall be made to the extent possible and shall include an explanation of why full compliance is not possible.
12. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) the privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author and addressee; and (e) the relationship of the author and addressee to each other.
13. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (stating its date, author, subject and recipients) and explain the circumstances under which the document ceased to be in your possession, custody, or control.
14. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, you should produce all documents which would be responsive as if the date or other descriptive detail were correct.
15. The time period covered by this request is included in the attached request. To the extent a time period is not specified, produce relevant documents from January 1, 2009 to the present.
16. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data or information, not produced because it has not been located or discovered by the return date, shall be produced immediately upon subsequent location or discovery.

17. All documents shall be Bates-stamped sequentially and produced sequentially.
18. Two sets of documents shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2471 of the Rayburn House Office Building.
19. Upon completion of the document production, you should submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control which reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, inter-office and intra-office communications, electronic mail (e-mail), contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.
2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, email, regular mail, telexes, releases, or otherwise.
3. The terms "and" and "or" shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information which might

otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neuter genders.

4. The terms "person" or "persons" mean natural persons, firms, partnerships, associations, corporations, subsidiaries, divisions, departments, joint ventures, proprietorships, syndicates, or other legal, business or government entities, and all subsidiaries, affiliates, divisions, departments, branches, or other units thereof.
5. The term "identify," when used in a question about individuals, means to provide the following information: (a) the individual's complete name and title; and (b) the individual's business address and phone number.
6. The term "referring or relating," with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with or is pertinent to that subject in any manner whatsoever.