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THE VIEWS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON REGULATORY REFORM: AN UPDATE

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

FIRST SESSION

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C O N T E N T S

	Page
Hon. Cliff Stearns, a Representative in Congress from the State of Florida, opening statement	1
Prepared statement	5
Hon. Henry A. Waxman, a Representative in Congress from the State of California, opening statement	8
Prepared statement	10
Hon. Fred Upton, a Representative in Congress from the State of Michigan, prepared statement	48

WITNESS

Sherry Glied, Assistant Secretary for Planning and Evaluation, Department of Health and Human Services	12
Prepared statement	15
Answers to submitted questions	49

SUBMITTED MATERIAL

Chart, "Estimates of the Cumulative Percentage of Employer Plans Relinquishing Their Grandfathered Status, High-End Estimate," from June 17, 2010, Federal Register, submitted by Mr. Stearns	3

THE VIEWS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON REGULATORY REFORM: AN UPDATE

MONDAY, JUNE 13, 2011

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 2:07 p.m., in room 2322 of the Rayburn House Office Building, Hon. Cliff Stearns (chairman of the subcommittee) presiding.

Members present: Representatives Stearns, Bilbray, Scalise, and Waxman (ex officio).

Staff present: Allison Busbee, Legislative Clerk; Todd Harrison, Chief Counsel, Oversight and Investigations; Sean Hayes, Counsel, Oversight and Investigations; Debbee Keller, Press Secretary; Alan Slobodin, Deputy Chief Counsel, Oversight; Sam Spector, Counsel, Oversight; John Stone, Associate Counsel; Kristin Amerling, Minority Chief Counsel and Staff Director for Oversight; Brian Cohen, Minority Senior Policy Advisor and Staff Director for Investigations; Karen Lightfoot, Minority Communications Director and Senior Policy Advisor; Bruce Wolpe, Minority Senior Advisor; Anne Tindall, Minority Counsel; Stacia Cardille, Minority Counsel; and Ali Neubauer, Minority Investigator.

Mr. STEARNS. Good morning, everybody, and the Subcommittee on Oversight and Investigations is convened. I will start with my opening statement.

OPENING STATEMENT OF HON. CLIFF STEARNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

We have convened this hearing of the subcommittee to examine how the Department of Health and Human Services is implementing President Obama's executive order, which was announced on January 18, entitled "Improving Regulation and Regulatory Review." Regulatory reform has been a priority of this subcommittee in the 112th Congress and will remain so as long as Americans suffer from prolonged high unemployment and sluggish economic growth.

A 2/10 study commissioned by President Obama's Small Business Administration places the total annual compliance cost of federal regulations at $1.75 trillion, a number that trumps the record federal budget deficit. Cass Sunstein, the head of the office of Information and Regulatory Affairs, a primary overseer of the administra-

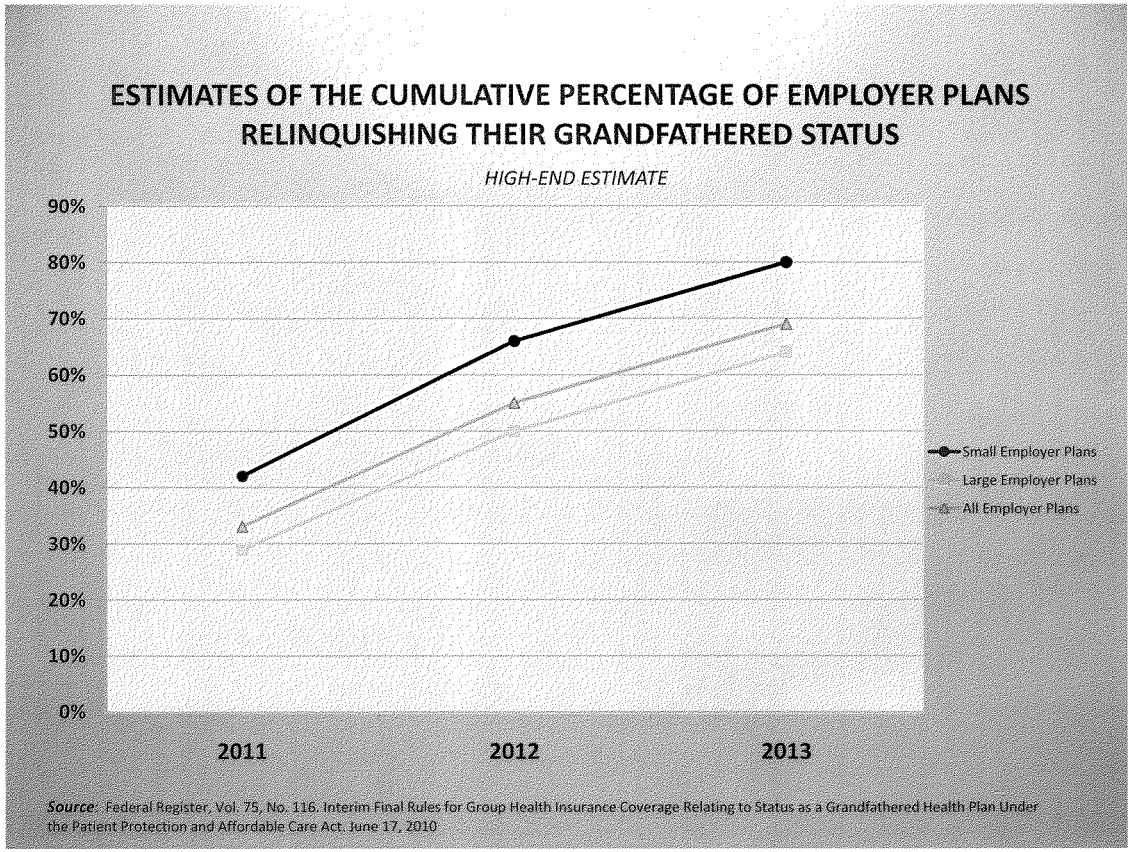
tion's reform efforts, disagreed with this study in his testimony before this subcommittee on June 3. This seemed to be a theme of the administration. If a study or report comes out that they disagree with, it is denounced as inaccurate or labeled an outlier, even if the administration actually commissioned the study themselves. Case in point is a White House response to a recently released study by the McKinsey Group, indicating a radical restructuring of employer-sponsored health benefits, following the passage of the President's health care plan.

Overall, 30 percent of the employers surveyed said that they will definitely or probably stop offering health care coverage in the years after 2014, due to the overwhelming burden and expense of Obamacare, and an incredible 50 percent of employers with a high awareness of the laws say they will stop offering coverage.

White House Deputy Chief of Staff Nancy-Ann DeParle shrugged off the report saying it misses some key points and doesn't provide the complete picture. This study, however, is not an outlier. Two other reports have been released by reputable independent experts within the last month. Each one concludes that the Obamacare has made coverage more expensive and that many individuals who like their current plan will simply be dropped from it.

In fact, according to the administration's own estimate cited in the interim final rule implementing the grandfathered health plans, its regulations will force half of all employers and as many as 80 percent of small businesses to give up their coverage in the next 2 years, as this graph clearly shows.

[The information follows:]



Source: Federal Register, Vol. 75, No. 116. Interim Final Rules for Group Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act. June 17, 2010

President Obama's executive order requires agencies, when promulgating rules, to consider costs and benefits to ensure that the benefits justify the costs and to select the least burdensome alternatives. It requires increased public participation. It directs agencies to take steps to harmonize, simplify, and coordinate rules. And finally, it directs agencies to consider flexible approaches that reduce burdens and maintains freedom of choice for the public.

I do not see how the regulations that will force as many as 80 percent of small businesses to drop their employees' health coverage can possibly pass any of these tests and criteria that the President outlined. Quite frankly, it seems like Obamacare itself has received a waiver from this executive order itself.

In addition to prospective requirement agencies are supposed to adhere to while promulgating regulations, the executive order directs agencies to conduct ongoing, retrospective analyses to identify rules that should be streamlined, reduced, improved, or eliminated.

HHS arguably touches more aspects of America's daily lives than any other agency. FDA in itself regulates more than 25 percent of the U.S. economy. We need to ensure that the regulations it has on the books as well as the ones it is currently drafting promote public health as well as private sector innovation and job creation. After all, the health and well being of our citizens is inherently tied to the health and well being of our economy. The number and size of the regulations that have been expedited through the review process at HHS and ORIA is matched only by the number and size of the rules still in the queue. Among these is the establishment of an essential benefits package, which will increase premiums and further put people's coverage at risk.

Hopefully our witnesses today—our witness today will share with us what HHS has learned from the process used to promulgate such rules and regulations as the grandfathered health plans rule. HHS will hopefully do better, while reviewing the essential benefits package and other large rules coming down the pike.

An unprecedented amount of authority has been delegated to HHS and other agencies in the administration. The principles President Obama affirms in his executive order are important. We agree. I am just concerned they are being ignored when it comes to the actual implementation of large scale government program such as the President's health care plan.

I would like to welcome our witness, Sherry Glied, who is the assistant secretary for planning and evaluation at the Health and Human Services Department. And with that, I recognize the ranking member of Energy and Commerce, the distinguished Henry Waxman from California.

[The prepared statement of Mr. Stearns follows:]

Opening Statement of the Honorable Cliff Stearns
Chairman, Subcommittee on Oversight and Investigations
The Views of the Administration on Regulatory Reform
June 13, 2011
773 words

We convene this hearing of the Subcommittee on Oversight and Investigations to examine how the Department of Health and Human Services is implementing President Obama's Executive Order, announced on January 18, entitled "Improving Regulation and Regulatory Review." Regulatory reform has been a priority of this Subcommittee in the 112th Congress and will remain so as long as Americans suffer from prolonged high unemployment and sluggish economic growth.

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Case in point is the White House's response to a recently released study by the McKinsey Group indicating a radical restructuring of employer-sponsored health benefits following the passage of the President's healthcare plan. Overall,

30 percent of the employers surveyed said they will definitely or probably stop offering health care coverage in the years after 2014 due to the overwhelming burden and expense of Obamacare. And an incredible fifty percent of employers with a high awareness of the law, say they will stop offering coverage. White House Deputy Chief of Staff Nancy-Ann DeParle shrugged off the report, saying it "misses some key points" and "doesn't provide the complete picture." This study, however, is not an outlier. Two other reports have been released by reputable independent experts within the last month. Each one concludes that Obamacare has made coverage more expensive and that many individuals who like their current plan will be dropped from it. In fact, according to the Administration's own estimates cited in the interim final rule implementing the "grandfathered" health plans, its regulations will force half of all employers—and as many as 80 percent of small businesses—to give up their coverage in the next two years.

President Obama's Executive Order requires agencies, when promulgating rules, to consider costs and benefits, to ensure that the benefits justify the costs, and to select the least burdensome alternatives. It requires increased public participation. It directs agencies to take steps to harmonize, simplify, and coordinate rules. And finally, it directs agencies to consider flexible approaches that reduce burdens and maintain freedom of choice for the public. I do not see how regulations that will force as many as 80 percent of small businesses to drop their employees' health coverage can possibly pass any of these tests. Quite frankly, it seems like Obamacare itself has received a waiver from this Executive Order.

In addition to prospective requirements agencies are supposed to adhere to while promulgating regulations, the Executive Order directs agencies to conduct

ongoing retrospective analysis to identify rules that should be streamlined, reduced, improved, or eliminated. HHS arguably touches more aspects of Americans' daily lives than any other agency. FDA, in itself, regulates more than 25% of the U.S. economy. We need to ensure that the regulations it has on the books, as well as the ones it is currently drafting, promote public health as well as private sector innovation and job creation. After all, the health and well-being of our citizens is inherently tied to the health and well-being of our economy.

The number and size of the regulations that have been expedited through the review process at HHS and OIRA (Oh-EYE-Ra) is matched only by the number and size of the rules still in the queue. Among these is the establishment of the essential benefits package, which will increase premiums and further put people's coverage at risk. Hopefully our witness today will share with us what HHS has learned from the process used to promulgate such rules and regulations as the "grandfathered" health plans rule. HHS will hopefully do better while reviewing the essential benefits package and other large rules coming down the pike. An unprecedented amount of authority has been delegated to HHS and other agencies in this Administration. The principles President Obama affirms in his Executive Order are important. I am just concerned they are being ignored when it comes to the actual implementation of large-scale government programs such as the President's healthcare plan.

With that I would like to welcome our witness, Sherry Glied, who is the Assistant Secretary for Planning and Evaluation at the Health and Human Services Department.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Mr. Chairman. The subject of regulatory reform deserves review, and Congress has a legitimate interest in making sure that the administration is living up to its promises with regard to making the regulatory process simple and more transparent. But as we investigate regulatory reform, we need to make sure we consider both the costs and the benefits of regulations.

This is the third hearing in this committee on regulatory reform this year. In these hearings, the administration's opponents have relentlessly focused on the negative with no regard for why we need regulations or for the good that they do. Regulations aren't pulled out of thin air for no reason. They exist to implement laws Congress enacted to help protect taxpayers' funds, improve public health and safety, keep our air and water clean, and keep consumers safe.

Today's hearing is a good illustration. Some of the administration's recent health regulations will do enormous good for American families. New food safety regulations promulgated by FDA will reduce salmonella contamination and prevent as many as 79,000 illnesses each year. New tobacco control regulations promulgated by FDA will protect children and adolescents from the dangers of addiction to cigarettes and smokeless tobacco.

New regulations issued by CMS under the Affordable Care Act will end the insurance industry's worst abuses. They will prevent health insurers from rescinding policies when beneficiaries get sick, end discrimination against children with preexisting conditions, prohibit the imposition of lifetime caps on coverage and require all health plans to put more of consumers premium dollars into actual care and less into insurance company profits.

Another set of CMS regulations also authorized by the Affordable Care Act will cut Medicare and Medicaid fraud and save taxpayers millions of dollars. No one wants unnecessary or duplicative regulations, but at the same time, no one should want to eliminate regulations that save taxpayers money and protect the health and welfare of America's families.

That is why we must look at both the costs and benefits of regulations. When we focus solely on costs, as often seems to happen in this committee, we lose sight of the critical benefits these regulations provide.

Before I yield back my time, I want to note that Ranking Member Diana DeGette regrets being unable to attend this hearing. Today is a return day. We don't have votes until 6:30, and unfortunately the ranking member of the subcommittee was not consulted about the hearing that was going to be called today before 6:30. In the last Congress, we engaged in a lot of these consultations. I think they are useful for everybody involved, and I would urge the majority to be sure to consult with the minority so that the minority ranking members of the subcommittee can change their schedules or can be accommodated in some possible way.

I have completed my opening statement. I want to welcome Ms. Glied to be here. We are looking forward to your testimony. I think

what HHS is doing by way of regulations is very important, very worthwhile, and while any regulation may have some downsides, we have to realize that many of them have very, very important upside for the American people. Thank you, Mr. Chairman.

[The prepared statement of Mr. Waxman follows:]

Opening Statement of Rep. Henry A. Waxman
Ranking Member, Committee on Energy and Commerce
"The Views of the Department of Health and Human Services on Regulatory Reform: An Update"
Subcommittee on Oversight and Investigations
June 13, 2011

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regulations. When we focus solely on costs, as often seems to happen in this Committee, we lose sight of the critical benefits that regulations provide.

Before I yield back my time, I want to note that the Ranking Member Diana DeGette regrets being unable to attend this hearing because of previous commitments. Today is a "return day" when the House is reconvening after recess and does not have votes until 6:30 pm. Unfortunately, the Chairman did not consult with the Ranking Member when scheduling today's hearing. In the last Congress, we engaged in such consultation for return day hearings because we believed it was a matter of basic courtesy and comity to work to ensure inclusion of the ranking member in hearings. I am disappointed that the Republican majority did not follow this approach.

I hope that today's hearing will be an aberration and that in the future, there will be more consultation before hearings are scheduled on return days.

In closing, let me thank the witnesses for being here today. I look forward to your testimony.

Mr. STEARNS. I thank the gentleman from California. I would point out that we gave 1 week's notice according to the rules for this hearing, but I also want to again reiterate we welcome Sherry Glied. She again is the assistant secretary for planning and evaluation at the U.S. Department of Health and Human Services.

And, madam, as you know, the testimony that you are about to give is subject to Title 18, Section 1001 of the United States Code.

When holding an investigative hearing, this committee has a practice of taking testimony under oath. Do you have any objection to testifying under oath?

Ms. GLIED. No, sir.

Mr. STEARNS. The chair then advises you that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Do you desire to be advised by counsel during your testimony today?

Ms. GLIED. No, sir.

[Witness sworn.]

Mr. STEARNS. You may now give your 5-minute opening statement. Thank you.

TESTIMONY OF SHERRY GLIED, ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Ms. GLIED. Mr. Chairman, Congressman Waxman, other members of the subcommittee, my name is Sherry Glied, and I am the Assistant Secretary for Planning and Evaluation in the U.S. Department of Health and Human Services. I am grateful to have the opportunity to appear before you today to discuss issues relating to regulation and to Executive Order 13563, Improving Regulation and Regulatory Review.

I will focus in particular on the retrospective review of the existing rules. The President's order laid the foundations for a regulatory system that is designed to protect public health and welfare while also promoting economic growth, innovation, competitiveness, and job creation. On May 18 and in compliance with the executive order, HHS released our preliminary plan. HHS's systematic review of regulations will focus on eliminating rules that are no longer necessary and strengthening or modernizing rules where appropriate.

For example, the Centers for Medicare and Medicaid services is working to address conflicting requirements between Medicaid and Medicare that potentially create barriers to high quality, seamless, and cost-effective care for dual eligible beneficiaries.

The Administration for Children and Families is also encouraging State's child support programs to use cost-effective technologies like electronic signature and document storage. And the Food and Drug Administration is going paperless with its adverse events reporting requirements for medical devices.

HHS's retrospective review plan has 4 goals: to increase transparency, to increase opportunities for public participation, to set retrospective review priorities, and to strengthen analysis of regulatory options. This administration believes that retrospective regulatory review must be accompanied by efforts to make more infor-

mation available to all interested parties and that regulations and the regulatory process should be as clear as possible.

HHS will increase transparency in its regulatory process by making available to the extent feasible and permitted by law information that is useful for businesses, States, local and travel government, and the public. It is essential that people be able to understand the basis of a proposed regulatory activity including the science or evidence base for a regulation.

Public participation is a very important part of our retrospective review plan. We are currently soliciting public comment on the HHS preliminary plan on the www.hhs.gov/open Web site through June 30. Suggestions are welcome, and HHS will carefully review all comments before finalizing our plans. HHS also intends to increase the breadth and quality of public participation in its rolemaking and retrospective review activities.

All HHS agencies already reach out to obtain public input and advice on regulation subject to review and modification. For example, twice a year, FDA sends letters to State and local elected officials and to small businesses, highlighting upcoming regulations and seeking suggestions o FDA's regulatory activities.

FDA also recently established a new web page specifically devoted to its regulatory review activities. CMS conducts monthly open-door forums and provider outreach activities. Feedback from these activities allows CMS to identify and change obsolete regulatory requirements and to reduce regulatory burden.

Moving forward, HHS is establishing a public participation task force within the department to explore way to increase interactivity in the public comment process including the use of podcasts, webinars, video teleconference sessions, wickeys, YouTube, and other social media.

HHS has also actively encouraged public participation as we implement the Affordable Care Act. For example, we solicited public comment even before putting out rules around medical loss ratios, grandfathered health plans, and rate review. Similarly, CMS held public forums on wellness and exchanges to provide opportunities for public input by effected stakeholders.

The last cornerstone of our plan is to strengthen the use of regulatory analysis such as cost/benefit analysis. The secretary has asked me to establish an agency-wide analytics team to share information, make the quality of analysis more consistent across the department, and ensure the integration of such analysis into regulatory decision making to improve the quality of the regulations we promulgate.

We have also redoubled our longstanding commitment to making regulatory review an integral part of our operations and culture.

As our work continues in the months and years to come, we will rely on the four key principles I have just highlighted: increasing transparency, improving public participation, being clear about our priorities, and ensuring that analysis guides our efforts. Our department's mission is to protect the health and safety of all Americans. The plan we will be discussing today does that while promoting economic growth, job creation and innovation.

I look forward to working with you in this endeavor and am happy to answer any questions.

[The prepared statement of Ms. Glied follows:]

Testimony of

Sherry Glied

Assistant Secretary for Planning and Evaluation

U.S Department of Health and Human Services

Before the

Subcommittee on Oversight and Investigations

Committee on Energy and Commerce

United States House of Representatives

June 13, 2011

Chairman Stearns, Ranking Member DeGette, and Members of the Subcommittee:

My name is Sherry Glied, and I am the Assistant Secretary for Planning and Evaluation at the U.S. Department of Health and Human Services (HHS). I am the principal advisor to the Secretary of HHS on policy development, and I am responsible for major activities in policy coordination, strategic planning, policy research, evaluation, and economic analysis.

I am grateful to have the opportunity to appear before you today to discuss issues relating to regulation and to Executive Order 13563, "Improving Regulation and Regulatory Review." I will focus in particular on retrospective review of existing rules.

With Executive Order 13563, issued on January 18, 2011, the President laid the foundation for a regulatory system that is designed to protect public health and welfare while also promoting economic growth, innovation, competitiveness, and job creation. Executive Order 13563 provides a series of directives and requirements. Among other things, and to the extent permitted by law, the Executive Order:

- Requires agencies to consider costs and benefits, to ensure that the benefits justify the costs, and to select the least burdensome alternatives.
- Requires increased public participation and an open exchange.
- Directs agencies to take steps to harmonize, simplify, and coordinate rules.
- Directs agencies to consider flexible approaches that reduce burdens and maintain freedom of choice for the public.

As you are aware, the Executive Order also requires a government-wide "look back" at existing Federal regulations. The requirement of retrospective analysis directs agencies to review their significant rules and to decide, on the basis of that review, which of such rules should be streamlined, reduced, improved, or eliminated. One of the goals of this approach is to eliminate unnecessary regulatory burdens and costs on individuals, businesses—both large and small—and state, local, and tribal governments.

On May 18, and in compliance with the Executive Order, HHS released our preliminary plan. While HHS's systematic review of regulations will focus on the elimination of rules that are no longer justified or necessary, the effort will also consider strengthening, complementing, or modernizing rules where necessary or appropriate – including, if relevant, undertaking new rulemaking. The plan highlights regulations already being modified or streamlined and identifies additional candidates for further review.

For example:

- The Centers for Medicare & Medicaid Services (CMS) is working to address conflicting requirements between Medicaid and Medicare that potentially create barriers to high quality, seamless, and cost-effective care for dual eligible beneficiaries. By improving coordination and partnering with states, we can improve access, quality, and cost of care for people who depend on both programs.

- The Secretary is reviewing and updating the methods and criteria used to identify Health Professional Shortages and Medically Underserved Areas. The previous criteria were last established in 1978. Establishing more consistent and comprehensive criteria will allow the Department to more effectively serve some of our most vulnerable populations.
- We are looking for opportunities to incorporate modern technology into our regulations in a way that increases flexibility for states and businesses while improving people's lives. For example, the Administration for Children and Families (ACF) is encouraging states' child support programs to use cost-effective technologies like electronic signature and document storage; the Food and Drug Administration (FDA) is also going paperless with its adverse events reporting requirements for medical devices; and CMS is working to reduce the barriers to telemedicine to provide better access to care.

In order to increase public participation in this retrospective review, we are now soliciting public comment on the HHS Preliminary Plan on the www.hhs.gov/open website through June 30. Suggestions are welcome, and HHS will carefully review all comments before finalizing our plans.

Statement of Commitment to a Culture of Ongoing Retrospective Review

The Department of Health and Human Services is the principal federal agency charged with providing health and other essential human services so Americans can live healthier, more prosperous, and more productive lives. Many of its activities are regulatory in nature. Through the FDA, HHS regulates the safety of the food we eat, and the safety and effectiveness of the drugs we take to improve our health and the medical devices we rely on for diagnosis and treatment of disease. Congress also recently gave FDA regulatory oversight of cigarettes and other tobacco products to reduce youth tobacco use and the illnesses and death caused by tobacco. Medicare, Medicaid, and the Children's Health Insurance Program, run by CMS, insure roughly one in three Americans. ACF provides guidance and funds to states and territories, as well as local and tribal organizations, so they can provide family assistance, child support, child care, child welfare, Head Start, and other programs serving the needs of children and families. Offices within HHS have responsibility for oversight of health information privacy and electronic health and medical records, protection of human subjects for research, and oversight of health insurance rate review and Exchange requirements.

While regulations can establish clear and transparent frameworks for competition and economic activity, unnecessary and duplicative regulations can also damage the economy by imposing unnecessary costs on the private sector and citizens.

HHS is committed to the President's vision of creating an environment where agencies incorporate and integrate the ongoing retrospective review of regulations into Department operations to achieve a more streamlined and effective regulatory framework. The objective is to improve the quality of existing regulations consistent with statutory requirements; streamline procedural solutions for businesses to enter and operate in the marketplace; maximize net benefits (including benefits that are difficult to quantify); and reduce costs and other burdens on businesses to comply with regulations.

HHS has four goals in mind as we develop our retrospective review plan:

- To increase transparency in the retrospective review process;
- To increase opportunities for public participation;
- To set retrospective review priorities; and
- To strengthen analysis of regulatory options.

All HHS Operating and Staff Divisions (Agencies) that establish, administer, or enforce regulations are included in our plan. The types of documents covered under this plan include final, significant regulations, as defined by Executive Order 12866; significant pending proposed regulations; and significant interim final regulations for which no final rule has yet been issued.

Undertaking the Initial Retrospective Review

As the first task in the regulatory review, HHS asked each agency to inventory its existing, significant regulations to provide information that will assist the Department in structuring an ongoing retrospective review process. Specifically, each agency identified when its significant regulations were originally promulgated and when they were last modified in any substantive way and pursuant to what authority (e.g., required by statute, response to citizen petition, pursuant to regulatory review requirements of prior administrations, etc.).

Prior to undertaking review of its regulations, each agency determined what priorities it would use to determine candidate regulations for retrospective review. The priority is to identify regulations that agencies can easily modify, streamline, or rescind to address regulatory burdens or inefficiencies. Agencies will thoroughly review other regulations to determine their regulatory impact in accordance with the President's objective to develop a streamlined, robust, and balanced regulatory framework.

For many regulations undergoing an extensive and thorough review, the agency will need to conduct a sound regulatory analysis to determine whether the regulatory activity is meeting the original objectives or whether an alternative, less prescriptive, activity would achieve the same result.

Existing Retrospective Review Requirements

HHS agencies currently conduct routine reviews of existing regulations pursuant to a variety of authorities, changes in law, or other circumstances. For example:

- The Regulatory Flexibility Act requires agencies to conduct reviews within ten years of regulations that have a significant economic impact on a substantial number of small businesses.
- Congressional appropriations as well as frequent amendments to authorization statutes require review and publication of Medicare provider payment rules every year.

- Retrospective review often occurs when there is a significant change in circumstances, such as advances in technology, new data or other information, or legislative changes.
- Under 21 CFR 10.25(a) and 10.30, the FDA may review a regulation if a person submits a petition asking the Commissioner of Food and Drugs to issue, amend, or revoke a regulation.

Initial List of Significant Rules that are Candidates for Retrospective Review Pursuant to Executive Order 13563 over the Next Two Years

Along with our plan for retrospective review, HHS put out for comment a list of regulations the agencies within the Department have identified as candidates for review over the next two years. These include the following categories of regulations:

- Revisions intended to increase flexibility for the regulated community
- Revisions intended to reduce burdens
- Rescissions or revisions to streamline the regulatory process
- Revisions that may increase benefits or reduce costs
- Notices of Proposed Rulemaking (NPRMs) that may not proceed to final rules
- Interim Final Rules that may be rescinded

HHS Goals for Ongoing Retrospective Review

Increasing Transparency

Ongoing retrospective regulatory review efforts will be more effective if they are accompanied by efforts to make more information available to all interested parties, introduce clarity into the regulatory system, and provide the foundation for regulatory decisions. Executive Order 13563 places a strong emphasis on an open exchange of information among government officials, experts, stakeholders, and the public. In particular, the President refers to a process in which the exchange of information and perspectives among state, local, and tribal officials; experts in relevant disciplines; affected stakeholders in the private sector; and the public will inform an agency's proposed regulatory scheme in advance of rulemaking activity. The President also directs agencies to give the public timely online access to the rulemaking docket on www.regulations.gov, including access to the relevant scientific and technical findings on which a proposed regulatory scheme rests.

HHS will increase transparency in its regulatory process by making available, to the extent feasible and permitted by law, information that is useful for businesses, state, local and tribal governments, and the public to understand the basis of a proposed regulatory activity, especially information on the scientific or evidence-based data underpinning the regulation.

Increasing Public Participation in the Ongoing Review of Regulations

HHS intends to increase the breadth and quality of public participation in its rulemaking and retrospective review activities. Consistent with this goal, HHS published a notice soliciting

preliminary comment on certain elements HHS should consider in drafting this plan. We are now soliciting public comment on the HHS Preliminary Plan on the www.hhs.gov/open website through June 30.

All HHS agencies already reach out in various ways to obtain public input and advice on regulations subject to review and modification. For example, as one of the major HHS regulatory agencies, FDA sends bi-annual letters to state and local elected government officials asking for suggestions on its regulatory activities. These letters are also posted on FDA's website. FDA also issues a bi-annual letter for small business entities, by posting it on the FDA website and sending it to the Small Business Administration for distribution to the small business community. These two letters highlight upcoming regulations that FDA believes may have an impact on these two groups. Additionally, as part of its Transparency Initiative, FDA recently established a new webpage specifically devoted to its regulatory review activities.

As another agency with substantial routine regulatory activity, CMS also seeks input from states, providers, stakeholders, and members of the public. CMS conducts monthly Open Door Forums and provider outreach activities, and is incorporating feedback from these activities into routine rulemaking efforts for 2011. This feedback allows CMS to identify and change obsolete regulatory requirements, reduce regulatory burden, and identify information that CMS can post online concerning the performance of CMS-regulated providers and suppliers. Further, CMS posts Quarterly Provider Updates on its website so the public, healthcare providers, and our partners in the states are aware of:

- Regulations and major policies currently under development during the quarter;
- Regulations and major policies completed or cancelled; and
- New or revised manual instructions.

HHS intends to increase its efforts to promote and develop meaningful public participation. As an initial matter, HHS is establishing a Public Participation Task Force within the Department to explore ways to increase interactivity in the public comment process with respect to regulatory review and ongoing regulatory activity, including the use of podcasts, webinars, video teleconference sessions, Wikis, YouTube and other social media. Some HHS agencies already use some of these technologies to great advantage. Other agencies can usefully enhance the regulatory review and development process with increased use of these technologies. With the advice and assistance of the HHS Chief Information Office (CIO) and Chief Technology Officer (CTO), the Department will identify and develop these and other online capabilities for the public to be involved in evaluating regulations over time. The Public Participation Task Force will pay particular attention to increasing the diversity of participation and improving the ability of persons with limited English proficiency or disabilities through podcasts and other vehicles to participate in the regulations review and development process.

Additionally, HHS will ask the Public Participation Task Force to work with agencies to develop a set of principles toward increased public participation and transparency in the ongoing review of regulations throughout the Department. These principles will help agencies think about innovative ways to involve interested parties in the retrospective review process so they

can more easily react to and benefit from the comments, arguments, and information of others as they refine their own comments. Among the principles to be considered are:

- Active engagement with thought-leaders through meetings and sponsored listening sessions on specific regulatory reform proposals. Thought-leaders might include the regulated community, affected groups, academics, public interest groups, and state, local, and tribal government leaders.
- Real-time access to information for the public and business community so they can provide more immediate, real-time, feedback to the agency on specific regulatory actions.
- Involvement of outside groups who may have not been included in past regulatory review activities through the Office of Intergovernmental Affairs and the Office of External Affairs as, well as other HHS offices to increase the level and diversity of public participation.

HHS will continue to seek, consider, and accommodate public input and comment while managing different statutory implementation schedules as we move forward in implementing the Affordable Care Act. For example, CMS received and considered input from consumers, industry, states, and other stakeholders through formal requests for comment as they developed regulations on rate review and medical loss ratio. In addition, CMS, with the Departments of Labor and the Treasury, considered input from comments received in the development of regulations regarding grandfathered health plans. CMS also held a public forum on Exchanges, and jointly hosted a forum on wellness with the Departments of Labor and the Treasury to provide additional opportunities for public input by affected stakeholders. As a result of these processes and the feedback received by CMS, the regulations that have been issued to implement the Affordable Care Act have been strengthened by the views and opinions expressed by affected stakeholders. As we transition to 2014, when many provisions of the Affordable Care Act will be fully in effect, HHS will continue to work closely with all interested stakeholders and to use the transparency of the regulatory process to ensure the new law best serves the American people.

The process for seeking public input continues after the issuance of regulations, including regulations under the Affordable Care Act. Based on comments and questions received by HHS, the Department of Labor, and the Department of the Treasury on regulations issued to date, we have provided additional interpretive guidance to affected parties on regulations relating to grandfathering, Medical Loss Ratio (MLR), the Pre-Existing Condition Insurance Plan (PCIP), the Early Retiree Reinsurance Program (ERRP), internal and external appeals, and provisions relating to annual limits on health plan coverage.

Setting Priorities

The President has repeatedly stated his goal of achieving a regulatory system that is balanced, flexible, and maintains freedom of choice. Thus, it is essential that agencies reduce burdens, redundancy, and conflict, and at the same time promote predictability, certainty, and innovation in their rulemaking activities. Two things are important to achieve this goal: establishing clear guidelines for the selection of candidate regulations subject to review and reform; and the sound, robust analysis of candidate regulations to determine whether and how

the regulation might be improved or whether viable alternatives exist. Retrospective review priorities must be ultimately guided by the goals of protecting the public health, welfare, safety, and environment based on the best available science, while using best efforts to promote economic growth, innovation, competitiveness, and job creation, to the extent permitted by law. The analysis applied to the retrospective review of regulations should inform decision-makers of the consequences of any proposed action and its alternatives in order to help those decision-makers determine the least burdensome and most effective approach (e.g., maximizing net benefits) to achieving the desired result.

HHS agencies already understand the importance of setting priorities in the retrospective review process. Agencies routinely take into account the following factors when reviewing regulations under existing retrospective review frameworks:

- Whether an action will have a positive impact on innovation in an area of public health, safety, or delivery of or access to care;
- Whether the public health benefits of an action have been realized;
- Whether the public or regulated community view modification or revocation of the regulations as important and have offered useful comments and suggestions for change;
- Whether the impact and effectiveness of a regulation has changed or been superseded by changes in conditions or advances in scientific or technological information;
- Whether there are or continue to be significant, unresolved issues with implementation or enforcement; and
- How long the regulation has been in effect and whether it has been subject to prior reviews.

Agencies will continue to use and refine these factors as they implement the retrospective review called for in Executive Order 13563 and the requirements of Section 610 of the Regulatory Flexibility Act. In particular, agencies will pay careful attention to the costs and benefits of rules; to choosing the least burdensome approaches and reducing administrative burdens on the private sector as well as state, local, and tribal governments; to the need to simplify rules and harmonize overlapping rules, both within HHS or between HHS and other federal departments; to the importance of promoting flexibility for the private sector; and to scientific integrity and the development of rules based on the best available science.

Strengthening Regulatory Analysis

Agencies already use analytic tools such as cost-benefit analysis, as appropriate, in setting priorities. To buttress those efforts, the Secretary has asked me to establish an agency-wide Analytics Team to share information, make the quality of analysis more consistent across the Department, and ensure the integration of such analysis into regulatory decision-making to improve the quality of regulation. Because many resources already exist within the Department to strengthen this analytic capacity, the Analytics Team will be composed of economists and other analysts from the various HHS agencies. For example, while FDA and CMS have very different regulatory missions, it may be that one agency's approach to regulation can inform how

the other agency approaches its regulatory activity. Interagency cross pollination may offer opportunities to take advantage of existing expertise.

The Analytics Team will review existing practices, establish the protocols for review of regulations on an ongoing basis, establish best practices, and promote consistent approaches to analysis. My office will provide guidance and expertise to help the Department ensure that its regulatory impact analyses are as comprehensive as possible. ASPE is a staff office to the HHS Secretary and independent of operating divisions that draft regulations.

It is important to emphasize that while a great deal has been accomplished in a short time, our plan is preliminary. As such, it is being offered to the public for their views and perspectives. Suggestions are eagerly welcome. HHS will be carefully reviewing all comments and suggestions before finalizing our plans.

While the current retrospective review is important, Executive Order 13563 reflects a broader ambition. To protect public and private dollars, and our future safety and prosperity, we are seeking to change the regulatory culture by eliminating unjustified burdens and constantly exploring what is working and what is not, using evidence and data. Our plan emphasizes the careful empirical investigation of rules, to be undertaken in advance if possible, and retrospectively as well.

I greatly look forward to working with you in this endeavor. I would be happy to answer your questions.

Mr. STEARNS. Dr. Glied, thank you very much. I will start the questions here. What we have in the Oversight and Investigation Subcommittee is a little different. We try to get succinct answers because we are more of an investigative body rather than a legislative body. So if you possibly can, just keep your comments short. Just by background, I understand you are an economics professor at Columbia. Is that correct?

Ms. GLIED. Yes, sir.

Mr. STEARNS. Did your background include any health-related things at being an academic professor at Columbia?

Ms. GLIED. Yes, sir.

Mr. STEARNS. Did you—is this your first job working in the administration?

Ms. GLIED. No, sir.

Mr. STEARNS. What other administrations did you work for?

Ms. GLIED. I worked for the first Bush administration back in 1992 and for the Clinton administration in 1993 at the Council of Economic Advisors.

Mr. STEARNS. And was that dealing with health too?

Ms. GLIED. Yes, sir.

Mr. STEARNS. So when you walked into this job, you didn't feel like you were walking into a brand new storybook?

Ms. GLIED. No, sir.

Mr. STEARNS. OK, how does Health and Human Service identify which rules that are already on the books will be reviewed?

Ms. GLIED. We have laid out, after process of public comment, a set of principles that are going to guide which rules we want to look at. And we have also opened our plan up to the public for further comment so they can also suggest rules they would like us to look at. But the main principles that guide our decisions are situations where circumstances have changed since the rule was originally promulgated, where new technologies or innovations have come along that should lead us to change how we do something, or there has been a failure to realize public health benefits that were anticipated on passing a rule.

So for example, HRSA, the Human Resources and Services Administration, has rules that were promulgated back in the 1970s defining health professional shortage areas. That is a real priority for us to go after because it has been a long time since we have looked at those rules.

Mr. STEARNS. You indicated there might be public comment to or—

Ms. GLIED. Yes, sir.

Mr. STEARNS. —the public can submit to you rules that they think are outdated too.

Ms. GLIED. That is correct. The Web site is open for comment through June 30.

Mr. STEARNS. Once a rule is identified for review, possibly reform or elimination if it goes back to 1970, what is the next step, and how long does the process take?

Ms. GLIED. I think that we will see that as we go through each rule. Each rule will go through a careful analysis including redoing the regulatory impact, trying to assess what the impact of that rule

is, and what potential for modification or rescission of that rule might be appropriate.

Mr. STEARNS. So is it possible that you could interpret through your office a way to enforce a rule in a totally different manner?

Ms. GLIED. We have to abide by the statutory authority under which the rule was promulgated, but we could look at that rule and come up with better ways of doing it.

Mr. STEARNS. But you are saying you could also decide not to enforce it.

Ms. GLIED. Only if that would be consistent with the statutory authority under which the rule was promulgated.

Mr. STEARNS. Well, if it is on the books and it is statutory authority, how could you suddenly decide not to enforce it?

Ms. GLIED. We would have to enforce it. We might come up with a different way to enforce it, a different way to implement the authority.

Mr. STEARNS. So you would come up with a new interpretation?

Ms. GLIED. Correct.

Mr. STEARNS. Would this go to public comment?

Ms. GLIED. All of our laws do go to public comment, yes.

Mr. STEARNS. And how long is that public comment?

Ms. GLIED. There is a standard process where we might put out a notice of proposed rulemaking and seek public comment on that. I don't remember exactly how long it is. A couple of months, I think.

Mr. STEARNS. Have you identified any rules already? I mean how many rules have you identified today?

Ms. GLIED. The first part of this process was for the various agencies within HHS to identify rules that they thought were important. We have identified many rules. I would say dozens of rules already that we are looking at. In a separate and parallel effort, CMS has looked at its own ways of doing business and has identified 80 practices including rules that it is going after. So there is a large number that we are investigating.

Mr. STEARNS. So you are saying at this date you have identified, in your office, 12 rules?

Ms. GLIED. No.

Mr. STEARNS. You said dozens.

Ms. GLIED. More than dozens. More than a dozen.

Mr. STEARNS. More than? So would you say 48 or 24?

Ms. GLIED. I don't have the exact number before me, and we are waiting for public comment to get more rules in. So we anticipate that we will get quite a few.

Mr. STEARNS. Anybody on your staff that could tell you how many rules you have identified so far? Just approximately.

Ms. GLIED. Probably——

Mr. STEARNS. Are we talking about 10?

Ms. GLIED [continuing]. 20, 25 so far.

Mr. STEARNS. Twenty? Twenty-five, OK.

Ms. GLIED. I am not—I don't want to be, you know——

Mr. STEARNS. No, I am not going to hold you to it. It is just a round figure.

Ms. GLIED. And we are waiting for public comment to get many more.

Mr. STEARNS. Of any of those 25, have you decided not to enforce any of those 25?

Ms. GLIED. We haven't—no, we have not decided not to enforce any of them. We are looking at ways to revise them. For example, to recalculate how we would determine to help professional shortage area or to change the way we use symbols and device labeling at FDA.

Mr. STEARNS. And so the criteria—I would like to understand how you decided to select those roughly 20 rules. How did you single those out? Was it age on the books or based upon implementation not working, or is it based upon not clear? What—

Ms. GLIED. We laid out five, a series of criteria including that there were new technologies, that there had been changes——

Mr. STEARNS. Which you mentioned earlier.

Ms. GLIED. Right, the ones that I had mentioned earlier.

Mr. STEARNS. Those are the criteria you mentioned earlier.

Ms. GLIED. So we looked at them. We asked all of the agencies to look at the rules on their own books to see ones that made the most sense to modify where they had opportunities to modify those rules and see that it looked like it was important. And now we have opened it up for public comment so that other people can also tell us where they think we should be looking.

Mr. STEARNS. It seems to me that, you know, the executive branch issued this executive order to look at these rules, but as I recollect, it is already on the books that HHS should be doing this on a regular fashion. Isn't that true?

Ms. GLIED. That is true. There are several authorities under which we already look at rules, the Regulatory Flexibility Act.

Mr. STEARNS. So would it be fair to say that the executive order really wasn't necessary because the legislation is already on the books to do exactly what you are doing, and it wasn't necessary for the executive order to be issued?

Ms. GLIED. We have routinely within the department looked over our rules, and we—even before the executive order came forward, we had rules that we were working on. But the executive order does tell us to prioritize this activity, and that is what we have done.

Mr. STEARNS. In your plan, it says "the priority will be to identify regulations that agencies can easily modify, streamline, or rescind to address regulatory burdens or inefficiency." You feel this is strong enough?

Ms. GLIED. I think those make sense as a criteria for us to look at, yes.

Mr. STEARNS. And you are saying one of your criteria is to take and prioritize regulations that are easiest to fix. Wouldn't also you determine what is the most impact?

Ms. GLIED. Of course, you want to look at both——

Mr. STEARNS. I mean I would think that that would be the criteria rather than easiest to fix because you might be putting a parentheses somewhere, and that is easiest to fix. But it really is a meaningless regulation. Whereas you might have a whole set within that 20 that has huge impact, that would impact constituents.

Ms. GLIED. As you know, Chairman Stearns, we want to weigh the costs and benefits of everything we do, including which regulations to pick. The ones that are——

Mr. STEARNS. Do you actually weigh the cost benefits?

Ms. GLIED. Yes.

Mr. STEARNS. Do you do an economic analysis?

Ms. GLIED. We do. For any regulation we put forward, we do an economic——

Mr. STEARNS. Even if it is easiest to fix?

Ms. GLIED. Well, if it is easiest to fix, the cost of repairing it are very small, and that has to be taken into account. So we take into account both what can be done easily and what is most important to do, and both of those things need to be weighed.

Mr. STEARNS. Now, I am sure this is pretty easy to understand for you. Aren't the most burdensome regulations the ones that are most complex? Is that a fair statement?

Ms. GLIED. Not necessarily, Chairman. Sometimes there could be very burdensome regulations that are very simple.

Mr. STEARNS. Let me give you an example. Under the President's health care plan, this is a regulation that those covering medical loss ratios—and I have talked to insurance companies about this—accountable care organizations and grandfathered health plans, these are pretty complex rules. Wouldn't you agree?

Ms. GLIED. Some of them are complex, yes.

Mr. STEARNS. OK, yet your plan says that that complexity on important rules would make it not a priority for your review. That is what we understand. That because of the complexity of it, you have not done a review. Yet everywhere I go, people are talking about medical loss ratio, how complicated it is and the impact it is going to have. It seems like that one would be one you would look at together with, as I mentioned, the grandfathered health plans, what that means in accountable care organizations.

Ms. GLIED. So, Chairman, you have spoken about three of our very important regulations under the Affordable Care Act, which promulgate regulations to really put forward a change in the U.S. health care system that I think is very important. Those regulations have only very recently been passed. So we are not going to look at them not because of their lack of complexity, but because there has been no change in circumstances. There have been no new technologies or innovations. There is really not much that has changed since we promulgated those rules that would lead it to make sense from a—to look at them again within this short period of time.

Mr. STEARNS. We both agree that you would look at burdensome regulations if they had a huge economic impact. I think you said you would.

Ms. GLIED. We have just completed doing the economic impact analysis of those regulations. So we have already weighed their benefits and costs and shown that their benefits considerably exceed their costs.

Mr. STEARNS. Well, if I identified—let us take medical loss ratio—as having huge economic impact, is it safe to say that you are going to look at that regulation in detail and allow public to comment on it in the very near future?

Ms. GLIED. Chairman, that regulation was actually developed after an extensive period of public comment, and we had assessed the cost and benefits. We estimate that the cost of that regulation for insurers are on the order of $100,000 per insurer for insurance to set up the plan and $25,000 per insurer to continue maintaining the plan over time. And then it is going to generate $3 billion in benefits to American consumers over the period from 2011 to 2013. That is a great benefit/cost ratio.

Mr. STEARNS. Now those analyses that you did are within—your department made those projections, right?

Ms. GLIED. That is correct.

Mr. STEARNS. That was not done by an outside accounting firm or an outside economic group? It was done by your people, right?

Ms. GLIED. As with all regulatory impact analyses, those are conducted within the agency and reviewed by OIRA.

Mr. STEARNS. Have you actually sat down with the people that have been impacted, insurance companies? Do they agree? Because I heard—I have not heard any of them think that it is just going to cost $100,000 plus the very small figures that you—none of them have told me that. So I don't know where you get your figures.

Ms. GLIED. Chairman Stearns, the rules for the medical loss ratio were actually developed by the National Association of Insurance Commissioners, which is an organization of all the state insurance commissioners from around the country. They are the ones who developed these rules, and we worked on the regulatory impact analysis in conjunction with those rules that that had developed.

Mr. STEARNS. Well, as you know, between the cup and the lip, if you develop a regulation based upon someone else, there could be some nuisances of parse language. Because the insurance companies are not coming back, at least to this member, and feeling the costs are so diminutive that you pointed out. Let me go to another series of questions here. I think I have the opportunity to speak a little longer. I assume that there is no one on the Democrat side, and I am sure they would want me to use my time as wisely as I could so that I will continue. Dr. Glied, if you don't mind, we will—I will be glad to—if another member shows up, I would be glad to—I am told Mr. Waxman might come back. I hope he will. He had very good questions to offer you too.

Dr. Glied, you have released your preliminary plan for retrospective review of existing rules. Is that correct?

Ms. GLIED. Yes, sir.

Mr. STEARNS. This is a retrospective plan though. Is that correct?

Ms. GLIED. This particular part of the plan is retrospective, yes

Mr. STEARNS. Because it only looks backwards.

Ms. GLIED. Many of the principles in the plan are also encapsulated in existing HHS practices, so the President actually specifically called for retrospective review. But we actually have implemented those principles both going prospectively and looking the regulations we are about to promulgate and concurrently, the regulations that we are working on right now as well as retrospectively, sir

Mr. STEARNS. That is a pretty good answer. You have it both ways there. Of the 20 regulations, how many of those are retrospective and how many...

Ms. GLIED. But those are retrospective. That is part of our retrospective review plan, but we are engaging...

Mr. STEARNS. Do you have any prospectively?

Ms. GLIED. So prospectively, we are working on many regulations right now, and we have already implemented those efforts by, for example, increasing the transparency with which we put forward those regulations, by putting them up on our Web sites in a much more easy to access way, and by getting public comment even before we start the rulemaking process

Mr. STEARNS. It is interesting with the passage of the President's health care plan, there is so much regulation that involves moving prospectively forward. And so yet you are talking at this point of retrospective. So I guess the question is how would your office address prospectively all of the regulations from the President's health care? Because as this is presented and enforced every year, there is going to be much complexity and much angst.

As you saw the graph I showed, small, medium, and large businesses, particularly small businesses have decided, almost 80 percent in the next 2 years, they are going to give up their health care plan, and they are going to go to the government option. So you see the angst is out there. So I guess the question is how does your plan address these prospective regulations that are all part of the President's new health care plan?

Ms. GLIED. Sir, the Affordable Care Act offers great new opportunities for small businesses. As you know, they are already eligible for tax credits, and they will be able to buy insurance on much better terms. We can really level the playing field once those exchanges get going.

As we develop those plans to get the exchanges going to move into 2014, we are soliciting a lot of public comment, both in advance of rulemaking and as part of the rulemaking process, including a lot of public comment from small businesses, from providers, from insurers, from all affected groups.

Mr. STEARNS. Dr. Glied, I think that what you can hear from me is, based upon the graph I showed you and the angst that is out there, that retrospective is fine, but there is a huge, burdensome number of regulations that are being implemented as we move forward. And I just—I think on this side of the aisle, we would certainly like to feel that you are using your general principles that you mentioned in your opening statement are being applied to the rules from—for the President's health care.

So that in addition to looking at rules that are obsolete, not effective, burdensome, complex, that same thing applies in probably a larger sense based upon what we see and the statistics and based upon that graph, that we would urge you to also concentrate and focus your energy on the President's health care plan moving forward.

With that, my time is expired, and we recognize the gentleman from California, Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman. Dr. Glied, regulations have two sides to them. There are downsides because we are re-

quiring some industries to have to do something often or regulations mean we are regulating certain activities. But there is an upside to it, and sometimes we don't hear about the upside, especially in this committee. For instance, there are estimated 19.4 million children living in this country with preexisting conditions. Until last year, it was perfectly legal for insurance companies to discriminate against these children, issuing riders that excluded coverage for critical medical problems or refusing to cover these children at all.

And when the Republicans said they wanted to repeal the ACA and then replace it, I would have thought they were saying they were going to replace some of these very same provisions. Otherwise, what are they doing to help children and families, Americans that can't get insurance because they are being discriminated against?

Is it true that extending coverage to children with preexisting conditions provides benefits to the children, their families, to the country as a whole?

Ms. GLIED. Yes, sir, it certainly does, and I think it also improves the efficiency of our economy because my providing coverage to children with preexisting conditions, we make it easier for their parents to choose the right job for themselves and to really seek employment opportunities that might not otherwise be available to them.

Mr. WAXMAN. Now, HHS has also issued regulations to end the lifetime caps on coverage, prevent insurance companies from using decades-old paperwork errors to justify canceling someone's insurance as soon as they get sick. These practices also have costs. They may cut into the insurance industry's bottom line. But, Dr. Glied, in issuing regulations that ban the practices, did HHS determine that such bans would have significant benefits?

Ms. GLIED. They certainly did. We certainly did. In fact, the estimates that those consumer protections and the patient bill of rights would increase insurance premiums by 4/100ths of 1 percent—between 4/100ths of 1 percent and 2/10ths of 1 percent, a tiny increase in costs. And in exchange for that, all Americans would get reliable valuable coverage. And about 25,000 people who already exhausted the lifetime limits in their coverage would actually have meaningful insurance for the first time.

Mr. WAXMAN. We hear a lot about burdens on industry from our Republican colleagues, but I think a conversation about HHS regulations, their focus is exclusively on costs borne by the insurance industry is dangerously misleading. To understand the real impact of regulations, we have to consider the health benefits and cost savings offered to consumers as well. And I assume that HHS considered the full range of both costs and benefits in issuing these regulations?

Ms. GLIED. Yes, sir, we did.

Mr. WAXMAN. Many of my colleagues on the other side of the aisle have raised concerns that these regulations, under the affordable care act, were not subject to retrospective review that HHS conducted. In the executive order issued in January, President Obama cited a number of principles of regulatory review. The President required regulations to be proposed or adopted only when

benefits justified costs. He asked for regulations to be tailored to impose the least burden on society. Then he called for regulations to be adopted through a process that involves public participation.

Dr. Glied, I would like to ask you some questions about regulations issued under the Affordable Care Act and the manner in which they were promulgated. Did the department issue regulations under the ACA only when it found the benefits of a rule outweighing the costs?

Ms. GLIED. Yes, sir, we did.

Mr. WAXMAN. Can you provide some examples of regulations issued under the Affordable Care Act where the benefits outweigh the costs?

Ms. GLIED. Well, for example, the regulation that requires that insurers allow young adults up to age 26 to remain on their parents' insurance coverage is estimated to increase premiums by about 1 percent for families and to cover over a million young adults, up to a million young adults. And that will improve the earnings of those young adults, reduce uncompensated care, improve job mobility within the American economy, so the benefits are enormous.

Mr. WAXMAN. In his executive order, President Obama emphasized the importance of public participation in the rulemaking process. He wrote "regulations shall be based to the extent feasible and consistent with the law on the open exchange of information and perspectives among state, local, and tribal officials, experts in relevant disciplines, effected stake holders in the private sector, and the public as a whole." Dr. Glied, can you explain how HHS incorporated public participation into the ruling making process under the Affordable Care Act?

Ms. GLIED. Yes, sir. As you know, the rulemaking process has periods of public comment built into it, but we went well beyond those required periods of public comment and actually solicited public comment even in advance of beginning our rule making around the medical loss ratios, rate review exchanges, and so on. We held open forums around external review and co-ops. We have been very proactive in getting out there and asking stakeholders to give us their views.

Mr. WAXMAN. Well, I know that the Republicans have a fervent opposition to the whole law, but I hope that that doesn't cloud their ability to thoughtfully examine the administration's steps to apply executive order principles to the health reform regulatory process. I know that they would want those principles applied to all regulations, which is what the President intended in opposition to a certain law. It is the law. Shouldn't affect their appreciation that the department, in your case of HHS, has tried to keep within the President's executive order in following the regulatory procedures that would weigh the benefits and the costs and do what is best after full participation of all the parties in establishing those regulations.

Thank you, Mr. Chairman. I yield back my time.

Mr. STEARNS. I thank the gentleman. We recognize the gentleman from Louisiana, Mr. Scalise, for 5 minutes.

Mr. SCALISE. Thank you, Mr. Chairman. If I could, I would like to ask a little bit about the waivers that have been issued for

Obamacare. We had a hearing on the issue in general. A lot of unanswered questions regarding the number of entities, both businesses and labor unions that have requested and received waivers. A lot of unanswered questions about who has requested and been denied waivers. So first if you can give me kind of the broad brush of the administration's policy on this. How long have waivers been granted? And can you further expand on who has not been granted waivers and why?

Ms. GLIED. So the criteria that we use for providing waivers around the annual limits within the Affordable Care Act, and those waivers are waivers that allow farms in the short run as a bridge to when we provide people with much better coverage in 2014, to continue to have plans that have annual limits in them.

So the waivers allow plans to maintain those annual limits just until 2014. We have—the criteria that have been established to grant waivers are up on the HHS Web site and are available, as is the complete list of all of the entities that have been granted waivers. And, sir, fewer than 10 percent—sorry, fewer than 2 percent of the health insurance market has been—is in plans that have been associated with waivers. So the waiver——

Mr. SCALISE. How many—if roughly 1,400 entities have been granted waivers, those are the most updated numbers I have. I don't know if you have more updated numbers. I think 1,372 entities, employers, unions, other entities have been granted waivers. What numbers do you have?

Ms. GLIED. Those are the numbers. I am not familiar with other numbers, sir.

Mr. SCALISE. OK, so you would say that that is a fair number to use?

Ms. GLIED. I believe so.

Mr. SCALISE. And that is who have been granted. Do you know how many have been denied, who have requested a waiver but have not been granted it?

Ms. GLIED. I believe the list of entities that requested waivers and were denied them was actually given to this committee. So you actually have those.

Mr. SCALISE. OK, and I will pull those if they are here. When you talk about fewer than 2 percent, have—I guess that is of all the companies that provide health care for their employees, fewer than 2 percent of the companies have been granted a waiver?

Ms. GLIED. Less than 2 percent of the market is affected by these waivers, yes.

Mr. SCALISE. Yes, and when you say affected, this gets, I guess, into the bigger question. You know when I talk to small business owners, and this last week we had a district work period. And again I was meeting with small businesses throughout my district, and I hear this from other colleagues of mine. Small businesses I talk to, they don't even know that there is the ability to go get a waiver. Many of these companies you talk to are struggling right now with how they are going to comply with Obamacare. One thing they do know is that it is going to be very difficult for them to comply, and they still don't know what all the rules and regulations are because there are still many rules and regs still yet to come out.

But what they do know from what they have already seen and what they have calculated, it is going to be very difficult for them to comply. And when I ask them about this waiver process and talk to them about the nearly 1,400 entities, many of whom were ironically entities that were asking for the bill to be passed. I mean you get groups like AARP, a lot of these organized union groups who were up here at the Capitol saying we need this law. It is going to be so great. And then they went and kind of got this secret deal with the White House to get a waiver.

A lot of these small businesses that didn't want Obamacare in the first place don't even know you can go get a waiver. So, you know, was this kind of some secret memo that was leaked? I mean why is it that our small businesses, who are on the front lines of creating jobs in America, who many of whom can't go and create new jobs because of this law and other regulations like it, they don't even know that this process is out there.

When I tell them about it, they say look, I would love to get the waiver. And of course, you know, they are not even aware of it. I direct them, you know, to go apply. I would love everybody to be able to get a waiver from the entire law, meaning repeal of the law. But, you know, can you tell me what process you all use to promote it? Because it seems like a lot of the administration's friends know about it and got the waiver, and a lot of small businesses across America don't even know it exists.

Ms. GLIED. The waiver process is—the information of the waiver process is publically available on our Web sites. And I think insurers particularly are very well aware of it. They are the ones who are selling the policies to small businesses that have the annual limits, if they have annual limits in them. Remember that the waiver is only applicable to 1 piece of the Affordable Care Act.

Mr. SCALISE. Right, I mean it is an important piece of it though, and it is a piece that many employers seem to have a problem with compliance on. In many cases, it is going to be yet another determining factor on whether or not these employers can continue to provide health care to their employees, and their employees like the health care plan.

Ms. GLIED. So it is providing—the annual limit regulation means that the health insurance that people buy actually has real value to them if they get sick. And the annual limit waiver process is simply a bridge to allow people to keep that coverage only until 2014 when we will have a much better insurance system available, particularly to small businesses.

Mr. SCALISE. Well, they are already paying higher premiums, but hopefully we don't have Obamacare on the books anymore, but it just seems like there was a favoritism that was shown because, like I said, ironically a lot of the companies and entities that have received the waivers were many of the same that were working with the administration to pass the law, and many of the people, our small businesses, our job creators across the country who didn't want this in the first place, don't even know it exists.

So, you know, again it just seems like a real peculiar situation that seems like some of the biggest proponents of the law and the favorites of the administration are the ones who know about it and

got the waivers. People who don't want it don't even know it existed. I yield back.

Mr. STEARNS. I thank the gentleman. I will continue with my questions. Mr. Waxman made some points in his opening statement. I thought I would follow up, Dr. Glied. He referred to the ban on preexisting exclusions for children. Are you aware that since passage of the President's health care plan, many insurers have opted not to offer child-only policies? So because of what the regulation says, they are getting around it by offering no child policies. Did you know that?

Ms. GLIED. I think it is horrifying, Chairman Stearns, that any insurer would choose to deny providing coverage to children who are sick, and I think it is one of the reasons that we needed the Affordable Care Act in the first place. Beginning in 2014, these practices will not be possible, and insurers will be providing insurance to all Americans.

In the meantime, the administration has taken serious steps to make sure that children who have been denied coverage because of insurance company practices can get it within every state.

Mr. STEARNS. So how would, for example, in the State of Florida, if the insurance company did not provide it, how would a person get it for their child?

Ms. GLIED. Chairman, I will have to get back to you about the details in Florida. Different arrangements have been made in different States.

Mr. STEARNS. Let us take your State of New York. How would you do it in New York?

Ms. GLIED. There is not a problem in New York because we have community rating and guaranteed issue already.

Mr. STEARNS. So a person would just apply?

Ms. GLIED. Yes, there is no problem in New York.

Mr. STEARNS. This whole question—we wrote a letter to Mr. Waxman, in all deference to him, last year, asking for a hearing on this. We never heard back. So he is making a point about this, but I just want to make it clear that we are on record of asking for a hearing on this.

He also mentioned that the ban on annual limits. This obviously could lead to increases in the premiums or loss of coverage. Don't you agree?

Ms. GLIED. Mr. Chairman, the basic economics of insurance that says insurance is most important and most valuable to people when it protects them against catastrophic losses, that is very high losses. Insurance that includes annual limits doesn't meet that basic economic test for value. It is really critical that we get rid of those lousy policies.

Mr. STEARNS. Mr. Scalise mentioned the waivers. These waivers are only good for one year, right?

Ms. GLIED. Correct.

Mr. STEARNS. So these 1,400 people that got waivers, McDonald's, Waffle House, seven States, they are all going to have to come back in a year, right? Would you be giving them waivers again?

Ms. GLIED. I believe that the annual limit waiver process is under discussion right now. I am not aware of where it is going.

Mr. STEARNS. But isn't the reason why you have these annual limits—this is why you have annual limit waivers. Is that correct?

Ms. GLIED. The reason we have annual limit waivers is that we need to get from here to 2014. These provide a bridge until people can be assured of better, more valuable insurance coverage.

Mr. STEARNS. When you passed legislation and you suddenly give out 1,400 waivers, what does that—wouldn't that tell you something about the angst, the feeling of the people who are asking for those waivers, they can't comply? Don't you think that that shows that perhaps—and as Mr. Scalise said, I don't think anybody in my congressional district knows they could get a waiver either. So if you really put the word out, I think you would find thousands of people asking for waivers.

Ms. GLIED. That would be very disappointing, Chairman Stearns, because it would suggest that the magnitude of the problem of really lousy insurance policies in the United States is much greater than we had anticipated.

Mr. STEARNS. That is funny. I would interpret it different. That is your—my interpretation is people do not want the President's health care plan, and they can't comply with the existing strategies and objectives that are outlined in your legislation, and they want out. Because if they thought it was going to be something they could comply with, they wouldn't ask for a waiver. And in fact, the graph that we showed you clearly shows the most—that small businesses, 80 percent, and going to get out and just say forget it. We are not going to be bothered. We will just pay a fee and just let all our employees go into the government plan. So that is my opinion.

Anyway, let me ask you another question. The key to this whole health care debate is what is the essential benefits package. That, I think, people have been asking me. What is the essential benefit package? And everybody is talking generalities. But what is the administration going to require, and what is the rule? Are you familiar with the rule yourself?

Ms. GLIED. Yes, sir.

Mr. STEARNS. And when will it be released? What date?

Ms. GLIED. Sir, we are waiting for the Institute of Medicine, which was commissioned to do a duty to provide us with principles for determining the essential benefits package. And that report from the Institute of Medicine, which is this expert group, is not expected until late September. Beginning then, we will be working on developing the notice of proposed rulemaking that will include the principles around that.

Mr. STEARNS. Within the legislation, they had sort of outlined what the essential benefits package. So here we are sometime after the passage, and yet you are saying that the essential rule will be released in September of this year. Is that fair to say?

Ms. GLIED. The Institute of Medicine—so the President's plan says that all Americans should be guaranteed a package that includes 10 critical categories of benefits——

Mr. STEARNS. Right.

Ms. GLIED [continuing]. And that is similar to that offered to a typical—by a typical employer today. So that is a very basic standard of benefits that all Americans should be entitled to.

Mr. STEARNS. So it has to be 10? It couldn't be 11?

Ms. GLIED. There are 10 categories——

Mr. STEARNS. 10 categories.

Ms. GLIED [continuing]. That have passed.

Mr. STEARNS. But there could be more categories, or is 10 the——

Ms. GLIED. It says that there are at least 10 categories that are laid out——

Mr. STEARNS. At least, OK.

Ms. GLIED [continuing]. In the legislation.

Mr. STEARNS. OK.

Ms. GLIED. Those are things like hospital benefits, pharmaceutical benefits, things like that.

Mr. STEARNS. Right.

Ms. GLIED. Those are the categories. We have asked the Institute of Medicine, which is an august body of experts, to help us in defining a process for developing those benefits.

Mr. STEARNS. All right.

Ms. GLIED. They have been meeting for 6 or 8 months——

Mr. STEARNS. No, I understand.

Ms. GLIED [continuing]. And have had a lot of public——

Mr. STEARNS. It is——

Ms. GLIED. It is a very challenging project.

Mr. STEARNS [continuing]. Challenging.

Ms. GLIED. But we are trying to get to get as much information as possible.

Mr. STEARNS. And not everybody is going to be in agreement on these 10 essential benefits. I understand that, but I would just like to pin down a date. Can I say by 15 September this rule will be released?

Ms. GLIED. No, sir, we are waiting for the——

Mr. STEARNS. How about 15 of September next year?

Ms. GLIED. The Institute of Medicine is coming back in——

Mr. STEARNS. Well——

Ms. GLIED. Wait, the—pardon me. The Institute of Medicine is coming back in September. Then we will go into the rulemaking process. We are likely to put out a notice of proposed rulemaking. Then, of course, you would want us to wait for public comment on that before we finalize the rule.

Mr. STEARNS. And public comment would be 60 days?

Ms. GLIED. It will be—I don't know how long it will be. I believe that there is a minimum, and I confess. I apologize. I don't know what that minimum is. It can go longer than that.

Mr. STEARNS. No, I understand, but let us just try to come up with a timeline. You are saying the report, this analysis, this study will be done by September.

Ms. GLIED. At some point in September.

Mr. STEARNS. And then after September, they will issue a rule within 30 days, 60 days?

Ms. GLIED. I don't exactly know. I am not privy to what exactly the timeline is.

Mr. STEARNS. Get a rule for——

Ms. GLIED. We are working on that rule.

Mr. STEARNS [continuing]. Before next year?

Ms. GLIED. We are working on the development of that rule, and there was be a notice of proposed rulemaking that will go out and that will lay out that and other elements.

Mr. STEARNS. So when you sit in a meeting and you talk about the most important aspect about the President's health care bill, what the essential benefits package is, no one ever says there is a drop dead date when we have to get this done? No one ever says that in the meeting? No one ever says we should get this done by X time? They just say we will just do it when we do it? Generally in planning of something of that magnitude, there is generally a timeline. You and I both know, and I think you would respect the fact, in your position, you would come up with a date. Let us shoot for this date, but you are telling me there is no date. There is no one that has asked the question what is the drop date, and you are just sort of winging along month after month?

Ms. GLIED. We know that we need to give this information to States and exchanges so that they can lay out——

Mr. STEARNS. What date do you have to give it by?

Ms. GLIED. The exchanges need to be up and——

Mr. STEARNS. Anyone on staff could tell us what date you expect to give it to the States?

Ms. GLIED. I don't think that there is a date that has been written down. We are trying to figure out when we can do this, and there are a lot of issues that are pending right now.

Mr. STEARNS. It is a little puzzling, don't you think?

Ms. GLIED. The key here, I think, sir, is that the basic structure of the plan is very much defined in the legislation itself which calls for it to mimic a typical employer plan. So there isn't that much leeway here. We are trying to lay down the specifics of this and many other provisions in the law through regulation, and this is one of them.

Mr. STEARNS. You are building a ship, and you got 10 aspects, categories of the ship that have to be built, and they have to be coordinated and everybody agrees upon it. But I will tell you, there is a date when that ship expects to be done, when that ship is complete and everybody knows it. So you are telling me here that the essential benefits package, no one in your office, no one in any meeting has ever said to you when there is going to be a date when we can provide, one, for the public comment, two, hopefully for the States to comply. You can't have it——

Ms. GLIED. Sir, I believe——

Mr. STEARNS [continuing]. 2014.

Ms. GLIED. I am aware that the noticed of proposed rulemaking which will include the essential health benefits is supposed to come out this fall. I don't have an exact date when in the fall.

Mr. STEARNS. OK, I mean you are not going to go through a trap door if——

Ms. GLIED. No, I don't know exactly what date it is in the fall. It is——

Mr. STEARNS. Because this trap door doesn't exist. All you have to do in your best estimation——

Ms. GLIED. It will be in the fall though.

Mr. STEARNS [continuing]. As the crowning chief here is to give us a little date.

Ms. GLIED. Fall, the fall. When in the fall? I don't know.

Mr. STEARNS. OK, the leaves turn in October.

Ms. GLIED. The leaves turn in October. It is likely to be in October.

Mr. STEARNS. OK.

Ms. GLIED. It could be in November, sir. There you go.

Mr. STEARNS. So we are going to say in October is when the rule will be released. Now, if you come back——

Ms. GLIED. It may be November. I don't want to be held to October, sir. I don't know.

Mr. STEARNS. Now, if I was a businessman and I felt that I wanted to work with you——

Ms. GLIED. Yes, sir.

Mr. STEARNS [continuing]. This uncertainty that you are creating by sort of double taking on this date provides me a feeling that I better not do anything until I start to see this essential rule. So you are an economics professor. You and I both know that uncertainty in the marketplace is not a good thing. Isn't that correct?

Ms. GLIED. That is correct, sir.

Mr. STEARNS. So you are creating uncertainty by giving us such a nebulous span here of you are not sure of a critical aspect for the rule to be released on the essential benefit package. So I would just suspect that if I went back to your people, you could say look, why don't we give the Oversight and Investigation Committee the best guess of what we can do because that would be better certainty than you are giving me today.

Ms. GLIED. I will be very happy to go back and see if we have a date that we would be able to give to the Oversight Committee.

Mr. STEARNS. Now, during this process here, are you going to meet with stakeholders?

Ms. GLIED. Yes, sir. We actually have an extensive plan for public comment. That is one of the reasons we want to get the NPRN out.

Mr. STEARNS. What individuals in the administration has HHS discussed this rule with, if any?

Ms. GLIED. Within the administration?

Mr. STEARNS. Yes, in other words, I assume these 10 categories, that you are talking to other people within HHS about these. I mean who is this cadre that we are talking with?

Ms. GLIED. Well, the 10 categories, of course, are laid out in the legislation itself as is required...

Mr. STEARNS. I know the categories are, but how about the people?

Ms. GLIED. And we have already done work. We have released, for example, a report from the Department of Labor looking at what typical employer plans include.

Mr. STEARNS. I am not being too clear on the question. When the FCC came up with the broadband plan, they went out and brought all these stakeholders in to help them write it. We didn't like some of it, and then they paid them money. And they also had staff, but you are not doing that.

Ms. GLIED. No——

Mr. STEARNS. You are not bringing in stakeholders to help you write the essential benefits package. You all are doing it in house.

Ms. GLIED. No, sir. That is actually one of the reasons we went to the IOM. The IOM is actually already engaged in a long period of public engagement.

Mr. STEARNS. Who is the IOM?

Ms. GLIED. The Institute of Medicine.

Mr. STEARNS. OK.

Ms. GLIED. They actually held two large public meetings back in January and April. They are——

Mr. STEARNS. Will they be writing the rule?

Ms. GLIED [continuing]. Eventually going to be—they will be providing us with this process. We will then be working on the rule. We will be engaging stakeholders. We are actually developing a plan for actively engaging all types of stakeholders. Then we will release an NPRM and get even more stakeholder comment.

Mr. STEARNS. OK.

Ms. GLIED. This is actually anticipated to be a very public process, but we have to wait for the IOM report since we did commission it.

Mr. STEARNS. OK, my time is expired. The gentleman from California, Mr. Bilbray, is recognized for 5 minutes.

Mr. BILBRAY. Thank you. Look, Doctor, I would like to try to do something very unique in the Oversight hearing process. I would like to work with you to come to a consensus of a strategy we should go to. Rather than talking about stakeholders to, you know, someone to the left means political activist stakeholder. Somebody to the political right means business community. Let us talk FDA, and let us talk about real stakeholders, patients, people who are ill——

Ms. GLIED. Yes, sir.

Mr. BILBRAY [continuing]. People who are dying, people who are waiting patiently for something to save their lives. Let us take a look at something that I think all of us can agree was a bipartisan effort that probably did—was more of a medical movement or success than anything we have seen probably since polio, and that is in the '90s. We not only put massive amounts of research out there, but we changed our FDA oversight and regulatory guidance for AIDS. We did things to fight the AIDS epidemic that we basically hadn't done in the past, at least the near past, and we haven't done since as far as I know.

And sadly, I think what happened was we were so successful that we walked away from that success and said OK, we have really done a great breakthrough here and pat ourselves on the back. But we left it at that. And this is what my challenge would be to you. What is the possibility of Democrats and Republicans getting together, taking a look at what we did in the '90s to put AIDS in that situation, move it from acute to a chronic, basically make it a livable, survivable process?

What is the possibility of us going back and saying damn it, we had a successful formula here? Why don't we go back and take a look at that? And one of the most important successful formulas was not one of you got to have a bureaucracy that is totally insulated from the private sector so they are not polluted by capitalism. Or we have to have somebody who has some reality and connection to the industry so they know the physical movements.

And let me tell you something as somebody who comes from local government, a former mayor and county chairman, building inspectors are required to have had private sector involvement. And that is one of the most successful local government aspect. But that aside, I think the one place we should be able to agree is that we should be looking at implementing the stakeholders' place at the table with all of these FDA reviews, not just on AIDS.

And what is the possibility, do you think, of the administration working with us at modifying the FDA process at least—maybe it is some targeted issues. Maybe we talk about cancer. Maybe we talk about diabetes, but changing the oversight process to allow patients, not advocates, patients at the table like we did with AIDS. What is the possibility of us resurrecting that model and applying it as being the happy medium, some place the Democrats and Republicans can agree on?

Ms. GLIED. That sounds like a very interesting idea, and I am actually not very familiar with the FDA is doing now to enhance patient engagement around medical innovation. I know that they have—they are working very hard to try and improve the speed and innovation process on several different fronts. But I am not actually sure how much patient engagement has played a part in that.

Mr. BILBRAY. OK, let me just tell you——

Ms. GLIED. I will get back to you on that.

Mr. BILBRAY. Doctor, if there is any place that I think the administration really is very vulnerable, and I praise the administration on—secretary of energy. I praise him what I think has been—you know, praise him about the team he put together for national defense. But if you look at the timelines since this administration has taken over—and granted it might be a timeline that started a little bit before this administration.

Patients are watching the clock slow down. They are watching it so much to where we end up with what happened this week where you had the First Lady, rightfully so, point out that obesity is a major crisis here. And at the same time, the FDA telling a drug company that may have a major breakthrough in obesity, we are going to require you to go 60,000 test site number, and they are just basically saying forget it. They are packing up and going to Europe.

At the same time that our system is doubling in certain applications, Europe is reducing their numbers with no more adverse impact. So if I can say frankly to you, I think we are in crisis at the FDA, and I am trying, rather than just screaming bloody murder about patients waiting, you know, on a death list, while the bureaucrats are fiddling. Why don't we take a look at, OK, let us go back and maybe we can both work together and learn from the past and move it forward.

Ms. GLIED. You know, the FDA has to balance patient protection and trying to take care of patients in need, and I understand that you know that too. Let me get back to you on some ideas that we have.

Mr. BILBRAY. OK, my biggest point is this. As somebody that has worked 35 years in bureaucracy, I don't care if it is FDA, I don't care if it is a planning director, I don't care if it is somebody put-

ting up stop signs. It is much easier to say stop than it is to say go. There is risk at go. The fact is the bureaucrat doing the oversight isn't at risk when he says stop. The patient who is dying of cancer, who is dying of AIDS, they are at risk, and they should be able to sit at the table and be able to look the bureaucrat in the eye, like they did on AIDS.

Ms. GLIED. Let me get back to you on what is happening on the FDA because I am just not very familiar with that, sir.

Mr. BILBRAY. OK, then I will ask that we look at this and bring in some balance, and I think that we have to understand there isn't balance now. As long as you have somebody who is coming out of the government structure and has no personal vested interest in the outcome, you are going to have it.

Now, some people say business there would have too much financial vested interest, but I think we should both agree that patients have the right type of vested interest. And so they will encourage and, let me say, force the process to be more responsive without it opening itself up to being abused by the private sector. And I hope they will leave that as an open invitation.

Ms. GLIED. OK.

Mr. BILBRAY. Thank you. I yield back, Mr. Chairman.

Mr. STEARNS. The gentleman yields back. The gentleman from Louisiana, Mr. Scalise, is recognized for 5 minutes.

Mr. SCALISE. All right. Thank you, Mr. Chairman. When Mr. Stearns was asking you kind of a follow-up about the waiver, you had made a comment that when he said, you know, all of these 1,300, almost 1,400 people have received a waiver from the component that would take effect in 2014, you had said that that shows that there is a lot of lousy plans out there. I am not sure if you are familiar. They are not asking for a waiver from their plan. They are asking for a waiver from Obamacare. So can you explain what you meant by that comment?

Ms. GLIED. Yes, sir.

Mr. SCALISE. It is an odd comment to make.

Ms. GLIED. They are asking for a waiver from the requirement in the Affordable Care Act that says that plans may not limit the amount that an insurance plan will pay out to a person who is very ill. So right now, there are plans before the Affordable Care Act came out, that would say this plan covers you unless you have more than $5,000 in medical expenses. Now, after $5,000, hey, buddy, you are on your own. Which actually means hey, the rest of us, we get to pay your bills because you are not going to be able to do it.

Mr. SCALISE. So——

Ms. GLIED. The Affordable Care Act——

Mr. SCALISE. You know, I guess what you are saying is that you have defined that yourself as that is a lousy plan. Is that what you are saying?

Ms. GLIED. Basic economic theory——

Mr. SCALISE. You referred to it as a lousy plan.

Ms. GLIED. —as well as, I think, U.S. taxpayers ought to see that as a lousy plan because we are going to pay your cost for you if you have any.

Mr. SCALISE. So if a family has that plan and they like that plan, you are sitting here in your ivory tower saying that is a lousy plan. We need to fix it. We need to go and change the rules in a way that your employer might drop your coverage all together. Because that is what these employers are saying.

The employers aren't saying, you know, I want to try to figure out how to add cost to health care in a way that they can't afford, they might go bankrupt. They have decided I can either provide health care to my employees or not provide it. And if I can provide a plan that gives their family something that their family likes, you are sitting here saying that is a lousy plan. We are going to change the law in a way that now you can't afford the plan anymore.

The companies have told you. This isn't me suggesting it. You granted them the waiver because they said they can't afford it. They are going to have to dump all their employees off of that health care plan that you just called lousy. They liked the plan. 80 percent of the employees like those plans, and you are calling them lousy saying no. But if you get a waiver, you can keep doing it. But if you don't get the waiver, your employer is going to dump the plan because they can't afford to do it anymore. So now you don't have any insurance and you are off fending for yourself out there because you decided in some ivory tower that their plan that they liked was lousy.

Now, you don't understand how a lot of people have trouble with that concept that somebody in Washington is now going to determine that their plan that they like is no longer valid, and if they get a waiver, they can keep getting it. But if they don't get a waiver from you, their employer said they can't provide it anymore. They are going to have to stop providing health coverage to their employees all together. And now that plan that they liked is no longer available for them.

Ms. GLIED. That, sir, is why we need to move to 2014 when everybody will have much better, more affordable coverage available to them. And the reason for the waivers is just to keep those plans, which we recognize are better than nothing, in existence until we can provide people with much better coverage that is comprehensive and that protects them against catastrophic expenses beginning in 2014.

Mr. SCALISE. There is a big flaw with that theory, and I am glad you acknowledge now that maybe it is a good plan because you were calling it a lousy plan earlier. That employee likes the plan. You might think it is lousy. That is not your decision. It shouldn't be your decision. I mean under Obamacare, I guess it is your decision. You can take it away from them. But the President said—I mean he pledged it time and time again before, during, and after this debate that if you like what you have, you can keep it.

And frankly that is a tenet that ought to be established in the law, and it is not. Because if you like what you have, you are going to lose it in many cases, and there was a study done by McKenzie and Company. I don't know if you had looked at it, but a very well-respected firm who did an in-depth study, the only one I have seen out there that really goes into detail about employers who do provide health care. It said 30 percent of employers would drop their

coverage when all the costly requirements of Obamacare become law.

Now, I don't know if you have disputed the McKenzie study, but it is out there. It has a lot of factual basis behind it. They talked to real people. They talked to employers who provide health care, to employees who like the care, and so when the President says if you like what you have, you can keep it. According to this study, over 30 percent of those companies said they are not going to be able to keep providing it. So the employees lose the care they like. That breaks the President's pledge.

Now I would like to see what your response is to the McKenzie study. Maybe it was flawed in how they asked the question. Maybe you think it is going to be a lot rosier when all those lousy plans are dumped, as you categorize them.

Ms. GLIED. Sir, we have actually seen many studies. The McKenzie study is only the most recent in a very long series of studies. Virtually all of them have not found anything like that result. They found very small changes in employer offering including previous surveys of employers. So the McKenzie study——

Mr. SCALISE. Would you dispute the findings of the McKenzie study?

Ms. GLIED. Wait a second. And moreover, we have one real world example of what happens when you do something very much like the Affordable Care Act, which is what happened in Massachusetts. And what happened in Massachusetts is that the number of employers offering coverage increased substantially and significantly even as the rest of the country——

Mr. SCALISE. Well, we have heard all kind of problems with Massachusetts, but regardless of that——

Ms. GLIED. Well, certainly whatever——

Mr. SCALISE [continuing]. This isn't Massachusetts. This is the United States, and you have 1,400 companies that your office has said they need a waiver. Otherwise, they are going to have to drop the plan. I mean if 1,400 entities, you know, unions and all kind of other groups that were supporting this law said we can't provide the health care anymore unless we get the waiver.

Well, what happens at 2014 when they can't get the waiver anymore? What happens to the countless others who have asked for the waiver and couldn't even get it, now 30 percent of them according to study. But even if you don't go by this study, 1,400 according to your own numbers of who you gave waivers to said they couldn't provide health care to their employees anymore. They were going to have to dump them if they didn't get the waiver from the component of the law.

Ms. GLIED. Beginning in 2014, everyone is going to be insured much better, more comprehensive, and affordable coverage. Right now, fewer than 2 percent——

Mr. SCALISE. I guess something magical happens in 2014 where today they are going to have to drop—they can't even comply with the law. But in 2014, somehow everything is going to be rosy, and then they can comply with the law even though nothing has changed because all of these other companies have said they can't comply. They are going to have to dump the health care that their employees liked.

Ms. GLIED. 2014 will have a new, much more competitive, patient-centered insurance marketplace in which people will be able to get coverage they can afford so——

Mr. SCALISE. Hopefully by 2014, the law is repealed, and then people really can keep what they like that they currently have. Thanks, I yield back.

Mr. STEARNS. Gentleman yields back. I have a series of questions here. Dr. Glied, are you familiar with the recent rule HHS released on accountable care organizations?

Ms. GLIED. Yes, sir, I am.

Mr. STEARNS. Are you aware that a number of premier organizations, such as the Mayo Clinic, wrote the administration saying that more than 90 percent of its members would not participate because the rules as written are so burdensome it would be impossible to succeed?

Ms. GLIED. Yes, sir. That is exactly why we want to have a robust public comment after we put forward a notice of proposed rulemaking.

Mr. STEARNS. OK, if less than 90 percent of the groups that you need to participate would not do so, how did it come about that a rule was ever released?

Ms. GLIED. There are many—we have received many, many comments on the notice of proposed rulemaking, and they vary considerably in what they think should and should not be in the rule. The administration has to chart a course between all the different goals that we are trying to do here, and we really want to bend the cost curve and change the delivery system. So we are listening to all the comments, and we will incorporate them in the final rule.

Mr. STEARNS. But wouldn't you think that the reaction was pretty dramatic here that the Mayo Clinic—I mean if you try to create these efficient rules and balance the competing interests, so-called, versus the government versus the private sector, you know, shouldn't the reaction to a rule like this not be so harsh? I mean wouldn't you—doesn't that tell you something?

Ms. GLIED. There are—this is a very important rule. This is one of the main goals of the administration is to bend the cost curve by changing the incentives that face the health care system today. And, of course, there are lots and lots of opinions about how it ought to be done. It is not at all a surprise that we have heard a lot of feedback. We also took a lot of public comment before we wrote the rule that is incorporated in it already.

Mr. STEARNS. The complete rejection of this rule by organizations you would need to rely on for its simple success seems quite lopsided. I mean that is our opinion. Do you agree?

Ms. GLIED. It will be very—it is important to wait until the final rule is promulgated, the program is supposed to take effect at the beginning of next year. And I think we should wait and see what happens at that point. We are really working on improving the rule and listening to the comment, and I can't really speak to it any much more than that.

Mr. STEARNS. I think this quote is from the Wall Street Journal. It called it, "these regulations have been called overly prescriptive, operationally burdensome, and the incentives are too difficult to

achieve to make this voluntary program attractive." In light of these statements, shouldn't this rule be completely reworked?

Ms. GLIED. We are responding to the rule by looking at the comments that we have received. Remember that we have to balance the protection of the Medicare trust fund against our desire to change the incentives in the health care system. Both of those are competing interests, and we are working on them.

Mr. STEARNS. So you don't think the rule should be reworked?

Ms. GLIED. Mr. Chairman, after an NPRM, we rework a rule before we finalize it. We listen to the comments, and we change it around.

Mr. STEARNS. So it can be reworked?

Ms. GLIED. That is the point of this process.

Mr. STEARNS. Does the President's executive order require you to do this? Do you consider that, or is this just part of your normal procedure?

Ms. GLIED. It is part of our normal procedure.

Mr. STEARNS. Yes, OK. One thing many have wondered in the aftermath of the rule, how did this rule come to be? For example, we talked earlier about you communicating with stakeholders. Evidently you didn't communicate with stakeholders in this case. Is that true you didn't communicate with stakeholders? That is why the reaction was so harsh?

Ms. GLIED. No, sir, we had extensive communications with stakeholders, and this has actually been an area where there has been tremendous public comment.

Mr. STEARNS. The stakeholders didn't alert you to the problems back then before you issued it?

Ms. GLIED. Different stakeholders had different opinions, sir.

Mr. STEARNS. OK, so you are going to reach out to these same groups again, I guess, and does that mean that—did you reach out to the Mayo Clinic?

Ms. GLIED. The rule is closed for comment on June 6. We received many, many comments on the rule.

Mr. STEARNS. OK, so you are saying to me this morning that—this afternoon you will probably redo this rule?

Ms. GLIED. We are looking at the comments, and we will revisit the rule and look at what we need to do to address those comments.

Mr. STEARNS. OK, I think I will probably conclude here shortly much to the loyal opposition's concern. I want to talk about the Data Quality Act.

Ms. GLIED. Sure.

Mr. STEARNS. To comply with President's January executive order, doesn't HHS have to base its regulation on the best available science?

Ms. GLIED. We endeavor to do so at all times.

Mr. STEARNS. Sure, OK, what is this best available science that you use?

Ms. GLIED. That would depend, sir, on the question that is, you know, the question that is being addressed by the scientists.

Mr. STEARNS. In addition to or prior to the President's executive order, did HHS have to base its regulation on the best available science pursuant to the Data Quality Act?

Ms. GLIED. We have always tried to base our regulations on the best available science.

Mr. STEARNS. I will take that as a yes. Since that is the case, can you represent to the committee today that all HHS regulatory efforts since you have assumed office have applied the Data Quality Act and are in compliance with the Data Quality Act?

Ms. GLIED. I believe so, but let me get back to you because I am not familiar with the precise details of the Data Quality Act.

Mr. STEARNS. That is a fair answer. Would you agree that if HHS is to base regulations or regulatory decisions on the best available science that HHS cannot act on the basis of conflicting studies? For example, if you decide on certain areas and you have conflicting studies, I guess the question is how are you going to make your regulatory decisions?

Ms. GLIED. Chairman Stearns, if we waited for science to come to a definitive conclusion on everything, we would never be able to act. It is always going to be—there are always going to be conflicting studies. The best available evidence doesn't mean that there are no conflicting studies. I means that the preponderance of sensible evidence leads in a particular direction. Scientists thrive on controversy.

Mr. STEARNS. OK, Mr. Scalise brought up the McKenzie study, and I think your indication was that you weren't discrediting it, but you said there is more than one study. And I think the White House has tried to discredit this study calling it an outlier and implying that the McKenzie study isn't a respected, independent organization. Did you know of that criticism?

Ms. GLIED. I think one of the concerns that we have about that study is that we haven't been able to see the methods that they used, and they haven't made those public. So I can't speak to whether that is a good study or not because I personally have not seen the methods used.

Mr. STEARNS. So you are not implying that the McKenzie Organization is not a credible organization?

Ms. GLIED. I believe the McKenzie Organization is a credible organization. I can't speak for this specific study.

Mr. STEARNS. OK, and I agree with you. The Federal Government has awarded McKenzie and Company over $182 million in government contracts to perform consulting and analysis work. And as you are aware, that $182 million that is disclosed on U.S. spending, more than $122 million of it comes from the Obama administration, $21 million of which are contracts with HHS. So clearly the Obama administration thinks McKenzie is doing reliable and honest work or they wouldn't employ them and they are spending money with them.

Doesn't McKenzie say what distinguishes this study from others is that McKenzie educated respondents on the President's health care requirements that will take effect in 2014? What I am trying to establish is once McKenzie went out and explained the implications, that is how they got their study, and that distinguished many other studies which just do analysis without asking and educating people about the impact of the President's health care plan? So I guess the answer is yes or no. So all I am saying is——

Ms. GLIED. We don't know how they educated them, so I don't know what that—I can't—I don't know what I can say about that.

Mr. STEARNS. OK, so you can't answer it. OK, I think we have covered most of the questions here. We thank you for your patience and with nothing else, no more on the minority side, the subcommittee is—before I adjourn, I would just like to let all members have an opportunity to offer their opening statements, and I ask unanimous consent that the written opening statements of all members be introduced in the record. Without objection, and I ask unanimous consent that the slide we had be put in part of the record. And with that, the subcommittee is adjourned.

[Whereupon, at 3:25 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Opening Statement of the Honorable Fred Upton
Chairman, Committee on Energy and Commerce
"The Views of the Department of Health and Human Services on Regulatory Reform: An Update"
June 13, 2011

Thank you, Mr. Chairman, for convening this hearing as part of the Committee's ongoing review of the Administration's approach to regulations and regulatory reform.

As I said in January at our first hearing following the issuance of Executive Order 13563, I commend the President for his stated commitment to reining in overregulation. The President is correct to demand attention to this issue at the highest levels of the Executive Branch.

However, the flood of regulations that have accompanied the President's first two years in office, not to mention the mass of future rulemakings still in queue, threaten to upset, if they have not already, any meaningful balance between regulation and economic growth. As we learned from the U.S. Chamber of Commerce testimony at this Subcommittee's hearing on June 3rd, we lose jobs when job-creating or job-saving companies can't bear the costs of overregulation.

With unemployment of over 9 percent and sluggish economic growth, a serious effort to streamline the most onerous and costly federal regulations is long overdue, and no environment is more target-rich than the Department of Health and Human Services, whom we will be hearing from today. By the count of Subcommittee staff, 370 proposed rules, final rules, notices and corrections related to Obamacare have been issued so far – the agency has clocked in more than 3,500 pages of rules, notices and corrections. It certainly does not appear that HHS is handling regulations related to the health care law in a way that complies with the letter and spirit of the President's executive order.

We must examine whether HHS is reining in those rules that not only burden our economy, but also limit the freedom of Americans to make decisions concerning their health and wellbeing.

Questions for the Record
U.S. House of Representatives Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Sherry Glied, PhD
Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services

Q: How many employees do you have in your office?

A: At the end of Fiscal Year 2010, The Office of the Assistant Secretary for Planning and Evaluation (ASPE) included 123 permanent employees, 2 Commissioned Corps Officers and 7 temporary employees.

Q: What is your office's budget?

A: ASPE's FY 2011 base budget is $41,272,040.

Q: Can you provide the Committee a total in dollar terms that your office has contracted out to private entities over the last two years?

A: In FY 2009 the allocation for contracts totaled $14,569,760, and in FY 2010, the allocation totaled $16,316,792.

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