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NOMINATIONS OF WILLIAM B. SCHULTZ AND CHRISTOPHER J. MEADE

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED TWELFTH CONGRESS

SECOND SESSION

ON THE

NOMINATIONS OF

WILLIAM B. SCHULTZ, TO BE GENERAL COUNSEL, DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND CHRISTOPHER J. MEADE, TO BE GENERAL COUNSEL, DEPARTMENT OF THE TREASURY

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THURSDAY, DECEMBER 20, 2012

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 2:34 p.m., in room SD–215, Dirksen Senate Office Building, Hon. Max Baucus, (chairman of the committee) presiding.

Present: Senators Wyden, Schumer, Stabenow, Cantwell, Carper, Hatch, Grassley, Roberts, Coburn, and Thune.

Also present: Democratic Staff: Amber Cottle, Chief International Trade Counsel; Rory Murphy, International Trade Analyst; and Tiffany Smith, Tax Counsel. Republican Staff: Chris Campbell, Staff Director; and Nick Wyatt, Tax and Nomination Professional Staff Member.

OPENING STATEMENT OF HON. MAX BAUCUS, A U.S. SENATOR FROM MONTANA, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The hearing will come to order.

I know that for some on this committee there is a hard 4 o'clock deadline. We will try to move expeditiously and in a way that all Senators who wish to ask questions will have an opportunity to do so, hopefully before 4, but, if not before 4 today, then at a later date they can ask questions. But I think there is a very good chance we can wrap it up today, again, by 4 o'clock.

In his speech on leadership delivered more than 100 years ago, President Theodore Roosevelt said, "It is not the critic who counts; not the man who points out how the strong man stumbles, or where the doer of deeds could have done them better. The credit belongs to the man who is actually in the arena, whose face is marred by dust and sweat and blood; who strives valiantly; who errs, who comes up short again and again, because there is no effort without error and shortcoming; but who does actually strive to do the deeds; who knows great enthusiasms, the great devotions; who spends himself in a worthy cause; who at the best knows in the end the triumph of high achievement, and who at the worst, if he fails, at least fails while daring greatly, so that his place shall never be with those cold and timid souls who know neither victory nor defeat."

This quote hangs on the wall in my office. It serves as a powerful reminder about the importance of political leadership. Today I want to thank four members of our committee who are leaving. This will be their last hearing. I am not sure how many will be able to attend, but I want to mention them because they are such terrific people.

The first is Kent Conrad. We all remember Kent for many reasons: for his charts—he informs us with great precision on various economic matters; second, as a valiant member of the Bowles-Simpson Committee, the Gang of 6, the Gang of 8, who has devoted himself to getting our debt down; as someone who worked so hard on the passage of health care legislation, especially the Affordable Care Act, and contributed greatly and mightily, with very precise questions and great contributions, always looking for a better solution, always trying to make something better—not critical, but constructive. I just want Kent to know how much we are going to miss him here.

Second, Jon Kyl. When I think of Jon, I think of a man of superior intelligence who has an encyclopedic knowledge of policy, who is tenacious, and who is a great multi-tasker. He is always very busy, with many balls up in the air. He works so hard, especially with respect to Federal estate tax. That means a lot to Jon to make sure it is written in a way that makes sense to him. All of this has not gone unnoticed. *Time* magazine named Jon one of the 100 most influential people in the world for his persuasive role in the Senate.

Next to Jon, of course, is Jeff Bingaman. I do not know anybody here with more quiet, thoughtful, statesmanlike perception, who devotes himself to hard work and does not pat himself on the back, than Jeff Bingaman. He is really something. I mean, he reminds me a little bit of the old commercial, the E.F. Hutton commercial: "When Jeff speaks, everybody listens." Because what Jeff says is very thoughtful, he has thought it through, and he is several steps ahead of everybody else. We will very much miss Jeff on this committee for his tireless work on the Children's Health Insurance Program, and helping to improve Medicaid. Not a show-horse at all, but he is a work-horse in the best sense of the term.

Fourth is Olympia, Olympia Snowe. When I think of Olympia, I think of someone who is so dedicated to her State, who just keeps asking the questions, what about this, what about that? Olympia, what do you think? I do not know. I have to think this through more; I am not sure. It is because she wants to make sure she gets it right.

Over here on the dais, if you look at her notes, I have never seen anyone with more underlines, with more highlights. Some are yellow highlights, others are red highlights, some are circled. She is prepared. She came to this hearing fully, totally prepared. She also is clearly a class act and a real statesman, very bipartisan.

I will never forget working with her. She is the only Republican who voted for the Affordable Care Act on the committee—not on the floor, but in the committee—and in just talking with Olympia, gee, we will change this, Olympia, what about this? Then, I do not know, let us see on this. Then finally she said, "Okay." She is a wonderful, wonderful person.

So, thank all four of you for all that you have done.

I also want to acknowledge the work of our friend Mark Matthiesen. There is Mark, sitting in the front row there, who recently announced his retirement. For the past 31 years, Mark has worked on tax legislation in the Office of the Senate Legislative Counsel. Thank you, Mark, very much for your work. Congratulations for your next endeavor, whatever you choose to do.

Let us give Mark a round of applause. [Applause.]

On a final note, earlier today I announced that our friend, whom all of you know and love, Russ Sullivan, will be leaving the Senate at the end of this Congress. A true friend, respected colleague for the last 18 years, he is just amazing. I do not know anybody else like Russ and his ability just to work with people on both sides of the aisle, talking quietly, looking for solutions, bipartisan, how do we get this done, how do we find the right way to do this, not partisan, just looking pragmatically, practically, getting a good solution for our country. I can think of no higher honor than the work that Russ has done for all of us in the committee, the Senate, and for the country. A big round of applause for Russ Sullivan. [Applause.]

While we are missing Russ, we are fortunate to have someone who is just as smart and talented as Russ to take Russ's position as Chief of Staff of the Finance Committee, and that is Amber Cottle. She has been my top trade person. She has the same tenacity, focus, intelligence, and dedication as Russ. So thank you, Amber, for agreeing to join us and keep up all our work.

Do you want to say something at this point?

Senator HATCH. Yes, why don't I? Then we can go back.

The CHAIRMAN. All right.

OPENING STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM UTAH

Senator HATCH. Well, I appreciate the chairman allowing me to pay compliments too. He has mentioned a number of the people, of course, whom I very much appreciate as well. I appreciate the opportunity to pay tribute to those who will be leaving the Senate and this committee at the end of the year.

I want to thank you, Mr. Chairman, for setting apart the time for this purpose. I appreciate all the hard work members of this Finance Committee have put in over the past 2 years. It has been a great experience to work with every member of this committee, more so than in some other committees in the Senate. You probably know some of them.

The Finance Committee is often able to accomplish its tasks on a bipartisan basis. Much of that is due to the leadership of Chairman Baucus, but it can also be attributed to the commitment and effort displayed by all of the individual members of the committee, and I appreciate it.

With the conclusion of this Congress, four great Senators will be leaving the Finance Committee. They will all be missed, so I would like to just take a second or two to say something about each of them.

Let me start by saying a few words about Senator Olympia Snowe. Senator Snowe has been a fiercely independent voice on the committee and in the Senate. I have long admired her commitment

to her principles and to the people of her home State of Maine as well. Maine has been very well-represented here in these past 18 years, as Senator Snowe has worked to advance and reflect Maine's values here in the Senate.

In 2006, Senator Snowe was named one of America's 10 best Senators by *Time* magazine. In bestowing this honor, they said that, while Senator Snowe is "a major player on national issues, she is also known as one of the most effective advocates for her constituents." I have to say that I agree with *Time*'s assessment. She has tirelessly worked to be responsive to the people of Maine, to address their concerns here in the Senate, and once again to reflect their values with her votes and her decision-making. It is no wonder that she has always enjoyed high approval ratings among her constituents.

And do you know who else was on that list? Senator Jon Kyl. I have worked closely with Senator Kyl on a number of issues over the years. I have worked with him here on the Finance Committee, on the Judiciary Committee, and of course in his position in the Senate Republican leadership. He is an incredible strategist and a brilliant lawyer, with an almost unparalleled intellect. I called him a lion of the law the other day, because he really is.

I do not know of a single Republican Senator who has not, at one time or another, relied on Senator Kyl's leadership and expertise on any number of issues. Senator Kyl has been a relentless advocate for conservative values on issues ranging from national security to judicial appointments, and in such areas he has been a leader that I personally have relied on for advice and counsel.

Senator Kent Conrad was also on the *Time* magazine list. I think this says something about this committee. For years he has led his party in some fierce budget battles here in the Senate. While I have not always agreed with his views, I have never doubted that, when it came to the budget, he always knew what he was talking about. I think it was all about the charts, myself. It is hard to debate someone who has so many charts to back up his arguments.

Over the last couple of years I have tried to follow Senator Conrad's example and have exponentially increased my use of charts on the Senate floor. I am not as good at it as he is, is all I can say. Now I see why Senator Conrad does it. When I use charts, no one wants to debate me either. [Laughter.] Joking aside, Senator Conrad and his charts will be missed, both on the Senate floor and here in the Finance Committee.

Well, I have to say that Senator Jeff Bingaman was not on that *Time* magazine Ten Best Senators list; of course neither was I or our distinguished chairman.

The CHAIRMAN. Speak for yourself. [Laughter.]

Senator HATCH. Were you on that list?

The CHAIRMAN. No.

Senator HATCH. Well, you should have been. [Laughter.] So it could not have been much of a list anyway. [Laughter.]

I have sat with Senator Bingaman for most of my time here in the Senate. If you know the both of us, you know that we do not often find ourselves on the same side of many of the issues. Even so, we found ways to work together. For example, for a number of years I worked with Senator Bingaman on his legislation to help

self-employed individuals deduct their health care costs when compiling their self-employment income.

Jeff has become something of an institution in New Mexico, having represented the State here in the Senate for 30 years. I know that there are many in his State who are, like us here in the Senate, sad to see him go.

Now, Mr. Chairman, an unfortunate part of serving in the Senate is seeing good Senators and good friends come and go. Each of the four Senators leaving our committee this year is a devoted public servant, and they have worked hard, and they have worked hard in the best interests of their constituents. I know that they will all continue to serve their country in different capacities after they leave the Senate.

I have come to admire each of these Senators. They are great Senators, and I am proud to call them all friends. I thank you for taking this time to do this, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Woodrow Wilson once said, "I not only use all the brains that I have, but all that I can borrow." This administration, like all administrations, faces a great number of challenges. They need a great number of bright and talented people to work together to find solutions. The two nominees before us today are among the best and the brightest. They seek to be the General Counsels of the Department of the Treasury and the Department of Health and Human Services. These agencies will depend on their advice and expertise for implementing laws informing our country's economic and health policies.

In August, President Obama nominated Christopher Meade to be the General Counsel of the Department of the Treasury. Mr. Meade came to the Treasury in 2010 and this summer took over as the acting General Counsel. This experience and his trusted knowledge of the law will serve him very well.

After graduating from Princeton and then the New York University School of Law, Mr. Meade clerked for Supreme Court Justice John Paul Stevens. Years later, he returned to the Supreme Court to argue four high-profile cases before the court. In reviewing his career, a consistent theme is apparent: he is respected, trusted, and Mr. Meade knows the law.

If confirmed, Mr. Meade will use his experience to counsel the Secretary and all at the Treasury Department on economic and financial affairs, both domestic and international. These policies affect every person in America, and Mr. Meade's sound judgment is essential.

President Obama selected William Schultz to be the General Counsel of the Department of Health and Human Services. This position demands a high level of expertise to assist in the analysis and implementation of our Nation's health care laws.

A graduate of Yale and then UVA Law School, Mr. Schultz gained experience through a long and varied career, much of it in public service. He currently serves as acting General Counsel at HHS. He came to the agency in 2011 after working at the Department of Justice, the FDA, and in the private sector.

Mr. Schultz was a well-respected professor at Georgetown Law, sharing his knowledge with hundreds of students. He published

many scholarly articles throughout the years, covering issues from the FDA to the Supreme Court. His writings have appeared in the *New York Times* and the *Georgetown Law Journal*.

Both Mr. Schultz and Mr. Meade must bring thoughtfulness and a command of the law to their respective agencies. Their records show them to be qualified for these positions. I believe the administration will benefit from borrowing the knowledge, experience, and perspective from both nominees, and I think they will do a great job.

[The prepared statement of Chairman Baucus appears in the appendix.]

Senator Hatch?

Senator HATCH. Well, thank you, Mr. Chairman. I want to take a moment to once again express my concerns about a growing problem relating to Congress's dealings with the Obama administration, because I believe it is relevant to today's hearing. But before I do, I know Mr. Schultz very, very well, and I do know of Mr. Meade, and I support both of them. I hope we can get you through before the end of the year. I doubt that is going to happen, but we will see what can happen.

But there is a growing problem relating to this Congress's dealings with the President, or should I say with the Obama administration, and I believe it is relevant to today's hearing.

As part of the case against King George III, the Second Continental Congress repeatedly noted in the Declaration of Independence that King George had consistently frustrated the attempts of the colonies to govern themselves. In these grievances, we see frustration with a strong executive authority that dominated the legislative authority.

The very first grievance against the King noted in the Declaration states, "He has refused his assent to laws, the most wholesome and necessary for the public good." Later, the Revolutionaries indicted the King "for suspending our own legislatures and declaring themselves invested with power to legislate for us in all cases whatsoever."

Now, these grievances were the inspiration for our Constitution, among other grievances, which created a system of checks and balances between the executive and legislative branches. Put simply, our system of government was designed so that Congress would be tasked with writing the laws that the executive branch implements.

Now, more than 200 years later, many would argue that the executive branch has become more powerful, perhaps too powerful, at the expense of Congress. Congress shares significant blame for this. In an editorial published last year in the *Washington Post*, former HHS Secretary Michael Leavitt noted that Obamacare contains the phrase "the Secretary shall" nearly 2,000 times.

Even during his tenure, Secretary Leavitt noted that he had been advised that HHS "has more power than a good person needs or a bad person ought to have." HHS is more powerful now than it has ever been before. Among literally hundreds of other functions, Obamacare designates that the HHS Secretary will develop "tooth-level surveillance."

As such, perhaps the next nomination to HHS Secretary ought to be jointly referred to this committee and the Committee on Homeland Security and Governmental Affairs. The continued abdication by Congress of legislative power and the accumulation of that power by the executive branch make the positions of Chief Counsel at HHS and Treasury very important.

The two nominees before us, if confirmed, would wield vast influence over decisions that might impact the lives of every American. This is why I, along with many of my colleagues, believe that thorough oversight of the executive branch is critically important to preserving our system of checks and balances. That is in spite of the fact that I support both of these gentlemen, knowing their qualifications.

The level of responsiveness from the administration, specifically HHS and Treasury, to written requests for information, has continued to be lackluster at best. I, along with many other members, have raised this issue numerous times, but to no avail.

Both of the nominees today are currently serving in an acting capacity in the roles to which they have been nominated. Consequently, they know agency practice—and have worked within the existing agency structure—including how the agency responds, or in many cases does not respond, to informational requests from Congress.

I would respectfully suggest that, when you return to your agencies, you pass along a reminder that at least some in Congress find the lack of responsiveness to be entirely unacceptable. My goal is to be able to work together with the executive branch, and I think our system of government works better when our two branches of government cooperate. I hope that any nominee who comes before this committee does not believe that their responsibility to work and communicate with Congress ends with their confirmation.

There have been several recent instances in which nominees have pledged to me and this committee that they would work to promote transparency and would be responsive to Congress. Unfortunately, following confirmation those pledges have too often been abandoned. I know that Chairman Baucus recognizes the need for transparency and responsiveness and that he will work with me on finding a solution to this problem.

To his great credit, he has repeatedly shown leadership in this committee, backing up any member's request to any agency of government. I want him to know that I appreciate his leadership and support in this matter, and in so many other ways as well.

Finally, I want to conclude with a brief statement on the scheduling of this particular hearing. Mr. Chairman, I assume that there are many in the administration and on your side of the aisle who would like to see these nominations move quickly. I may be among them. However, when we rush these proceedings, it seems to me, particularly so near to the end of this Congress, we may be doing the committee and the nominees a disservice.

As you know, there is a very important Republican conference meeting today at 4 o'clock. Despite that, it was decided that a good portion of this hearing would be devoted to honoring our colleagues leaving the Senate.

Now, I appreciate the desire to honor those who deserve it, as our colleagues do, but that should not cause the hearing to get short shrift. In particular, I do not want to unduly limit questions from members of the committee in order to complete the hearing in a shortened time line.

Now, these nomination hearings are more than just a box to be checked: they are essential to ensuring that we adequately fulfill our advice and consent responsibilities here in the Senate. I just hope that, as we go into the future, we will keep that in mind under all circumstances.

One other thing. I hope when you folks finally get confirmed that, when we send a request for information, we do not get stiffed like we have been getting stiffed the last 4 years. Frankly, it has been not only noticeable, it is offensive. We are going to have to see that that changes.

We do not ask these questions just for meanness or just to try to make political points; we are asking them because we do not have the knowledge and we do not have the understanding we would like and we have some things that we are concerned about. So, if you will keep that in mind as you serve back there—and when I say back there, with the administration back over there—we would appreciate it.

Mr. Chairman, I am sorry I went on so long, but I can appreciate both of you and I am for both of you, but I wanted to make those points.

The CHAIRMAN. Thank you, Senator. Those are very good points. Number one is the importance of oversight, in this case especially with the Affordable Care Act and HHS—this next year is going to be a very busy year before this committee—to make sure that that Act is implemented well.

[The prepared statement of Senator Hatch appears in the appendix.]

The CHAIRMAN. There are a lot of questions—a lot of questions—with respect to implementation, some of them have to do with the exchanges, and there is going to have to be interplay between HHS, IRS, and probably other agencies too. To be honest, I am getting nervous that we are not going to be ready when the first person is filed, I guess in October, I think it is. So I am asking you, both of you, especially you, Mr. Schultz, when you go back, to say, we have to get ready, because this committee is going to have a lot of oversight hearings with respect to the Affordable Care Act.

Point number two is just confirming what Senator Hatch said, namely that this committee is going to be looking for prompt responses to written requests, written questions that Senators may ask. We have backed each other up. Sometimes this party is in the majority, sometimes the other party is in the majority, but we back each other and every other member of this committee. We could just be doing ourselves a lot of good if we just, again, promptly answer.

We are really a team here. We want to help. We are not performing an adversarial role. We are not here to criticize; we are here to work, to make this government work, so take advantage of that. You can take advantage of that by working very closely, al-

most even aggressively and cooperatively and constructively, with this committee.

Senator SCHUMER. Mr. Chairman?

The CHAIRMAN. The Senator from New York.

Senator SCHUMER. Yes. I would like to make a brief introduction of one of the nominees who is a New Yorker. Thank you.

The CHAIRMAN. You are welcome.

OPENING STATEMENT OF HON. CHARLES E. SCHUMER, A U.S. SENATOR FROM NEW YORK

Senator SCHUMER. Before I do that, I would just like to mention—I am sure we will have time to say more—that Russ Sullivan, as you have said, Mr. Chairman, has done an incredible job. I cannot think of a single staff person who will be more sorely missed than Russ.

So thank you, Russ, for your total dedication all the years I have been on the Finance Committee, and you were even very helpful to many members, myself included, before we were on the Finance Committee. So, we will miss you, and wish you godspeed.

It is my honor, Mr. Chairman, to be able to introduce to this committee Chris Meade, who has been nominated by the President to be General Counsel of the Treasury. Chris is a New Yorker. He was born in Yonkers, NY. He met his wife Stella, who is here today with him, in New York. Joining him today are his mother, Mary Ann, and his beautiful young children: Nora, who is three, and Elliot, who is 3 months. If they would like to stand so we can just say hi. Hi, Mary Ann. I think we heard from either Nora or Elliot a second ago. Anyway, thank you.

Chris completed his undergraduate studies at Princeton before attending NYU Law School, where he was editor-in-chief of *The Law Review* and graduated magna cum laude.

Up until coming to work for the administration, he had spent almost his entire life in New York. The only 2 years away prior to his joining Treasury were when he served as a law clerk to John Paul Stevens, a justice of the U.S. Supreme Court, and Judge Harry T. Edwards of the DC Circuit.

In addition to these very impressive clerkships, Chris has been a partner at Wilmer, Cutler, Pickering, Hale, and Dorr. There he was a member of both the litigation and securities departments, and the appellate and Supreme Court litigation group.

Almost 3 years ago, Chris moved his family from New York to Washington—boo-hoo—in order to serve in the administration. He has served as the principal Deputy General Counsel at Treasury since March 2010, and by all accounts has done an exceptional job. So, Mr. Chairman, I am delighted the President nominated him to serve as General Counsel, and I hope he is confirmed quickly.

The CHAIRMAN. Thank you, Senator.

I would now like you each to give your statements. Before you do, Mr. Schultz, I will give you an opportunity to introduce any friends, family, associates who may be here whom you want to recognize.

Mr. SCHULTZ. Yes. Thank you so much, Mr. Chairman. I would like to introduce my wife, Sari Horwitz, and my daughter, Rachael Schultz. Rachael is completing her senior year at Washington Uni-

versity in St. Louis. They are the best part of my life. They make everything worthwhile.

The CHAIRMAN. Are they here? Could you stand? Please stand and be recognized. Welcome, very much. [Applause.]

And, Mr. Meade, Senator Schumer mentioned some of your family. Why don't you also, again, recognize your family and friends?

Mr. MEADE. Thank you, Mr. Chairman. I would like to introduce and welcome my family: my wife Stella, who is standing in the back; my beautiful daughter Nora, who is 3½ years old; and my baby son Elliot, who is nearly 3 months old. He is in the BabyBjorn with my wife there.

The CHAIRMAN. We see him. Right.

Mr. MEADE. My mother, Mary Ann Meade. I also want to acknowledge my father, Bill Meade, who passed away a few years ago. We miss him today. Also, I have a number of friends and colleagues here, and I am very grateful for their coming and for their support.

The CHAIRMAN. Could you all stand up, everybody? Let us recognize you. Come on, let's go. [Applause.]

All right. Good. Very good. Wonderful. All right.

Mr. Schultz, as you know, your written statement is automatically included in the record, and we urge you to summarize for about 5 minutes.

STATEMENT OF WILLIAM B. SCHULTZ, NOMINATED TO BE GENERAL COUNSEL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Mr. SCHULTZ. It is a brief statement. Thank you, Mr. Chairman, Senator Hatch, and members of the committee. I am honored to appear as the President's nominee to be General Counsel of the Department of Health and Human Services.

The Department has more than 65,000 employees whose mission is to assure that the American people have access to high-quality and affordable health care, to support children and families, to ensure the safety of the food supply and that medical products are safe and effective, and to support research that will improve health and save lives.

The Office of General Counsel advises the Department on the legal authorities that Congress has given the agency and on the legal constraints that Congress has imposed. It also works with components of HHS and the Department of Justice to ferret out fraud against the government, to ensure compliance with the law, and to defend the government against legal challenges to government programs.

I believe my experience has prepared me for this position and has equipped me with the relevant skills, as well as with an understanding of the appropriate role of a General Counsel. I have worked in all three branches of government and in the private sector on litigation and regulatory matters.

Since March 2011, I have served as the Acting General Counsel of the Department. Prior to that time, I was a partner at the law firm of Zuckerman Spaeder, and prior to that I spent 11 years in government. This included 5 years as counsel to the House Subcommittee on Health and the Environment, 4 years as the Deputy

Commissioner for Policy to the Food and Drug Administration, and 2 years as Deputy Assistant Attorney General at the Department of Justice in charge of civil appellate litigation.

I began my career as a law clerk to a Federal District Court judge here in Washington, DC and then worked for 14 years at Public Citizen Litigation Group, a public-interest law firm.

I am fortunate that the HHS Office of General Counsel is populated by enormously talented and committed attorneys and other staff, many of whom are here today, and I appreciate that.

I am also grateful to have the opportunity to work with Secretary Sebelius, Deputy Secretary Bill Corr, and the other extraordinary officials at the Department. Throughout my career, Mr. Chairman, I have found public service, and in particular government service, both to be extremely challenging and extremely rewarding.

I feel very fortunate to be nominated for this position. The mission of HHS could not be more important. If I am confirmed, I look forward to working with the members of this committee and will do my very best to ensure that the laws that Congress has enacted are faithfully implemented. Thank you for the opportunity to be here today, and of course I would be happy to answer any questions.

The CHAIRMAN. Thank you very much, Mr. Schultz.

[The prepared statement of Mr. Schultz appears in the appendix.]

The CHAIRMAN. Mr. Meade, you are next.

STATEMENT OF CHRISTOPHER J. MEADE, NOMINATED TO BE GENERAL COUNSEL, DEPARTMENT OF THE TREASURY, WASHINGTON, DC

Mr. MEADE. Thank you, Chairman Baucus, Ranking Member Hatch, Senator Schumer for the kind introduction, and members of this committee, for the opportunity to appear before you today. I am honored that President Obama nominated me for this position, and I am grateful to Secretary Geithner for recommending me to the President.

My parents instilled in me a deep commitment to public service, a value that I hope to pass on to my children. This commitment has been reinforced throughout my career. At the beginning of my career, I had the honor and privilege to serve as a law clerk to Justice John Paul Stevens and Judge Harry T. Edwards of the DC Circuit. They are not only great jurists, they are great public servants.

I spent the core of my legal career as a partner at a law firm that is deeply committed to public service. I learned from many great lawyers there, including many who have served our country with distinction.

I have spent nearly 3 years now serving as the Principal Deputy General Counsel at Treasury. The scope of legal issues within Treasury is vast, ranging from domestic and international economic affairs, terrorist financing and enforcement, tax, ethics, and administrative law.

My service has given me great respect for the Treasury Department and, in particular, for the talent and expertise of the career lawyers at Treasury. If confirmed, I look forward to working closely with Congress, and in particular with members of this committee.

I have enormous respect for this institution, and it is an honor to appear before you today. I am deeply committed to maintaining a close working relationship between Treasury and Congress.

Mr. Chairman, I am grateful to you for bringing me before this committee today, and I would be pleased to respond to any questions that you or other members of the committee may have. Thank you.

The CHAIRMAN. Thank you, Mr. Meade.

[The prepared statement of Mr. Meade appears in the appendix.]

The CHAIRMAN. I have four obligatory questions I would like to ask each of you, if you would just indicate, hopefully affirmatively, your response to each.

Is there anything that you are aware of in your background that might present a conflict of interest with the duties of the office to which you have been nominated?

Mr. SCHULTZ. No.

Mr. MEADE. No.

The CHAIRMAN. Do you know of any reason, personal or otherwise, that would in any way prevent you from fully and honorably discharging the responsibilities of the office to which you have been nominated?

Mr. SCHULTZ. No.

Mr. MEADE. No.

The CHAIRMAN. Do you agree, without reservation, to respond to any reasonable summons to appear and testify before any duly constituted committee of Congress, if you are confirmed?

Mr. SCHULTZ. Yes, I do.

Mr. MEADE. Yes, I do.

The CHAIRMAN. And finally, do you commit—this is a new one—to provide a prompt response in writing to any written questions addressed to you by any Senator of this committee?

Mr. SCHULTZ. Yes.

Mr. MEADE. Yes.

The CHAIRMAN. Thank you both very much.

Now, my basic question to each of you is, why in the world does each of you want this job? What do you want to accomplish? How do you want to be remembered when you leave and people look back 10, 15 years from now? I will start with you, Mr. Schultz.

Mr. SCHULTZ. People, when I was in my law firm, said, what is the difference between working here and working for the government? What I used to say is, the difference is, I work here on issues that I would never have time to get to in government. The reason that I love public service is that you get to work on things that are important, the most important kinds of challenges, the same way I did when I was on the staff on the Hill and in other government jobs.

I am fortunate to have at HHS this terrifically talented group of lawyers and others to be able to work with. Our goal is to ensure that the laws that Congress has passed are implemented and instituted in a faithful way, in the most honest way. That is our job as General Counsel, in a sense to protect you, to ensure that we are following the laws, and to defend the government against challenges to those laws.

The CHAIRMAN. You have been here a little while. Is there anything more specific that you are working on where there is more focus, something a little more identifiable, so when you look back after several years you can say, boy, we did that?

Mr. SCHULTZ. The big thing is the Affordable Care Act. It is so thrilling to be at the Department at a time when we have the opportunity to provide health care to 35 million Americans, which is the goal of the Affordable Care Act. I hope I will look back and say, we got it right, we got it implemented, and we did it in a way where there were not many challenges and they were not very successful. That is the basic goal.

There are other extremely important challenges. The Food and Drug Administration regulates a quarter of all the products sold in the economy and has the mission of ensuring that medical products are safe and effective, and there are constant challenges there, whether they are court cases or other issues that come up. But I think the Affordable Care Act——

CMS, as you know, has a budget of about $800 billion, and we are constantly trying to ensure that that money is spent only in a way that is permitted by Congress, that it is efficient. There are many court cases. I told somebody recently, if I only worked on matters that involved $1 billion or more, I would still be too busy. So part of the effort is obviously to try to protect the government fisc, but assure that the agency can do its job and that these very talented officials can do their work.

The CHAIRMAN. Thank you.

Mr. Meade, what about you? Why do you want this job? What did you tell your family when you told them you wanted to do this?

Mr. MEADE. For me, it relates to the commitment to service that I outlined in my opening statement. To me, it is a question that answers itself, because there is really no higher honor than to be able to serve the country in this way. I am honored to be considered, and it is a great privilege and honor to serve. If confirmed, I would look forward to continuing.

In terms of how I would want to be remembered, I mean, one of my mantras in life is to always want to do better. That is how I think about us within the Legal Division at Treasury. We have excellent lawyers, great lawyers, thoughtful lawyers, careful lawyers, lawyers who strive to be the best lawyers they can be and to give the best advice to the Secretary and other officials within Treasury. But in my view, I think we always want to do better, we want to be more thoughtful, more careful, more analytically precise. That is what I would hope to do, if I am confirmed as General Counsel.

The CHAIRMAN. Next year could be a big year. We could be deeply involved with tax reform. Do you think the IRS and Treasury have sufficient resources? What assistance do you think Treasury and IRS could provide this committee as we work toward reform? How do you see your role, your office? What assistance can you provide?

Mr. MEADE. So, Mr. Chairman, the lawyers within Treasury, at IRS, and the Office of Tax Policy are a group of excellent lawyers who, time and time again, I am impressed by their substantive expertise. I am committed, if confirmed, to work with you and this committee to provide whatever assistance we can.

But again, I am, time and time again, impressed by this substantive expertise and the care with which they go about thinking about the tax laws.

The CHAIRMAN. Thank you.

Senator Hatch?

Senator HATCH. Mr. Schultz, on July 12, 2012, the Department of Health and Human Services issued an Information Memorandum regarding the TANF program, Temporary Assistance to Needy Families. Now, this memorandum attempted to explain how States could seek waivers of work requirements for welfare recipients. At my request, the Government Accountability Office determined that this memorandum actually constituted a rule and therefore was subject to the Congressional Review Act, or CRA.

As part of their analysis, GAO requested the views of HHS General Counsel to determine why HHS had not determined that the memorandum qualified as a rule. According to GAO, HHS responded as follows: "The Information Memorandum was issued as a non-binding guidance document and HHS contends guidance documents do not need to be submitted to the CRA."

Now, GAO disagreed with that conclusion reached by HHS's General Counsel's Office and noted that HHS provided "no support for this position."

Can you please explain what role you played in making this determination?

Mr. SCHULTZ. Thank you, Senator Hatch. I was involved in the determination. We went back and looked at the statute and the cases and also what prior administrations have done. This is obviously an administration-wide issue.

For the 16 years since the Congressional Review Act, every administration, Republican and Democratic, has submitted regulations for review, regulations that require notice and comment and so on. This was an Information Memorandum, essentially a notice to the States saying, we are open for business. If you have a waiver that meets the requirements, you can submit it, and we will consider it. This is not the sort of thing that has ever been submitted. There are, I think, tens of thousands of guidances and so on that are not submitted.

We did know how important this was to Congress, Senator Hatch. The Department did, on the day it was issued, submit it to the minority and the majority staff in the House and Senate, so we were trying to be very respectful and notify Congress.

Senator HATCH. Well, in the GAO's language, it said that "we cannot agree with HHS's conclusion that guidance documents are not rules for the purposes of the CRA," and HHS cites "no support for this position." The definition of "rule" is expansive and specifically includes documents that implement or interpret law or policy. This is exactly what the HHS Information Memorandum does.

Then they also say, "In addition to legislative history, the CRA specifically includes guidance documents as an example of an agency pronouncement subject to the CRA." So I am concerned about that, as you can imagine. I have raised the issue, and I really do not understand.

Mr. SCHULTZ. No, I understand your concern, Senator Hatch. I am disappointed that GAO disagreed with us. We have looked at

it very carefully, and we looked at the history very carefully. In Republican and Democratic administrations, we have followed the same practices as everybody else. I think we got it right, but I understand the other side.

Senator HATCH. But can you show any instances where people applied for this type of a waiver in the past?

Mr. SCHULTZ. I am not aware that there have been any applications for the waiver. The authority was requested by a bipartisan group of Governors. The Secretary simply announced, you can apply for a waiver. But I am not aware that there have actually been applications; certainly none have been granted.

Senator HATCH. Well, see, I disagree with you on this. I think it is a very, very important question. On that question, I do not know whether you can or cannot, but can you explain to me why the administration has ignored the Hatch-Camp request for correspondence relating to the development of the waiver rule between the Office of General Counsel and the policy officials at HHS? As you can see, I am very concerned that a recent staff inquiry to the HHS Office of Legislation has not even been acknowledged.

Mr. SCHULTZ. Well, yes, I can certainly try to respond. I want to say, I worked as a staffer in the House. I did oversight, and I understand the importance of oversight and how, in order to do oversight, the administration has to respond, and we have the duty to do that. I am told that that response is being worked on, and you will get a response.

Senator HATCH. Well, I hope so, because I do not think they have been very forthcoming down there on a whole raft of issues. Certainly they are not forthcoming with any kind of speed or any type of real cooperation, it seems to me. I hope you can bring about a change there.

Mr. SCHULTZ. Yes. I agree with you that you are entitled to a prompt response. I will do what I can to be that voice. These are not all my decisions, but I will certainly be the voice on your side on this.

Senator HATCH. Well, thank you.

My time is up.

The CHAIRMAN. Senator, when did you make the request? How long ago did you make the request?

Senator HATCH. Well, here is the chronology on the request for information from the General Counsel's Office. Chairman Camp and I sent a letter to Secretary Sebelius requesting answers to questions regarding the development of the Information Memorandum on welfare work waivers. That was sent September 21st.

We requested information no later than October 25th, which was more than a month. On October 25th, committee staff sent an e-mail to the Office of the Assistant Secretary for Legislation, requesting the information. We were informed "not today." Committee staff requested a time frame for complying with the request and were told "working on it."

On November 8th—and here we are almost into the next year—committee staff once again requested a time frame for compliance with the request and were once again told "oversight staff working on it."

On December 11th, committee staff requested an update on the request. That e-mail has not been responded to. That was December 11th. It has not been responded to by the Office of the Assistant Secretary for Legislation. I just think it is completely unacceptable and shows a lack of respect and responsiveness by this administration.

The CHAIRMAN. Senator, I agree.

Mr. Schultz, if you can get the Department to make a prompt response, that will not go unnoticed.

Mr. SCHULTZ. I will do everything I can.

The CHAIRMAN. All right.

Senator HATCH. This is not some itty-bitty issue; this is an important issue.

The CHAIRMAN. No, I understand.

Senator Stabenow?

Senator STABENOW. Thank you very much, Mr. Chairman. I want, first of all, to thank you for recognizing all four colleagues who are leaving, and the extraordinary efforts of Senator Conrad, Senator Bingaman, Senator Snowe, and Senator Kyl. Thank you for doing that.

Also, I want to send my thanks and best wishes to Russ Sullivan—I do not believe I see him here at the moment—for all of his efforts. We all collectively owe him a great deal for his public service.

Welcome to both of you, and thank you for being willing to be involved in public service as well.

Mr. Schultz, I want to, just for the record, talk about something you and I have talked about that is very important to me in health reform. I care about all pieces of it, and having it done promptly, and having it done well.

There is one particular issue dealing with pediatric dental coverage, which, as you know, because of some ambiguity after we had passed an amendment here in the Finance Committee about the intent of the law, that has needed to be cleared up in the rules.

In health reform we worked to ensure that children are able to get dental care that they need, and in some cases that would save their lives. We have had very unfortunate tragedies that have occurred. We expanded access to affordable dental coverage for children and wanted to do it in a way that would not disrupt current dental coverage of families.

So to accomplish this, the law intended to ensure that standalone dental plans of families could meet the essential health benefit's pediatric dental requirement in combination with a medical plan outside the health exchange marketplace, as well as inside. I have spoken to the Secretary a number of times, and a number of us, as Senators, have sent letters asking to make sure that this is clarified.

The law intended to ensure that, regardless of how the coverage is attained, pediatric dental coverage is still required as a part of the essential health benefits package and that all relevant consumer protections, such as out-of-pocket limits, would apply to stand-alone plans. I just wanted, for the record, for you to indicate your awareness of this and willingness to work with me and many

other Senators to make sure we are clarifying this in the final rules.

Mr. SCHULTZ. Yes, I am aware of it. We have talked about it, and it will certainly be a priority.

Senator STABENOW. Thank you very much.

Mr. Meade, thank you also for your service. You have a broad role as General Counsel when we look at tax reform and all of the issues that are so important to moving the economy forward in a global economy. I am wondering if you have any comments about how we, in our economic recovery, focus on manufacturing, which of course is very important in Michigan but also in other States, every State actually.

In fact, according to a *New York Times* article published in January of this last year, for the first time since 1997 manufacturing employment has risen in two consecutive years and in fact is driving much of the recovery as we are making more things in America again. So, when we are looking at tax reform, do you have any suggestions in terms of growing the manufacturing sector as we look at broader tax reform or particular policies that you have looked at that would help us to continue to grow that part of the economy?

Mr. MEADE. Thank you, Senator, for that question. With the lawyers at Treasury, we work very hard with our various policy clients to provide them advice on a range of questions. Many of the questions that you raise are important policy questions that could be considered by the Office of Tax Policy on the one hand, or also by the Office of Domestic Finance.

We see our role very much as partners with those policy offices. In some instances we are asked to consider possible legislation, possible proposals, looking at the scope of authority under current law to do whatever we can to support the policy officials.

I do not know of any particulars on the question that you raised. I would be happy to bring those concerns back to Treasury and commit that the Office of General Counsel will work with the policy officials to support those goals.

Senator STABENOW. And just very quickly—thank you. If we are not able to come to agreement as it relates to the fiscal cliff—and I certainly hope we are going to be able to do that—and we do not extend the AMT patch, how do you work with IRS to ensure that families have some certainty? What happens from your end?

Mr. MEADE. That is a critical question that the country is focused on at the moment. Right now, obviously, there is a fair amount of uncertainty with respect to what will happen with the fiscal cliff. The Acting Commissioner, Steven Miller, put out a letter yesterday on the AMT. I think there are a lot of questions about what will happen with the return season if the AMT patch is not put into place. So the lawyers work with the policy officials on those questions, but I think right now the hope is that the AMT patch is fixed so that there is some certainty around that question.

Senator STABENOW. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator. I want to just second what you said. I very much hope we reach sufficient resolution by the end of this year that addresses not just the AMT patch, but there is SGR, there are a lot of provisions which, if not addressed by the

end of this year, are going to cause just terrific hardship at the beginning of next year.

I will go out on a limb. I think we are going to get some kind of agreement this year. We certainly must, for all the reasons that we know. But thanks for mentioning AMT. That is all the more reason to get an agreement this year.

Senator Coburn, I apologize to you. I did not notice that you were earlier on the list than Senator Stabenow. You are next.

Senator COBURN. Thank you. Welcome, both of you. Mr. Schultz, I enjoyed our talk yesterday. You can see from what the ranking member had to say the problem with HHS and responsiveness, and your commitments to me personally that we would see a change in that, I will hold you to that. I think you are a man of your word.

I am sorry I did not have a chance to meet with Mr. Meade. I have a big burr in my bonnet, and, unfortunately, you are the only leverage I will have to get it cleared up, so it is going to become an issue. As part of our oversight in Governmental Affairs, we were looking at the New Market Tax Credits. We sent a letter to the agency asking for information on it.

After our letter was sent—and, Mr. Chairman, this is very important, because section 6103 of the code provides protection for taxpayers, and the protection was not placed on this until after I sent a letter requesting the information on the two previous times they had readily granted the information to members of Congress or GAO.

So the question I have is, until I see the background, with substantial clarity and transparency, of the decision-making process that went into it, that all of a sudden, when a member of the Senate starts asking questions about it, we now decide we are going to use 6103 to not share the information—I would just say, if I can get my chairman to agree, we can have the information with his blessing if he so asks for it.

But that is not the question that I am concerned about. I am concerned about, when we ask GAO to do further work on this and when we ask about it, all of a sudden you all make a determination that it is now protected, and it was not before. You can understand that that might raise some certain questions on our part. Our whole purpose is to do good oversight.

As ranking member on the Permanent Subcommittee on Investigations, as well as ranking member-to-be on Homeland Security and Governmental Affairs, these are important issues for us to look at: how, when we put something into the tax code, it actually plays out. Not having the availability of this information limits our ability to assess the effectiveness of tax policy.

So unfortunately, until I see with real clarity an explanation, with transparency, which would include all the background information, I am going to be hesitant—and I have no other reason, after reading all the files on you, to say that you are anything other than a perfect fit for this job. Until I can be satisfied on that, this nomination is going to be held by me, and I am going to work with my colleagues if it is brought to the floor, because this is the very thing that Senator Hatch is talking about.

If we cannot have transparency from the agencies when we are trying to do a good job for the American people on policy, and then

we see a ruling invoked that was not invoked until a Senator asked for the information, that raises serious questions.

So I do not know if you are prepared to answer that today. You do not have to answer that. But I am going to have to be satisfied on that, because I think it is highly inappropriate, what was done and the way it was done. What we want is truth. We are not trying to gore anybody's ox. What we want to know is how we are spending tax money in tax policy, and is it working and where is it going?

I do not think we had an illegitimate request. Other than that, I know you are highly qualified for this job, and I support you fully, but I want that information, and I want it in detail with complete transparency.

I yield back.

The CHAIRMAN. Mr. Meade, are you prepared to address this question?

Mr. MEADE. Senator Coburn, unfortunately I am not familiar with the particulars of the situation. But of course I will take it back to Treasury. I hear your concern, and I want to work with you to get your concerns resolved.

Senator COBURN. That is all I can ask.

Mr. MEADE. I think it is critical that oversight happen, that we get back to Congress. We work closely, and I work very closely with our three Inspectors General to make sure that oversight happens. That is one of my most important relationships at Treasury. But I will work with you to make sure you get the answers that satisfy you.

The CHAIRMAN. And I will be watching the development of this and the resolution of this as well, because it is important.

Senator Roberts, you are next.

Senator ROBERTS. Thank you, Mr. Chairman. I associate myself with the comments of Senator Hatch and yourself regarding our outstanding members who are leaving, and I regret that I was not here to put a little frosting on the cake.

I have, I think, three questions. The answers are "yes," and "as soon as possible," so you do not have to worry about it.

Mr. Schultz, along with the Senate HELP Committee, we have been looking into the New England Compounding Center, the actions by the NECC, and the potential action by the Congress in response to the outbreak. But we have made repeated requests for information and have yet to receive any really adequate information. It really has hindered any progress.

Of particular interest to me is the timeline of events related to the NECC inaction by the Department of Health and Human Services and FDA, both prior to and following the outbreak. We made this request in early October at the start of the meningitis crisis, and, even after asking Dr. Hamburg about it during the HELP Committee hearing a while back, we have yet to receive a response.

You are 60 days—well, not you, but the folks in charge—in violation of the new Baucus-Hatch doctrine. If you go 90 days, you will be sentenced to come to Kansas in January and visit every rural hospital and say, I am from CMS, and I am here to help. That might not be something you want to do in January. So anyway, if

you can get that back to us, or at least give us a report, I would appreciate it.

In addition to that, what do you believe are the scope and limits of FDA authority as it relates to compounding? What is the FDA role, and what is the appropriate role for State boards of pharmacy in oversight of this industry? I realize you cannot go into that right now, but if you could make a note of that, and we will submit that for the record for you, and then if you could get back to us.

Recently, HHS, Treasury, and the Department of Labor have issued regulations to implement the provisions of PPACA, the Affordable Health Care Act. These include the essential health benefits mandated, the actuarial value calculator, market rules, and wellness provisions, as well as rules to implement provisions relating to risk programs, cost sharing, the federally facilitated exchange, user fees, and medical loss ratio. There is somewhere between 6 to 8 there that I have noted.

Many of the initial rules in trying to implement the statute were called the Interim Final Rules, which allowed very little or no stakeholder input. Of the most recently issued rules, while none of them are IFRs, many of these only provided 30 days for public comment.

Now, this is after the administration took over 18 months to draft the regulations and OMB was allowed 4 months for their review. That is 22 months. I am just going to tell it like it is on what I am hearing from the rural health care delivery system, and for that matter our entire health care delivery system there in the State of Kansas.

We have already heard from many stakeholders. A lot of them fear they will be unable to meet the timelines for these comments. The comments will not represent a thorough review of the new policies, and the administration does not value stakeholder input in the process—that is not a good thing, to say the least—to the point that many stakeholders are considering whether time, effort, and expense is even worthwhile when they believe their comments are not even being considered, but instead are treated as a check-the-box exercise to comply with existing executive orders and statute-related stakeholder input.

My question is, what is a reasonable and standard amount of time for review and comment on regulations issued in regard to PPACA? We also have an important consideration when drafting and issuing these regulations. I would repeat, if the folks who are drafting the regulations do not know what is in a rule after 18 months of drafting and 4 months of OMB review, how can we expect stakeholders to know such things and provide valuable feedback in a much shorter time frame? There. You have 35 seconds to respond.

Mr. SCHULTZ. I certainly agree, notice and comment are critical, because regulations have the force of law, Senator Roberts. I agree with you that we should use IFRs very reluctantly, because, in that case, the comment is after the fact. We did it early on because of tight timelines that Congress asked us to meet. But as you say, we have done it very rarely recently, and I would think that would continue to be so.

We truly value comments from the public. We spent a lot of time responding to them and typically make many changes in the regulations in response to them. I think we will continue to do that. I hope this effort is apparent.

Senator ROBERTS. Do you ever go out in the field? I mean, out to, say, a typical critical access hospital in Montana, Kansas, Oklahoma, Iowa?

Mr. SCHULTZ. I have not. No, I have not in this job. I talk to people——

Senator ROBERTS. Do you have time to do that at all?

Mr. SCHULTZ. No.

Senator ROBERTS. I did not think so.

Mr. SCHULTZ. No.

Senator ROBERTS. Could you send a deputy? We have a lot of deputies out there.

Mr. SCHULTZ. We could.

Senator ROBERTS. I am not going to do this in January for you, but maybe in the spring.

Mr. SCHULTZ. Well, maybe it would be good.

Senator ROBERTS. I think that would be a good thing. I might stand a little part away from you. No, I would stand right by your side. We will see all the hospital administrators, doctors, nurses, and everybody else, all these forms and regulations they have to put up with. It will be an interesting exercise.

Mr. SCHULTZ. Senator Roberts——

Senator ROBERTS. I have done it twice myself.

Mr. SCHULTZ. I would, of course, do that with you if you would like me to. I do want to say that we have a lot of outreach to all the States, and there has been a lot of interaction with many officials and others in the States that is informal, outside the rulemaking process.

Senator ROBERTS. We could do it pretty quickly, and we could get you a good balance, and I think it would be very helpful. I am not going to put you on the spot on that. I know you have a ton of things to do, and so do we. But I think it would be a good thing if we did that.

Mr. SCHULTZ. I think it would too.

The CHAIRMAN. Thank you. Thank you, Senator, very much.

Senator Wyden?

Senator WYDEN. Thank you very much, Mr. Chairman. First, with respect to our retiring colleagues—Mr. Chairman, I think you would remember this—I hope some of them will in effect do a Conrad. As you know, Senator Conrad retired once because he said the budget was in balance. Then there was a death, and he came back. We were lucky he came back. We have a terrific group of colleagues. Maybe we can persuade some of them to do a Conrad.

The CHAIRMAN. Is one of the conditions that the budget has to be in balance?

Senator WYDEN. Yes.

The CHAIRMAN. I think you are in for a long wait. [Laughter.]

Senator WYDEN. Well, I want them back sooner than that.

The CHAIRMAN. Okay. We all do.

Senator WYDEN. I want to say a good word about Russ Sullivan. He has such a wealth of knowledge. Mr. Chairman, as you know,

we spent years talking about Build America Bonds. I do not think there was anybody on the planet, other than Russ Sullivan, who mastered that subject, along with scores of other technical ones.

The fact that he has all this technical knowledge, while he cares for this huge group of children, I think tells you a lot about what kind of heart Russ Sullivan has. I often see him, as you do, Mr. Chairman, with those kids in the corridor because Russ is taking them on a family outing. To have that kind of heart for people while you stay here and handle all these technical issues says a lot about a person, and we are very grateful for your service.

Mr. Chairman, we have two outstanding public officials. I have one question for each of them.

The first one, for you, Mr. Meade, deals with electioneering by tax-exempt social welfare organizations. As you know, in the wake of the Supreme Court's decision, there has been a proliferation of these entities organized under section 501(c)(4) of the code. It just looks like they are doing pure politics. I do not want to talk about Democrats or Republicans, I just want to talk about what seems to me is an abuse of the tax exemption.

During the 2012 election cycle, an estimated $400 million went into secret contributions that were associated with these 501(c) organizations. In July of 2012, a letter was sent responding to a request from the Campaign Legal Center and Democracy 21 to change the rules.

The IRS Exempt Organizations Division Director stated that the IRS is aware of the interest in the issue and noted that the agency will consider proposed changes in this area as we work with the IRS Office of General Counsel. As I understand it, you have involvement with them in terms of the reporting.

The reason I am asking the question is, in November of 2012, the IRS released its priority guidance plan. It contained 317 projects that are priorities for allocation of resources. Nowhere in the list of agency priorities was there any mention of the need to revise and clarify the rules dealing with political activities by section 501(c)(4) organizations. When you are confirmed, will you try to get this issue on the priority list for that agency?

Mr. MEADE. Thank you, Senator, for that question. In terms of any particular issue about any particular 501(c)(4), that is a question of enforcement for IRS, and we stay away from those questions.

Senator WYDEN. I understand.

Mr. MEADE. But in terms of the policy question, I know it is something that the Office of Tax Policy and IRS are looking at, and I would be happy to look at that issue, to talk to the Chief Counsel of the IRS, who is, as you know, a Senate-confirmed official, and talk about that question and about making that a priority for the——

Senator WYDEN. Do you personally think it ought to be a priority? I do not want you to have to speak for anybody else. Do you personally think it ought to be a priority?

Mr. MEADE. Senator, I have not studied the question. I hear your interest in the issue and the fact that you think it is a priority. What I want to do is take a look at it and talk to the officials within Treasury, talk to the officials within the Chief Counsel's Office,

and analyze the issue. So I do not know enough to know whether it should be a top priority or not, but I definitely hear your concern, and I will take that concern back to Treasury.

Senator WYDEN. Well, I understand why you want to talk to people in the Department. I hope you will come away and say it ought to be a priority. This ought to be a priority for good government. These abuses are completely out of hand, and you know that I am not bringing any kind of partisan tinge in this group and that. I think this is an abuse of what is really a tax exemption that is supposed to go to social welfare organizations.

A question for you, Mr. Schultz. I have watched your outstanding work since the days when we were back on the Health Subcommittee over in the House and I had a full head of hair and rugged good looks and all. My question is a legal one. That is, we have been working very hard to try to get the hospice program off the ground, where, for the first time in America, the vulnerable would be eligible for curative services as well as hospice services.

The Congress wrote this so that it would be budget-neutral. We have been having a lot of challenges at CMS, trying to get them to accept the intent of Congress. They say hospice providers would have to pay for curative treatment out of their own pockets. That was never the intent of Congress.

Will you work with us so that we can get the congressional intent here nailed down and, for the first time, say to the vulnerable in America—again, this was supported by people all across the political spectrum. They said, when you need hospice—Senator Hatch, Senator Grassley, and others have worked on these issues for years—you should not have to give up hope. That was the intent of Congress. Will you commit to working with us?

Mr. SCHULTZ. Thank you, Senator Wyden. I know this is a very important program, and I will certainly work with you and do what I can. As you know, I am not the decision-maker on this.

Senator WYDEN. Understood.

Mr. SCHULTZ. So I am happy to work with you on it.

Senator WYDEN. Well, thank you. The reason I ask is, not only have I watched you in the past approach these issues professionally and fairly, but it has become a legal issue with respect to the intent of Congress.

Thank you for the time, Mr. Chairman.

The CHAIRMAN. Thank you, Senator, very much.

Senator Grassley?

Senator GRASSLEY. Well, thank you, Mr. Chairman, for holding this hearing. I would like to put in the record a statement that I would have about our four colleagues retiring.

The CHAIRMAN. Without objection.

[The prepared statement of Senator Grassley appears in the appendix.]

Senator GRASSLEY. Mr. Schultz, I have many unanswered questions and document requests, as you have heard from other members. I have received no response to my December 6, 2011 letter on eliminating the age requirement for Plan B. I have received none of the documents that Chairman Issa and I requested regarding monitoring of FDA employees; no response to a letter Chairman

Upton and I sent on the oversight of Federal exchange grants to States.

I received no response to my September 10, 2000 letter regarding Keokuk. I hope you know that, as my other colleagues have said, this is unacceptable. Until I receive answers to my letters and document requests, I am hesitant to move forward on these nominations.

Question number one. I have some remarks preliminary to it. For the past 5 months, Chairman Issa and I have been investigating the FDA regarding its spying activities against whistle-blowers. The FDA intentionally spied on confidential communications with Congress and the Office of Special Counsel and the whistle-blowers' private attorneys.

We have completed four voluntary transcribed interviews with key FDA individuals who participated in the spying. Three out of the four employees declined to answer when asked about anything related to personnel action. They said they were told by the agency not to answer such questions, citing the Privacy Act. Obviously you know that Congress is exempt from the Privacy Act.

I understand that you were involved in the discussions about prepping the FDA employees before their interviews. I also understand that, during conversation with my staff, you could not recall whether or not you advised the FDA employees not to answer questions regarding personnel management.

Given the clear exemption in the Privacy Act for disclosures to Congress, I assume you agree that the FDA employees are free to answer questions about personnel action during congressional investigations. Is that true?

Mr. SCHULTZ. Yes. Thank you, Senator Grassley. I was not involved in the conversations, but I have gone back and looked at the Privacy Act and so on. We will not instruct employees or their attorneys not to answer your questions. We certainly agree that there is an exemption for Congress from the Privacy Act. There are debates about whether it applies to committees, chairmen, individual members, and so on. But in this particular situation that you are talking about, we believe that at most the risk would be very small, and we will certainly not instruct the employees not to respond.

Senator GRASSLEY. You have answered my second question. Let me state it anyway, and you do not have to speak further to it. Well, let me make a statement. I think you have assured me in what you just said that, in the future, you will ensure that witnesses know that they are free to make disclosures to Congress that might otherwise be prohibited by the Privacy Act.

For Mr. Meade: on November 1st, Senator Thune and I wrote Secretary Geithner a letter in his capacity as chair of the Committee on Foreign Investment in the United States regarding bankruptcy stimulus recipient A123. We asked seven questions. The response we received did not answer a single question.

When you reviewed this reply letter, did you find any legal bases for refusing to answer our questions, and, if so, what were they? Finally, does the Treasury still take the position that it does not have to respond fully to the letter?

Mr. MEADE. Thank you, Senator Grassley, for that question. I did not review that letter before it went out. I know in general, with

the CFIUS, there are certain statutory prohibitions where Treasury is permitted to share information with Congress at some point but not at other points under the statute passed by Congress. I would be happy to look at that particular instance and give you whatever information I can, and if not, provide the legal basis for that.

But what I can say is, I think oversight is critically important and providing prompt responses to members of Congress is critically important.

Senator GRASSLEY. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Thune?

Senator THUNE. Thank you, Mr. Chairman.

I want to thank our panelists today for your willingness to be here and to continue to serve. I also want to acknowledge the departing members of this committee, Mr. Chairman, that have been already mentioned. Obviously a lot of firepower, a lot of skill and knowledge on the issues that this committee deals with will be lost when we lose Senators Snowe, Kyl, Bingaman, and Conrad, all people who have tremendous amounts of expertise. Hopefully we will be able to muddle along without them, but we certainly appreciate their great service and all they have contributed to this committee and to our country.

Let me ask a question, if I might, to Mr. Meade first. This question has to do with sort of where we are with regard to the fiscal cliff. We are now less than 2 weeks away from seeing tax rates rise across the board, that is assuming that Congress and the administration cannot come to an agreement on the fiscal cliff.

So my question has to do with the paycheck withholding levels for 2013. First, how much latitude do you believe the Treasury Department has under the statute when setting withholding rates? Second—and again, knock on wood, hope this does not happen—should we go over the cliff without an agreement, how would Treasury make a decision with regard to the withholding tables?

Mr. MEADE. Thank you for that question, Senator Thune, a very important question that obviously the country is thinking about at this time. The Secretary's discretion on this score is limited. The law says that the Secretary needs to set withholding tables consistent with the tax laws set by Congress.

The Secretary does not have the authority to unilaterally set the tax rates, he needs to reflect the rates set by Congress. Hopefully, though, a deal will be reached such that this will be unnecessary, but the bottom line is the Secretary's withholding tables—any tables that he issues—need to reflect the laws set by Congress.

Senator THUNE. So, if there is a scenario where, in the near term, it looks like there might be an agreement but that has not been struck or at least has not been voted on by the end of the year, but there is sort of a framework, or at least it looks like there is going to be some closure, your view is that the Treasury Department does not have authority even on a near-term basis, an interim basis, to maintain the withholding tables the way that they are?

Mr. MEADE. So, Senator Thune, that is a slightly different question in terms of the particulars of that kind of hypothetical. As a

lawyer, I want to be very careful giving answers to hypothetical questions. As your question reflects, there could be many different components of such a hypothetical about what the particulars look like.

The Secretary does have some discretion, but that discretion is limited. At the end of the day, what his authority is is to reflect the law set by Congress.

Senator THUNE. Thank you.

Let me ask Mr. Schultz a question, if I might. This one has to do with the passage of the health care law. There was a particular provision in there that I was concerned about and was trying to keep from having added to the law. That is the CLASS Act, which is a new long-term care entitlement program that was created by the Affordable Care Act.

Last year on October 14, 2011, Secretary Sebelius announced that, based on actuarial legal analysis, the CLASS program is both legally and fiscally unsustainable. The report went on to conclude that they cannot predict that the CLASS program will be able to "honor its commitments to individuals who had already enrolled or entered beneficiary status in the program or avoid leaving them worse off."

So the question is, do you agree with the analysis contained in this report that the CLASS Act is unsustainable? If you do not agree with that, why? Then second, if you do agree with this report, then would you support the efforts that I and others are making to repeal that program?

Mr. SCHULTZ. Thanks for that question, Senator Thune. We worked very hard to try to find a way to implement the act because Congress passed it, but looking at the legal constraints—including that it had to be sustainable for 75 years, there were certain guaranteed benefits, certain groups that had very reduced rates—the Secretary concluded that she could not go forward with a program that people would buy under the requirements that Congress imposed. Yes, I do support that conclusion.

We put the legal analysis out there so Congress could see it. Whether it should be repealed or not, I think is a decision for Congress. We have not been sued on it. I do not think we would be. I think what we did is very sustainable. So, I would leave it to Congress as to whether to repeal it or not.

Senator THUNE. All right. But in terms of taking a position supporting efforts by Congress to repeal it based upon the conclusions that you all have drawn—that it is not sustainable in its current form—would the administration be able to support legislation that would repeal it?

Mr. SCHULTZ. I would have to leave that to others in the administration to speak to. I am merely a nominee at this point.

Senator THUNE. On October 17th, HHS received a letter regarding concerns that some of my colleagues and I had, and still have, regarding the Final Rule for the stage 2 of "meaningful use" for the adoption of electronic health records.

To date, we have about $10 billion that has been paid out in incentives to health care providers to implement a useful EHR system, and we still have several unanswered questions and concerns

about the direction of this program. When might we anticipate a response on that letter, if it is something you are familiar with?

Mr. SCHULTZ. I am not familiar with it, but I will certainly go back and raise this and do what I can to get a response.

Senator THUNE. That would be great. That was a couple of months ago now. Hopefully we are going to get a response on that, so, if you could check that out, that would be great.

Mr. SCHULTZ. I would be happy to. Thank you, Senator.

Senator THUNE. I see my time has expired, Mr. Chairman. Thank you.

The CHAIRMAN. It has.

Senator Grassley?

Senator GRASSLEY. Yes. Mr. Meade, on October 2nd, Senator Kirk and I wrote Secretary Geithner a letter about manipulation of LIBOR. The manipulation has led to billions of dollars in losses to the Federal Government. My concern is that the Treasury Department is not fully committed to informing Congress about the scope of the problem. I understand that, as acting General Counsel, you are familiar with the letter and the response.

My letter asked five questions. The reply we received, almost 2 months later, did not answer any of them. Here is one example. We asked whether Secretary Geithner considered the litigation risks of not reporting his knowledge of LIBOR manipulation to U.S. enforcement authorities. The letter you reviewed did not answer this question. Why did the reply that we received not answer this question?

Mr. MEADE. Thank you, Senator Grassley, for the question. I am familiar with that letter. My understanding is, in follow-ups with your staff after the response, we answered that question and the other questions.

The questions asked I believe for the most part, or maybe exclusively, for answers about the Secretary during his time at the New York Fed. We, I believe, now have answered those questions to the satisfaction of your staff. We think the LIBOR issue is very important. I think we are pleased that the actions of the CFTC and others that began in 2008 have led to very strong enforcement actions which we are beginning to see the fruit of today.

Senator GRASSLEY. Yes.

Also, Mr. Meade, I ask this question as a champion of whistleblowers and for changes in whistle-blowers legislation, but, particularly in this case, tax whistle-blowers. I am concerned that some within the IRS and Treasury continue to be unsupportive of whistle-blowers. My concern results from recent regulations proposed by Treasury that unnecessarily put roadblocks in the way of whistle-blowers. What was your role in preparing those regulations?

Mr. MEADE. Senator Grassley, I personally did not play a role in crafting those regulations. I would say two things. First, these are proposed regulations. They are regulations that set out the proposed definitions of a variety of statutory terms, as well as give a comprehensive view of a whistle-blower's experience with the IRS. These are proposed regulations. We look forward to input from stakeholders, from you, from members of the whistle-blower bar, to make sure that we are reaching the right conclusion under the law.

But I want to say, personally, I am committed to the whistle-blower program. I have heard others in Treasury talk about their commitment to the whistle-blowers program. But I can commit to you that, if confirmed, I will carry that commitment through in my role as General Counsel.

Senator GRASSLEY. All right. You answered my next question. I will follow it up with this, that I do plan to propose regulations and expect a thorough response. I expect you to help in facilitating a quick response to my concerns. So, you answered your concern about protecting whistle-blowers, but would you commit to getting me a response when I submit my comments on those regulations?

Mr. MEADE. I would be happy to work with you and help prepare a response, or at least review a response and make sure that you are getting a proper response.

Senator GRASSLEY. All right.

Then my last question is for you, Mr. Schultz, and then I will be done. The FDA says that spying on its employees was justified because they were warned by a security banner on their FDA computer that it was being monitored. However, the wording of that banner changed during the course of the spying.

When asked why the banner was changed, all four employees interviewed could not recall. Why was the wording of the banner changed, and was the language changed in the summer of 2010 to justify spying activities that had already taken place?

Mr. SCHULTZ. I am not aware. I have not seen the two banners. I could get you a written response to that, but I do not know why the banner was changed. I certainly was not involved in that.

Senator GRASSLEY. I will let you give me a written response.

Could you tell me, was the change reviewed by your office?

Mr. SCHULTZ. I do not know.

Senator GRASSLEY. All right.

Mr. SCHULTZ. It certainly was not reviewed by me.

Senator GRASSLEY. All right. Then you have answered my last question as well, so I will look for your response in writing.

I thank both of you for being kind enough to answer my questions, but I will thank you more if I get regular responses, in time.

Thank you.

The CHAIRMAN. Thank you, Senator, very much.

Thank you both very much. This committee looks forward to a very vigorous and constructive relationship with both of you and with your departments, and we wish you both well in the new year.

Thank you very much.

Mr. SCHULTZ. Thank you very much, Senator Baucus.

Mr. MEADE. Thank you, Mr. Chairman.

The CHAIRMAN. The committee is adjourned.

[Whereupon, at 4:04 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

Hearing Statement of Senator Max Baucus (D-Mont.)
Regarding Departing Committee Members and Nominations for HHS and Treasury General Counsels
As prepared for delivery

In a speech on leadership delivered more than 100 years ago, President Theodore Roosevelt said:

"It is not the critic who counts; not the one who points out how the strong man stumbles, or where the doer of deeds could have done better.

"The credit belongs to the person who is naturally in the arena, whose face is marred by dust and sweat and blood; who strives valiantly, who errs and who comes up short again and again, because there is no effort without erring and shortcoming.

"But who does actually strive to do the deed. Who knows the great enthusiasms, the great devotions, who spends himself in a worthy cause; who at the best, knows, in the end, the triumph of high achievement, and who, at the worst, if he fails, at least fails while daring greatly."

This quote hangs on a wall in my office. It serves as a powerful reminder about the importance of political leadership.

Today, I want to thank the four members of this committee who are leaving the Senate at the end of this year — Kent Conrad, Olympia Snowe, Jon Kyl and Jeff Bingaman. They have served valiantly in the arena of the United States Senate and I'd like to say a few words about each of them.

For the past 26 years, I've had the opportunity to work in the Senate with Kent Conrad. Kent has many of the same values that we have in Montana – he is honest, hardworking and straightforward, and he is committed to improving the future of our nation.

Kent has been a member of the Finance Committee since 1993, when he was appointed to fill the seat vacated by Lloyd Bentsen. And for the past 20 years, he has been a champion for expanding trade for farmers and ranchers, ensuring families affordable health care and working tirelessly to reduce America's deficit and debt.

There are few people in Congress who know economic policy as well as Kent, and none match his love of charts. Whether as a member of the Gang of Six, Simpson - Bowles, the Finance Committee or at the helm of the Budget Committee, Kent has been a voice of reason on fiscal matters.

As a senior member of the Finance Committee, he also played a key role in shaping the Affordable Care Act and has been a leader in fighting for rural health care. He has also been a strong ally echoing my call

for comprehensive tax reform. A former tax commissioner, Kent will be missed as we take on this next great challenge.

Thank you Kent — we are grateful for all your hard work.

Today, we also thank my good friend from Arizona, Jon Kyl, for his long service to the American people.

Over the years, Jon has developed a reputation for hard work, leadership, and an encyclopedic knowledge of policy. He has served on the Finance Committee for more than 12 years with such persistence and tenacity, fighting for the causes he believes in.

It has not gone unnoticed. TIME Magazine named Jon one of the 100 most influential people in the world for his persuasive role in the Senate. Throughout the years, we have worked together for the good of our nation -- working to create sound policies for the American people.

Jon has been passionate about many issues. Maybe none more so than the estate tax. Jon has worked across the aisle with me and others to protect America's family-owned small businesses, farms and ranches from the burden of the estate tax. Jon's skills as an advocate on the issue are unmatched.

We will miss Senator Kyl's perspective and his strong representation of the citizens of Arizona and, even more so, the American people.

At the end of this year, the Senate will lose another great statesman, and New Mexicans will lose an extremely effective legislator in Jeff Bingaman.

Jeff has been a tireless advocate on health care, Native American and energy issues. He is the Chairman of the Energy and Natural Resource Committee and is responsible for some of the most important energy policies on the books.

On this committee, he authored the advanced biofuel tax credits and led the effort to improve energy efficiency incentives. His ideas have helped set the course for this committee to work on energy tax reform.

On health care, Jeff and I have accomplished much together. He was vital to the Children's Health Insurance Program — or CHIP — and the health reform legislation. He also worked tirelessly to simplify and streamline enrollment in Medicaid and the children's health care program, and ensured Indian health was included as well.

Jeff is a work horse, not a show horse. He thinks long and hard about the issue, figures out the best policy and gets it done. And after it's completed, he quietly moves right on to the next challenge.

Jeff doesn't seek out credit or a pat on the back. That is just his personality. Well today, you can't avoid the recognition, Jeff. We are giving you the credit you deserve.

Senator Olympia Snowe is another member more interested in progress than politics. She has demonstrated over and over that ideological purity should not prevent Washington from tackling the great challenges of our country.

We will miss Olympia's thoughtful approach to building bridges and crafting compromise.

From her start on the committee in the 107th Congress, Olympia worked to form consensus.

That January, we were addressing the 2001 tax cuts proposed by President Bush. Olympia worked with all members of the committee — especially Democratic Senator Blanche Lincoln — to strengthen the child tax credit. I know she is proud of that work, an effort to help the poorest of children.

More recently, Olympia worked with me as part of a bipartisan group to create the foundation of health care reform. I remember appreciating how detail-oriented Olympia is. Always taking notes, highlighting passages, focusing on every detail and always looking out for her constituents back home in Maine.

Olympia is one class act. And as the longest serving and highest ranking woman to serve on the committee, she has set a great example for all those who follow. We thank you for your service, Olympia.

Over time, each of these four Senators has made their mark. Each has had an impact on this committee and on this Congress. They have — as Roosevelt said — been in the arena and made a tremendous difference to our nation.

I also want to acknowledge the work of our friend Mark Matthiesen, who recently announced his retirement. For the past 31 years, Mark worked on tax legislation in the office of the Senate Legislative Counsel.

The Senate community regularly relies on Mark's expertise, and while we wish him the very best in retirement, this committee will miss him.

And on a final note, earlier today I announced that our friend, who all of you know and love – Russ Sullivan, will be leaving the Senate at the end of this Congress. He has been a true friend and respected colleague for the last 18 years. I know I speak for all of us in wishing him the best in his future endeavors.

While Russ will be greatly missed, we are fortunate to have Amber Cottle taking on this leadership role. You all recognize her as she has been with me for close to six years as one of my closest advisors. Amber is a proven problem solver who works across party lines to get results. She is exactly the type of person I want leading my team for years to come.

Woodrow Wilson once said, "I not only use all the brains that I have, but all that I can borrow."

This administration, like all administrations, faces a great number of challenges. They need a great number of bright and talented people to work together to find solutions. The two nominees before us here today are among the best and the brightest. They seek to be the general counsels of the Department of Treasury and the Department of Health and Human Services. These agencies will depend on their advice and expertise for implementing laws and forming our country's economic and health policy.

In August, President Obama nominated Christopher Meade to be the General Counsel at the Department of Treasury. Mr. Meade came to Treasury in 2010, and this summer took over as the Acting General Counsel. This experience, and his trusted knowledge of the law, will serve him well.

After graduating from Princeton and then NYU Law School, Mr. Meade clerked for Supreme Court Justice John Paul Stevens. Years later, he returned to the Supreme Court to argue four high profile cases on behalf of his clients. In reviewing his career, a consistent theme is apparent: He is respected, trusted and Mr. Meade knows the law.

If confirmed, Mr. Meade will use his experience to counsel the secretary and all at the Treasury Department on economic and financial affairs, both domestic and international. These policies affect every person in America, and Mr. Meade's sound judgment is essential.

President Obama selected William Schultz to be the General Counsel at the Department of Health and Human Services. This position demands a high level of expertise to assist in the analysis and implementation of our nation's health care laws.

A graduate of Yale and then UVA Law School, Mr. Schultz gained expertise through a long and varied career, much of it in public service. He currently serves as Acting General Counsel at HHS. He came to the agency in 2011 after working at the Department of Justice, the FDA, and in the private sector.

Mr. Schultz was a well-respected professor at Georgetown Law, sharing his knowledge with hundreds of students. He's published many scholarly articles throughout the years covering issues from the FDA to the Supreme Court. His writings have appeared in the New York Times and the Georgetown Law Journal.

Both Mr. Schultz and Mr. Meade must bring thoughtfulness and a command of the law to their respective agencies. Their records show them to be qualified for these positions. I believe the administration will benefit from borrowing the knowledge, experience and perspective both nominees possess.

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Remarks of Senator Chuck Grassley
On the Retirement of Four Finance Committee Members
Thursday, December 20, 2012

Of the 10 senators retiring from service this year, four of those senators are on the Finance Committee. Maybe serving on the Finance Committee is tiring work, or maybe the rest of us are tiresome company. Joking aside, the retirement of Senators Bingaman, Conrad, Kyl, and Snowe is a tremendous loss for the committee and the public.

Senator Conrad joined the committee in 1993. Senators Bingaman, Kyl, and Snowe joined the committee in 2001. As a former chairman of the committee, I had the opportunity to work with all of these senators on a number of issues. They've contributed to dozens of pieces of legislation, hearings, and policy debates over their tenure.

The Finance Committee covers a broad range of issues, and our committee's output has been significant. Since 1996, the committee has taken on welfare reform; helped to develop the Children's Health Insurance Program; made several changes to IRS reform legislation; passed the Economic Growth and Tax Reconciliation Act, a major tax relief bill; passed the Trade Act renewing fast-track authority; approved of a number of free trade agreements; passed additional tax relief; created a new benefit under Medicare providing for coverage of prescription drugs; and played a major role in enacting sweeping health care changes.

These undertakings weren't necessarily supported by all of us in the end, but the point is Senators Conrad, Bingaman, Kyl, and Snowe were at the table for committee business. They contributed amendments, raised points of discussion, listened to hearing testimony, and otherwise fulfilled their roles as thoughtful, engaged legislators.

These four senators, although from different parts of the country, and of varying political philosophies, shared several key elements. All brought intellectual rigor to Finance Committee discussions. All represented their constituent states to the best of their abilities. All took their roles seriously and put their stamp on the final legislative product.

We've been able to accomplish a lot and reach consensus in the Finance Committee because the members have understood the art of compromise even as they fought for their priorities. That includes Senators Bingaman, Conrad, Kyl, and Snowe. I'm guessing that the bipartisan bills passed through this committee haven't been 100 percent ideal for any one person, but they've advanced the public good to the extent of earning bipartisan support.

It's been a pleasure to serve with four senators who have appreciated this committee to a great extent and who have done their jobs so well.

STATEMENT OF HON. ORRIN G. HATCH, RANKING MEMBER U.S. SENATE COMMITTEE ON FINANCE HEARING OF DECEMBER 20, 2012 NOMINATIONS OF WILLIAM B. SCHULTZ AND CHRISTOPHER J. MEADE

WASHINGTON – U.S. Senator Orrin Hatch (R-Utah), Ranking Member of the Senate Finance Committee, today delivered the following remarks during a Senate Finance Committee hearing considering the nominations of William B. Schultz to serve as General Counsel of the Department of Health and Human Services (HHS) and Christopher J. Meade for the position of General Counsel for the Department of the Treasury:

Thank you, Mr. Chairman. I want to take a moment to once again express my concerns about a growing problem relating to Congress's dealings with the Obama Administration because I believe it is relevant to today's hearing.

As part of their case against King George III, the Second Continental Congress repeatedly noted in the Declaration of Independence that George had consistently frustrated the attempts of the colonies to govern themselves. In these grievances we see frustration with a strong executive authority that dominated the legislative authority.

The very first grievance against the king noted in the Declaration states "He has refused his Assent to Laws, the most wholesome and necessary for the public Good."

Later, the revolutionaries indicted the king "For suspending our own Legislatures, and declaring themselves invested with Power to legislate for us in all Cases whatsoever."

These grievances were the inspiration for our Constitution, which created a system of checks and balances between the Executive and Legislative Branches.

Put simply, our system of government was designed so that Congress would be tasked with writing the laws that the Executive Branch implements. Now more than 200 years later, many would argue that the Executive has become more powerful, perhaps too powerful, at the expense of Congress.

Congress shares significant blame for this.

In an editorial published last year in The Washington Post, former HHS Secretary Michael Leavitt noted that Obamacare contains the phrase "the secretary shall" nearly 2,000 times. Even during his tenure, Secretary Leavitt noted that he had been advised that HHS "has more power than a good person needs or a bad person ought to have."

HHS is more powerful now than it has ever been before. Among literally hundreds of other functions, Obamacare designates that the HHS secretary will develop "tooth-level surveillance."

As such, perhaps the next nomination to HHS secretary ought to be jointly referred to this committee and the Committee on Homeland Security and Government Affairs.

The continued abdication by Congress of legislative power and the accumulation of that power by the executive makes the positions of Chief Counsel at HHS and Treasury very important.

The two nominees before us, if confirmed, would wield vast influence over decisions that might impact the lives of every American. This is why I, along with many of my colleagues, believe that thorough oversight of the Executive Branch is critically important to preserving our system of checks and balances.

The level of responsiveness from the administration, and specifically HHS and Treasury, to written requests for information has continued to be lackluster at best. I, along with many other members, have raised this issue numerous times, but to no avail.

Both of the nominees today are currently serving in an acting capacity in the roles to which they have been nominated. Consequently, they know agency practice and have worked within the existing agency structure, including how the agency responds – or, in many cases, does not respond – to information requests from Congress.

I would respectfully suggest that when they return to their agencies, they pass along a reminder that at least some in Congress find the lack of responsiveness to be entirely unacceptable.

My goal is to be able to work together with the Executive Branch, and I think our system of government works better when our two branches of government cooperate.

I hope that any nominee that comes before this committee does not believe that their responsibility to work and communicate with Congress ends with their confirmation. There have been several recent instances in which nominees have pledged to me and this Committee that they would work to promote transparency and would be responsive to Congress. Unfortunately, following confirmation, those pledges have too often been abandoned.

I know that Chairman Baucus recognizes the need for transparency and responsiveness and that he will work with me on finding a solution to this problem. To his great credit, he has repeatedly shown leadership in this Committee by backing up any Member's request to any agency of government. And I appreciate his leadership and support.

Finally, I want to conclude with a brief statement on the scheduling of this particular hearing. Mr. Chairman, I assume that there are many in the administration and on your side of the aisle that would like to see these nominations move quickly. However, when we rush these proceedings – particularly so near to the end of the Congress – we do the Committee a disservice.

As you know, there is a very important Republican Conference meeting today at 4:00 pm. Despite that, it was decided that a good portion of this hearing would be devoted to honoring our colleagues leaving the Senate.

I appreciate the desire to honor those who deserve it, as our colleagues do, but that shouldn't cause the hearing to get short shrift. In particular, I do not want to unduly limit questions from members of the Committee in order to complete the hearing on a shortened timeline.

These nomination hearings are more than just a box to be checked. They are essential to ensuring that we adequately fulfill our advice and consent responsibilities here in the Senate.

Mr. Chairman, I hope that you will recognize this and work with me to ensure that every member of the Committee gets ample opportunity to ask the nominees their questions and to receive answers, even if it means that we have to reconvene the hearing – and bring the nominees back before the Committee – at a later date. Thank you, Mr. Chairman.

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Opening Statement of Christopher J. Meade
Nominee, General Counsel of the Department of the Treasury
Senate Committee on Finance
December 20, 2012

Thank you, Chairman Baucus, Ranking Member Hatch, and Members of this Committee for the opportunity to appear before you today in connection with my nomination to be the General Counsel of the Treasury Department.

I am deeply honored that President Obama nominated me for this position, and I am grateful to Secretary Geithner for recommending me to the President.

I would like to begin by introducing my family: my wife, Stella; my daughter, Nora; and my new son, Elliot. As you know, public service places great demands on one's family – and I am very thankful to my family for their constant love and support. I would like to introduce my mother, Mary Ann Meade, and acknowledge my father, Bill Meade, who passed away a few years ago. I would also like to acknowledge my friends and colleagues who are here with me today.

My parents instilled in me a deep commitment to public service – a value that I hope to pass on to my children. This commitment has been reinforced throughout my career. At the beginning of my career, I had the honor and privilege to serve as a law clerk to Justice John Paul Stevens and to Judge Harry T. Edwards of the D.C. Circuit. They are not only great jurists; they are great public servants. I spent the core of my legal career as a partner at a law firm that is deeply committed to public service. I learned from many great lawyers there, including many who have served our country with distinction.

I have spent nearly three years serving as the Principal Deputy General Counsel at Treasury. The scope of legal issues within Treasury is vast, ranging from domestic and international economic affairs, terrorist financing and enforcement, tax, ethics, and administrative law. My service has given me great respect for the Treasury Department and, in particular, for the talent and expertise of the career lawyers at Treasury.

If confirmed, I look forward to working closely with Congress, and especially Members of this Committee. I have enormous respect for this institution, and it is an honor to appear before you today. I am committed to maintaining a close working relationship between Treasury and Congress.

Mr. Chairman, I am grateful to you for bringing me before this Committee, and I would be pleased to respond to any questions that you or other Members of this Committee may have.

Thank you.

SENATE FINANCE COMMITTEE
STATEMENT OF INFORMATION REQUESTED OF NOMINEE

A. BIOGRAPHICAL INFORMATION

1. Name: (Include any former names used.) Christopher J. Meade

2. Position to which nominated: General Counsel, U.S. Department of the Treasury

3. Date of nomination: August 2, 2012

4. Address: (List current residence, office, and mailing addresses.)

5. Date and place of birth: 10/29/1968; Yonkers, NY

6. Marital status: (Include maiden name of wife or husband's name.)

7. Names and ages of children

8. Education: (List secondary and higher education institutions, dates attended, degree received, and date degree granted.)

   NYU School of Law; 9/1993 to 5/1996; J.D., 5/1996
   Princeton University; 9/1986 to 6/1990; A.B., 6/1990
   Mark T. Sheehan High School; 9/1982 to 6/1986; high school diploma, 6/1986

9. Employment record: (List all jobs held since college, including the title or description of job, name of employer, location of work, and dates of employment.)

   U.S. Department of the Treasury, Washington, DC; March 2010-present;
   Principal Deputy General Counsel (Acting General Counsel as of June 2, 2012).

   Wilmer Cutler Pickering Hale and Dorr LLP, New York, NY; February 2001-February 2010; Partner (as of January 1, 2005); previously counsel and associate.

American Civil Liberties Union Immigrants' Rights Project, New York, NY; October 1998-November 2000; Skadden Fellow.

Hon. John Paul Stevens, Supreme Court of the United States, Washington, DC; August 1997-August 1998; Law clerk.

Hon. Harry T. Edwards, U.S. Court of Appeals for the D.C. Circuit, Washington, DC; July 1996-July 1997; Law clerk.

Neighborhood Defender Service of Harlem, New York, NY; Summer 1995; Summer intern.

Alabama Capital Representation Resource Center, Montgomery, AL; Summer 1994; Summer intern.

Legal Action Center for the Homeless, New York, NY; August 1990-October 1992; Advocate.

10. Government experience: (List any advisory, consultative, honorary, or other part-time service or positions with Federal, State or local governments, other than those listed above.)

N/A.

11. Business relationships: (List all positions held as an officer, director, trustee, partner, proprietor, agent, representative, or consultant of any corporation, company, firm, partnership, other business enterprise, or educational or other institution.)

Wilmer Cutler Pickering Hale and Dorr LLP, New York, NY; Partner; January 2005-February 2010.

Partnership for Children's Rights (non-profit), New York, NY; Member of Board of Directors; March 2003-February 2010.

Urban Justice Center (non-profit), New York, NY; Member of Board of Directors; March 2005-February 2010.

12. Memberships: (List all memberships and offices held in professional, fraternal, scholarly, civic, business, charitable, and other organizations.)

I have listed below, to the best of my recollection, current and past memberships (including bar admissions):

Bar admissions
New York State (6/10/97 to present)
Supreme Court of the United States (10/9/01 to present)
U.S. Court of Appeals for the First Circuit (9/17/99 to present)
U.S. Court of Appeals for the Second Circuit (2/12/02 to present)
U.S. Court of Appeals for the Third Circuit (11/19/03 to present)
U.S. Court of Appeals for the Fourth Circuit (2/4/02 to present)
U.S. Court of Appeals for the Federal Circuit (2/15/06 to present)
U.S. District Court for the Eastern District of NY (3/12/99 to present)
U.S. District Court for the Southern District of NY (4/12/99 to present)

Other current memberships
Friends of the National Zoo

Prior non-profit boards of directors
Partnership for Children's Rights (non-profit), New York, NY; Member of Board of Directors (March 2003-February 2010)
Urban Justice Center (non-profit), New York, NY; Member of Board of Directors (March 2005-February 2010)

Prior memberships
American Bar Association
New York State Bar Association
New York City Bar Association
Supreme Court Historical Society
NYU School of Law, Class of '96, 15th Reunion Committee
NYU School of Law, Class of '96, 10th Reunion Committee (Chair)
NYU School of Law, Class of '96, 5th Reunion Committee
NYU School of Law, Root-Tilden-Kern Scholarship, 50th Anniversary Committee
NYU School of Law, Dean's Strategic Council
Appalachian Mountain Club
U.S. Servas
Princeton Terrace Club

13. Political affiliations and activities:

a. List all public offices for which you have been a candidate.

None.

b. List all memberships and offices held in and services rendered to all political parties or election committees during the last 10 years.

In 2008, I served on a host committee for an Obama fundraising event. I believe I served on one or two host committees for Kerry fundraising events in 2004 and a host committee for a fundraising event for Dave Friedman (candidate for Massachusetts House of Representatives) in 2002.

c. Itemize all political contributions to any individual, campaign organization, political party, political action committee, or similar entity of $50 or more for the past 10 years.

To the best of my recollection, I have made the following political contributions over the past 10 years:

Year	Committee	Amount
2008	Obama for America	$1,800
2008	Obama for America via Obama Victory Fund	$500
2008	Democratic Senatorial Campaign Committee	$250
2007	Hillary Clinton for President	$1,000
2007	Biden for President	$350
2004	John Kerry for President	$500
2004	Democratic Executive Committee of Florida	$254
2002	Committee to Elect Dave Friedman (Candidate for Massachusetts House of Representatives)	$350

I believe that I also made a contribution to Anthony Foxx, for Charlotte City Council, in 2005. I have not been able to confirm this fact or the amount (though I believe it would have been under $500).

14. Honors and Awards: (List all scholarships, fellowships, honorary degrees, honorary society memberships, military medals, and any other special recognitions for outstanding service or achievement.)

Professional
Selected for LawDragon 500 Leading Lawyers in America (2008)
Included in Super Lawyers (New York Metro edition, 2007, 2008, and 2009; Corporate Counsel edition, 2010)
Empire State Counsel, New York State Bar Association (2007)
Legal Aid Society Pro Bono Award for Outstanding Service (2005)
President's Pro Bono Service Award, New York State Bar Association (2003)
John H. Pickering Pro Bono Award, Wilmer, Cutler & Pickering (2001)
Pro Bono Society, New York City Bar Association (2001 to 2004)
Skadden Fellowship (1998-2000)

Law school
Graduated *magna cum laude* from NYU Law School (May 1996)
Editor-in-Chief, New York University Law Review (previously selected to be an editor of the Law Review)
Order of the Coif
Sinsheimer Service Scholar: First recipient of full-tuition merit scholarship (part of the Root-Tilden program)
Benjamin F. Butler Memorial Award ("for unusual distinction in scholarship, character, and professional activities") (May 1996)
American Jurisprudence Award in Civil Procedure

College
Graduated *magna cum laude* from Princeton University (June 1990)

15. Published writings: (List the titles, publishers, and dates of all books, articles, reports, or other published materials you have written.)

I have done my best to identify all books, articles, reports, or other published materials I have written, including through a review of my personal files and searches of publicly available electronic databases. I have located the following:

- "Reading Death Sentences: The Narrative Construction of Capital Punishment," 71 *New York University Law Review* 732 (June 1996)
- Letter to the Editor, *New York Times* (March 14, 1994)
- "Debating the Causes of Homelessness," *Princeton Alumni Weekly* (November 1993)
- "My Brother's Keeper," *Princeton Alumni Weekly* (February 1993)
- "The Myth of Welfare," *Z Magazine* (September 1992)
- "The Myth of Welfare as an Acceptable Way of Life," *In These Times* (August-September 1992)
- *Catholic Worker* (January-February 1992)

- Letter to the Editor, *New York Times* (January 3, 1992)
- "SHARE [Sexual Harassment/Assault Advising, Research, and Education] Funds Must Not Be Refused; Administrators Not Taking Rape Seriously," *Daily Princetonian* (March 1990)
- "Sexual Violence: More than Just a 'Women's Issue,'" *Daily Princetonian* (November 1989)

16. Speeches: (List all formal speeches you have delivered during the past five years which are on topics relevant to the position for which you have been nominated. Provide the Committee with **two** copies of each formal speech.)

None.

Over the past five years, and before joining the U.S. Government, I was on a number of panels relating to the Supreme Court. During these panels, the other panelists and I each gave remarks and then took questions from the audience. I did not deliver prepared remarks.

17. Qualifications: (State what, in your opinion, qualifies you to serve in the position to which you have been nominated.)

Over the course of my career, I have gained experience in a wide range of areas, and have represented clients before federal and state regulatory agencies, district courts, courts of appeals, and the U.S. Supreme Court. I have served as Principal Deputy General Counsel of the Department of the Treasury since March 2010 (and as Acting General Counsel since June 2, 2012) and, therefore, have specific experience in the legal issues facing Treasury.

B. FUTURE EMPLOYMENT RELATIONSHIPS

1. Will you sever all connections with your present employers, business firms, associations, or organizations if you are confirmed by the Senate? If not, provide details.

I am currently an employee of the Treasury Department.

2. Do you have any plans, commitments, or agreements to pursue outside employment, with or without compensation, during your service with the government? If so, provide details.

No.

3. Has any person or entity made a commitment or agreement to employ your services in

any capacity after you leave government service? If so, provide details.

No.

4. If you are confirmed by the Senate, do you expect to serve out your full term or until the next Presidential election, whichever is applicable? If not, explain.

Yes.

C. POTENTIAL CONFLICTS OF INTEREST

1. Indicate any investments, obligations, liabilities, or other relationships which could involve potential conflicts of interest in the position to which you have been nominated.

In connection with the nomination process, I have consulted with the Office of Government Ethics and the Department of the Treasury's designated agency ethics official to identify potential conflicts of interest. Any potential conflicts of interest will be resolved in accordance with the terms of an ethics agreement that I have entered into with the Department's designated agency ethics official.

2. Describe any business relationship, dealing or financial transaction which you have had during the last 10 years, whether for yourself, on behalf of a client, or acting as an agent, that could in any way constitute or result in a possible conflict of interest in the position to which you have been nominated.

In connection with the nomination process, I have consulted with the Office of Government Ethics and the Department of the Treasury's designated agency ethics official to identify potential conflicts of interest. Any potential conflicts of interest will be resolved in accordance with the terms of an ethics agreement that I have entered into with the Department's designated agency ethics official.

3. Describe any activity during the past 10 years in which you have engaged for the purpose of directly or indirectly influencing the passage, defeat, or modification of any legislation or affecting the administration and execution of law or public policy. Activities performed as an employee of the Federal government need not be listed.

I have not been engaged as a lobbyist and have not engaged in any lobbying activity during the past 10 years.

4. Explain how you will resolve any potential conflict of interest, including any that may be disclosed by your responses to the above items. (Provide the Committee with **two** copies of any trust or other agreements.)

In connection with the nomination process, I have consulted with the Office of Government Ethics and the Department of the Treasury's designated agency ethics official to identify potential conflicts of interest. Any potential conflicts of interest will be resolved in accordance with the terms of an ethics agreement that I have entered into with the Department's designated agency ethics official.

5. **Two** copies of written opinions should be provided directly to the Committee by the designated agency ethics officer of the agency to which you have been nominated and by the Office of Government Ethics concerning potential conflicts of interest or any legal impediments to your serving in this position.

See attached.

6. The following information is to be provided only by nominees to the positions of United States Trade Representative and Deputy United States Trade Representative:

Have you ever represented, advised, or otherwise aided a foreign government or a foreign political organization with respect to any international trade matter? If so, provide the name of the foreign entity, a description of the work performed (including any work you supervised), the time frame of the work (e.g., March to December 1995), and the number of hours spent on the representation.

No.

D. LEGAL AND OTHER MATTERS

1. Have you ever been the subject of a complaint or been investigated, disciplined, or otherwise cited for a breach of ethics for unprofessional conduct before any court, administrative agency, professional association, disciplinary committee, or other professional group? If so, provide details.

No.

2. Have you ever been investigated, arrested, charged, or held by any Federal, State, or other law enforcement authority for a violation of any Federal, State, county or municipal law, regulation, or ordinance, other than a minor traffic offense? If so, provide details.

Arrested on 7/25/89 in Chicago, IL, for holding a sign on a highway overpass. (Charge: 36 30; Circuit Court of Cook County, IL.) On 8/11/89, the court dismissed the charges because the activity was protected by the First Amendment.

Arrested on 2/22/90 for interrupting a speech on the Princeton campus. On 2/11/91, paid $75.00 fine for violating Princeton Borough Ordinance 21-1 (loud, unnecessary, annoying noises).

3. Have you ever been involved as a party in interest in any administrative agency proceeding or civil litigation? If so, provide details.

From 1998-2003, I lived at 269 East 10th Street, #5, New York, New York. The building suffered from neglect, and had serious plumbing and electrical problems. The landlord sought to increase my rent during my last year in the apartment. In light of the conditions, I refused to pay the rent increase, and the landlord sued in housing court. After the landlord learned that I was willing to go to trial, and that the former superintendent was planning to testify on my behalf at trial, I reached a favorable out-of-court settlement with the landlord.

4. Have you ever been convicted (including pleas of guilty or *nolo contendere*) of any criminal violation other than a minor traffic offense? If so, provide details.

No.

5. Please advise the Committee of any additional information, favorable or unfavorable, which you feel should be considered in connection with your nomination.

None.

E. TESTIFYING BEFORE CONGRESS

1. If you are confirmed by the Senate, are you willing to appear and testify before any duly constituted committee of the Congress on such occasions as you may be reasonably requested to do so?

Yes.

2. If you are confirmed by the Senate, are you willing to provide such information as is requested by such committees?

Yes.

Senate Finance Committee Hearing of December 20, 2012
Nominations of William B. Schultz and Christopher J. Meade
Responses to Questions for the Record From Christopher J. Meade

SENATOR ORRIN HATCH (R-UT):

Question 1:

In reviewing your resume and the materials you supplied to the Committee, it seems you have a strong interest in many social issues. I know you have written on topics such as the death penalty and homelessness. Given a clear interest in these policy areas going back many years, do you think you are prepared to take on the challenge of being Treasury General Counsel, which involves an expertise in different policy areas? I know you have worked at the Treasury since 2010, but for most of that time you worked under a predecessor who had an MBA.

In your committee questionnaire, you note that since 2010 you have experience in the issues facing Treasury. However, many of the issues facing Treasury have been developing since long before 2010. How did you decide to undergo what appears to be a significant shift in policy interests, and please give more detail on how your background will enable you to be an effective Counsel for Treasury?

I believe I am prepared to serve as General Counsel of the Department of the Treasury, if the Senate confirms my nomination. My legal interests have developed over the course of my career. I wrote the articles you referenced before I graduated from law school. After law school, I clerked for Judge Harry T. Edwards of the U.S. Court of Appeals for the D.C. Circuit, and for Justice John Paul Stevens of the U.S. Supreme Court. These clerkships exposed me to a wide variety of areas of law and, in particular, gave me a strong grounding in administrative law.

I spent the core of my legal career at Wilmer Cutler Pickering Hale and Dorr LLP (formerly known as Wilmer Cutler & Pickering). I worked there for nine years, and was a partner for the last five of those years. I was a member of the firm's Litigation and Securities Departments, and a member of the Government and Regulatory Litigation, the Securities and Enforcement, and the Appellate and Supreme Court Litigation Practice Groups. I litigated complex commercial cases involving securities and financial institutions. I represented major financial institutions in investigations conducted by the SEC, the New York Attorney General, and other national and state regulators. I also had an active appellate practice, and argued four cases before the U.S. Supreme Court. My appellate experience involved a number of areas of law including, among others, constitutional law, administrative law, securities, bankruptcy, and banking. I have found my experience at Wilmer to be highly relevant to my service at Treasury.

Since March 2010, I have served as the Principal Deputy General Counsel at Treasury (and, since June 2012, have served as the Acting General Counsel). During that time, I have gained first-hand knowledge of, and experience in, the legal issues facing Treasury.

SENATOR PAT ROBERTS (R-KS):

Question 1:

Recently HHS, Treasury and Department of Labor have issued regulations to implement provisions of the Patient Protection and Affordable Care Act (PPACA). These include the essential health benefits (EHB) mandate, actuarial value (AV) calculator, market rules and wellness provisions, as well as rules to implement provisions related to risk programs, cost-sharing, the federally-facilitated exchange (FFE) user fees, and medical loss ratio (MLR).

I would like to ask several questions related to these rules, rules that have been issued since then, and future rules:

a. **Many of the initial rules implementing the PPACA statute were interim final rules which allowed little or no stakeholder input. Of the most recently issued rules, while none of them were IFRs, many of these only provided 30 day comment periods. This is after the Administration took over 18 months to draft the regulations and OMB was allowed 4 months for their review.**

We have already heard from many stakeholders that a lot of them fear they will be unable to meet the timelines for comments, that comments will not represent a thorough review of the new policies, and that this Administration does not value stakeholder input in the process, to the point that many stakeholders are considering whether the time, effort and expense is worthwhile, when they believe their comments are not even considered, but instead treated more as a 'check the box' exercise to comply with existing Executive Orders and statute related to stakeholder input.

So aside from voicing my strong concern with these developments, I would like to know what value you put on stakeholder involvement in the regulatory process? What is a reasonable and standard amount of time for review and comment on regulations issued by this Administration?

Treasury highly values stakeholder involvement in the regulatory process. It is an important part of developing regulations that are effective and do not impose unnecessary burdens on the public. Treasury gathers input from stakeholders through the formal notice and comment process, as well as through a variety of other means.

For example, in connection with Affordable Care Act (ACA) regulations, Treasury has arranged meetings with stakeholder groups before issuing proposed regulations—in addition to reviewing comments and following up with stakeholders after proposed regulations are published. Treasury also has suggested possible approaches and

solicited comments in Notices before issuing proposed regulations, including, for example, Notices related to the employer responsibility provisions of the ACA.

The amount of time for review and comment on a regulation depends on a number of factors, including the complexity of the regulation and the deadline for implementing it. It is common for Treasury regulations to have a comment period between 60 and 90 days, consistent with Executive Order 13563. In limited instances, Treasury regulations have had a 30-day comment period.

b. **PPACA implementation represents novel legal and policy issues. Many of the regulations implementing the PPACA statute have been considered 'significant' which requires additional review, transparency, and allowance for stakeholder input among other requirements. However many of the regulations being issued are only outlining the options for being considered significant without defining which of the reasons make those rules significant. We have been unable to get clarification on this issue.**

Isn't this an important consideration when drafting and issuing regulations? And if the folks drafting the regulations don't know what is in a rule after 18 months of drafting, and 4 months of OMB review, how can you expect stakeholders to know such things and provide valuable feedback in a much shorter timeframe.

The Office of Management and Budget designates and reviews "significant regulatory actions" as that term is defined in section 3(f) of Executive Order 12866. These include rules with an annual economic impact greater than $100 million, rules that raise novel legal and policy issues, rules that interfere with the actions of other agencies, and rules that materially impact the budgets of certain agency programs. For any rule that is covered by E.O. 12866 and reaches the $100 million threshold, Treasury analyzes the costs and benefits of the proposed rule and its alternatives, consistent with OMB Circular A-4. For rules that do not reach the economic threshold, but that are designated by OMB as significant regulatory actions, Treasury adheres to the principles set forth in Executive Orders 12866 and 13563.

I agree that it is important to promote transparency and to encourage stakeholder input during the course of the rulemaking process. I understand that Treasury officials would be happy to discuss these issues further with you and your staff.

c. **Similar to the previous question, many of the regulations recently issued have been labeled by OMB as 'economically significant'.**

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any 1 year).

For many of these rules the Departments have been unable to define how they reached the $100 million threshold, expressed disbelief, concern, or disagreement with OMB's determination, or have been unresponsive to requests for further clarification.

I, along with many of my colleagues expressed concerns to the Departments in a letter that "the RIA in each of these rules seem to lack consistency, or accuracy without any methodical standards. The estimates of the costs are minute considering the rules will be implementing reforms that will establish an entirely new market and create new regulatory standards and definitions."

Considering the potential cost implications of the PPACA implementation don't you think knowing and understanding the costs are important? Can you assist us in getting clarification on the 'economically significant' rules and the $100 million threshold?

I agree that assessing the potential economic costs and other burdens imposed by regulations on the public is an important part of the rulemaking process. Treasury routinely solicits input from stakeholders through a variety of means, including the formal notice and comment process, public hearings, meetings with stakeholders attended by senior officials and staff, and other outreach efforts. Treasury carefully considers this information when promulgating final regulations. Moreover, for any rule that is covered by Executive Order 12866 and is expected to have an annual impact on the economy of $100 million or more, Treasury analyzes the costs and benefits of the proposed rule and its alternatives, consistent with OMB Circular A-4.

As noted above, I understand that Treasury officials would be happy to discuss the Department's rulemaking process further with you and your staff.

Question 2:

As part of your policy role, you would advise the Secretary on tax reform. What are your views on the need for and benefits of fundamental tax reform?

If I am confirmed to serve as General Counsel, my role would be to advise the Secretary on legal matters. Because the contours of tax reform generally raise policy – not legal – questions, I would defer to the policy experts at the Treasury Department on those particular issues. Nonetheless, I agree that our tax code is in need of reform and that tax reform should simplify the tax code. The Administration has set forth key elements of tax reform in the FY 2013 Budget, and I agree that those elements should be the foundation of any reform.

Question 3:

I am concerned that the President's Framework for Business Tax Reform could actually hurt smaller companies. Lowering the corporate tax rate and removing tax incentives without also cutting the individual tax rate would favor large C corporations over "pass-through entities" (typically small and medium-sized businesses organized as limited liability companies or S corporations) that pay the individual tax rate rather than the corporate rate. The plan would effectively raise those entities' taxes by removing their incentives while keeping their rates the same. Can you tell me how restructuring the tax treatment of a significant portion of the economy, the area where most jobs are created, will help spur economic growth?

If I am confirmed to serve as General Counsel, my role would be to advise the Secretary and other Treasury officials on legal matters. The details of the President's Framework for Business Tax Reform raise policy questions, and I defer to policy experts on these matters. Nonetheless, I strongly support small businesses, and I agree that the tax code is in need of reform.

I understand that the President's Framework would provide tax relief and simplification for small businesses. Although some of the base-broadening provisions and other reforms described above would apply to both C-corporations and pass-through entities, the President's Framework would provide a net tax cut to small businesses, including small pass-through entities.

Specifically, I understand that the President's Framework would allow small businesses to expense up to $1 million in annual investments in property and equipment on a permanent basis, which would provide significant tax relief for small businesses and would allow them to avoid the complexity of following depreciation schedules. I also understand that the Framework would increase the threshold for using cash accounting from $5 million to $10 million. This would simplify and reduce taxes for an important segment of America's small business.

Question 4:

As part of the Troubled Asset Relief Program (TARP) Treasury has begun winding down the Capital Purchase Program (CPP). The majority of the approximately 300 banks remaining in CPP are community banks. Implementing and executing a program to exit the program has been a daunting task for these banks. Community banks were hit especially hard by turmoil in the financial industry, are under extreme regulatory pressure, and have little access to the capital markets. Treasury is implementing three approaches to helping these banks exit TARP, including repayments, restructurings, and auctions. Some of the community banks have had difficulty participating in the CPP auctions, particularly because they essentially are bidding to buy back their own shares. Several community banks have said that their bids to buy back their own stock were rejected as insufficient or otherwise failing to comply with the auction procedures. A particular concern is a lack of communication from Treasury personnel on the auction procedures and on the reasons for the rejection of the bids.

a. **Can you assure the committee that the procedures for these auctions will be clearly communicated to the community banks, and that banks attempting to bid for their own securities will receive ample feedback from CPP staff on potential inadequacies in their bids?**

b. **What steps should Treasury take to ensure that it is transparent with regard to the prices agreed upon in the CPP auctions? Should Treasury disclose exactly how it determined that the offer from the financial institution was reasonable?**

The Office of the General Counsel advises Treasury policy officials regarding their legal obligations and authorities. Your questions about the Capital Purchase Program (CPP) generally raise policy issues, and I defer to policy officials on these matters. Nonetheless, I agree that clear and transparent communication is critical to the success of the program.

I understand that Treasury communicates with participating CPP institutions about all aspects of the program, including the auction process. In total, 707 institutions received investments through CPP. Today, fewer than 220 institutions remain in the program. In May 2012, Treasury announced that it would wind down CPP through a three-pronged strategy consisting of repayments by institutions able to repay in the near future, restructurings of a few investments, and dispositions of the remaining investments through auctions or other competitive means. Treasury communicated further information about its strategy, including the auction process, to all remaining CPP institutions, both in writing and in individual telephone calls. Treasury also posts information on its website at www.financialstability.gov.

As of December 15, 2012, Treasury had auctioned its CPP investments in 91 institutions. Treasury follows procedures similar to those it previously established for selling warrants. Treasury sets a minimum price and sells securities to the qualified bidders with the highest bids

above that price. In certain instances, CPP institutions have participated in the auction of their CPP investments (after conferring with their respective regulators). Treasury supports the participation of CPP institutions, because it makes the auctions more robust. In some instances, CPP institutions have successfully bid on their CPP investments.

Again, I agree that clear and transparent communication is critical to the success of CPP, including the auction process. I believe it is in the best interests of all parties, including the taxpayers, for CPP institutions to be fully informed about the process.

Question 5:

Can I have your assurances that you will look into making sure that the Federal Home Loan Banks are sufficiently strong to continue to achieve their core mission of providing liquidity and supporting community banks and thrifts?

If I am confirmed to serve as General Counsel, my role would be to advise the Secretary and other Treasury officials on legal matters. Your question about the Federal Home Loan Banks (FHLBs) raises policy issues, and I defer to policy experts on these matters.

As you know, the Federal Housing Finance Agency (FHFA), not Treasury, is the regulator of the FHLBs. I understand, however, that Treasury officials view the FHLBs as an important component of the housing market and, more broadly, the financial system. Treasury and the Department of Housing and Urban Development highlighted the importance of the FHLBs in a February 2011 White Paper entitled, *Reforming America's Housing Finance Market*. As noted in the paper, the FHLBs have played a vital role in our housing finance system by helping smaller financial institutions access liquidity to compete in an increasingly competitive marketplace. The White Paper also noted that the FHLBs have developed weaknesses that should be addressed as part of housing finance reform. Treasury continues to support the role of the FHLBs in providing stable mortgage credit for financial institutions of all sizes.

SENATOR JOHN THUNE (R-SD):

Question 1:

I would like to bring to your attention two recent reports from the Treasury Inspector General for Tax Administration (TIGTA). The first report, released on August 2nd of this year, found that there are billions of dollars in identify-theft-related tax refund fraud that is going undetected by the IRS. The report identified potentially fraudulent tax refunds totaling in excess of $5.2 billion in tax year 2011. The report estimated that there could be $21 billion in potentially fraudulent refunds as a result of identity theft over the next 5 years. The second report, released October 22nd, found that taxpayers have been required to repay more than $2.3 billion in erroneous refundable tax credits during tax years 2006 through 2009, yet as of the end of last year roughly $1B of this amount had not yet been recovered. These two reports made a number of suggestions as to how the IRS and Treasury can do a better job of preventing tax fraud, as well as recovering fraudulent payments.

At a time when the Obama Administration is calling for higher taxes, I believe we should instead be working to close the tax gap and prevent tax fraud. Has Treasury implemented all of the recommendations made in these reports? If not, please explain why. I would appreciate your assurance that, if confirmed, you will to work to ensure that the Treasury Department and the IRS are doing everything possible to prevent tax fraud, including implementing the recommendations in the reports I cited.

If I am confirmed to serve as General Counsel, my role would be to advise the Secretary and other Treasury officials on legal matters. Your question raises policy issues regarding tax administration and enforcement, and I defer to policy experts on these matters. Nonetheless, I strongly support the efforts of the IRS and TIGTA to prevent tax fraud. If confirmed, I will continue to support their efforts to close the tax gap, and I would be pleased to work with you to advance that objective.

In addition, I believe that Congress and the Inspectors General play a critical role in overseeing the Treasury Department. I meet often with the Inspectors General that oversee Treasury programs, including with the TIGTA, and will continue to do so if confirmed.

Closing the tax gap and preventing tax fraud are important goals for Treasury and the IRS. Although I understand that the IRS disagrees with the size of TIGTA's estimate regarding potentially fraudulent refunds due to identity theft, the IRS accepted TIGTA's recommendations in both reports and is working to implement them. The recommendations generally relate to IRS processing and enforcement efforts. In response, the IRS has developed a strategy to reduce the number of fraudulent refunds paid, including developing new filters to identify potentially fraudulent claims during the return processing stage.

In addition, the TIGTA reports also contain recommendations for legislative change. The August report recommends expanding IRS access to the National Database of New Hires information for tax administration purposes. This legislative proposal was previously included in the President's Budget, and Treasury supports this legislative change as a means for reducing tax fraud. The October report recommends that the due diligence requirements and penalties that apply to the Earned Income Tax Credit should be expanded to apply to the Additional Child Tax Credit. I understand that IRS and Treasury policy officials are considering this proposal.

Question 2:

There have been concerns raised by many Americans, including Members of Congress, regarding the rapid increase in the number of taxpayers using Individual Taxpayer Identification Numbers (ITINs) to file for refundable child credits. ITINs are typically used by taxpayers who are not eligible to legally work in the U.S. These taxpayers are unable to claim other public benefits, such as Earned Income Tax Credit payments, by virtue of a 1996 law that limits such benefits to those using a valid Social Security number. Refundable child credit payments to taxpayers using ITINs is increasing rapidly, from $924 million in 2005 to $4.2 billion in 2010. A report released by the Treasury Inspector General for Tax Administration (TIGTA) on July 7, 2011 estimated that conforming the treatment of the child credit outlays to other public benefits would save taxpayers $8.4 billion over two years. Given the recent growth in ITIN refund filings and the expectation that Congress is likely to continue to extend the child tax credit at the $1,000 per child level, it is not unrealistic to assume that bringing the refundable child credit in line with other government outlays with respect to ITIN filers could save American taxpayers at least $40 billion over the next ten years, and possibly much more.

I understand that the Treasury Department has made the legal judgment that the provisions of the 1996 law that require a social security number to claim the refundable Earned Income Tax Credit and other federal benefits does not apply to the refundable child credit. How was this determination arrived at? Is this a determination that Treasury might reconsider in light of the potential for fraud regarding refundable credits in general and the child credit in particular? If Treasury believes it does not have the authority to disallow these payments to ITIN filers, does Treasury support congressional action to clarify the treatment of child credit payments to bring them in line with how government spending on other public benefits is currently treated?

Treasury and the IRS have considered this issue carefully and have concluded that the IRS does not have authority to deny the refundable child credit to Individual Taxpayer Identification Number (ITIN) filers. The Internal Revenue Code differs in its treatment of the Earned Income Tax Credit (EITC) and the refundable child credit. The relevant Code provision governing the EITC expressly requires taxpayers to include Social Security Numbers (SSN) with their returns. In contrast, the relevant Code provision governing the refundable child credit requires taxpayers to include a "taxpayer identification number." Taxpayer identification numbers include not only SSNs, but also ITINs and Adoption Taxpayer Identification Numbers (ATINs).

Accordingly, Treasury and the IRS believe that Congress expressly gave the IRS differing statutory authority regarding these tax credits. Although the Code grants the IRS the authority to deny the EITC to ITIN filers, Treasury and the IRS do not believe it grants similar authority regarding the refundable child credit. I understand your interest in this issue, and I am happy to work with the Committee on this and other important matters of tax administration.

Follow-up Questions for the Record for Christopher J. Meade
From Senator Orrin Hatch

Question 1:

Income Tax Withholding Tables: There have been reports in the press recently suggesting that some people believe the income tax withholding tables for 2013 can reflect a continuation of the Economic Growth and Tax Relief Reconciliation Act of 2001, the Jobs and Growth Tax Relief and Reconciliation Act of 2003, and the American Recovery and Reinvestment Act of 2009 – even though those Acts mostly expire at the end of 2012. Do you share this belief? Please explain your answer.

We understand that the Treasury Department plans to issue these tables this coming Monday, December 31, 2012. Per section 1(f)(1) of the Internal Revenue Code, should these tables have come out by December 15, 2012?

If you believe the Treasury Secretary has the authority to issue income tax withholding tables for 2013 reflecting a continuation of the 2001, 2003, and/or 2009 acts mentioned above, could the President also direct the Treasury Secretary to enforce the tax laws as if those laws had been extended? That is, could the President cite prosecutorial discretion in not collecting tax above levels that the President wanted? That is, could the President direct the Secretary to enforce the tax law as if the Clinton-era rates were in effect for income above $250,000, say, but as if the Bush-era rates were in effect for income below that threshold?

I believe that Treasury's authority with respect to withholding tables is set forth in laws passed by Congress. The Secretary's discretion is limited: under the statute, he needs to set withholding tables consistent with the tax laws set by Congress. Specifically, the Secretary must issue tables "in such form, and provide for such amounts to be deducted and withheld, as the Secretary determines to be most appropriate to carry out the purposes [of the withholding chapter of the Internal Revenue Code] and to reflect the provisions [of the income tax chapter] applicable to such periods." *See* § 3402(a)(1)(B). When issuing the withholding tables, the Secretary does not have the authority to set the tax rates to reflect the Administration's position.

This year, due to the possibility that changes in the law could occur late in the calendar year, the Secretary delayed issuing the withholding tables to minimize the administrative burden on employers. (The statute cited, section 1(f)(1) of the Internal Revenue Code, relates to the inflation adjustment for tax rates, not the withholding tables, although you are correct that withholding tables are typically released by mid-December.) The Secretary has delayed issuing the withholding tables in some prior years where changes in the law were expected to occur late in the calendar year. For example, in 2010, the Secretary did not issue the withholding tables for the 2011 tax year until December 17, 2010, the date that the legislation extending the 2001 and

2003 tax cuts was signed into law. Employers were permitted to continue using the 2010 withholding tables for a limited period in early 2011 to give them adequate time to update their systems to reflect the new withholding tables. I understand that the Secretary intends to release withholding tables for 2013 shortly. Finally, I do not believe it would be appropriate to comment on the scope of the President's legal authorities, given my current role as a lawyer at the Department of the Treasury.

Question 2:

Question re Health Premium Credit Availability for Purchases of Insurance via Federal Exchanges

The Treasury Department and the Internal Revenue Service have promulgated regulations regarding the new premium credits established in Section 1311 of PPACA. It appears that these regulations, implementing Section 36B of the Internal Revenue Code, are inconsistent with the relevant statutory language. I am concerned that these rules violate the Secretary's authority, violating the Constitution's separation of powers.

Internal Revenue Code section 36B provides for a refundable credit for coverage under a qualified health plan. The amount of the credit equals the "premium assistance credit amount," which in turn equals the annual sum of the monthly "premium assistant amounts." The Premium Assistance Credit Amount equals the lesser of ... (A) "the monthly premiums for such month for 1 or more qualified health plans offered in the individual market within a State which cover the taxpayer, the taxpayer's spouse, or any dependent ... and which were enrolled in through an Exchange established by the State under 1311 of the Patient Protection and Affordable Care Act" or (B) an amount calculated with reference to the "applicable second lowest cost silver plan." An applicable second lowest cost silver plan must be a plan offered "through the same Exchange through which the qualified health plans taken into account under" the immediately-aforementioned subparagraph (A) – that is, through an Exchange established by the State under [section] 1311 of PPACA.

So, to the extent there is not "an Exchange established by the State under [section] 1311" of PPACA, there are no premium assistance amounts and thus the section 36B Health Insurance Premium Tax Credit would be zero. ***Do you agree? Please explain your answer.***

I believe that Treasury has a responsibility to implement the laws passed by Congress in a careful and thoughtful manner. With respect to section 36B of the Internal Revenue Code, I understand that Treasury's Office of Tax Policy (OTP) and the IRS have reviewed this issue closely.

As your question suggests, section 36B provides that the amount of the premium tax credit is based on the premiums for one or more qualified health plans in which a taxpayer enrolls through an exchange "established by the State" under section 1311 of the Affordable Care Act (ACA). Section 1311, in turn, provides that an exchange "shall be a governmental agency or a nonprofit entity that is established by a State." If a state, however, chooses not to establish an exchange—or will not have an exchange in operation by January 1, 2014—section 1321 of the ACA directs the Secretary of Health and Human Services to "establish and operate such Exchange within the State" to serve the residents of that state.

Treasury regulations implementing section 36B provide that individuals who enroll in coverage through either a state-run or a federally-facilitated exchange are eligible for premium tax credits. OTP and the IRS Office of Chief Counsel interpreted the statutory language in context and consistent with the structure and purpose of the ACA as a whole. For example, ACA section 1311 refers to an exchange being "established by a State." Congress provided in section 1321, however, that where a state was not proceeding with an exchange, HHS would establish and operate "*such* Exchange within the State," (emphasis added) making a federally-facilitated exchange the equivalent of a state exchange in all functional respects. Moreover, throughout the ACA, Congress refers to the exchanges as "exchanges," "exchanges established by a state," and "exchanges established under the ACA," and there is no discernible pattern that suggests Congress intended the particular language in section 36B(b)(2)(A) to limit the availability of the tax credit.

In addition, the information reporting requirements of section 36B(f)(3) apply to exchanges under both ACA sections 1311 and 1321. This requirement relates to administration of the premium tax credit. The placement of this provision in section 36B and the information required to be reported—including information related to eligibility for the credit and receipt of advance payments—provides further support that all taxpayers who enroll in qualified health plans, either through the federally-facilitated exchange or a state exchange, should qualify for the premium tax credit. Treasury's interpretation is consistent with the explanation of the ACA released by the non-partisan Congressional Joint Committee on Taxation and with the assumptions made by the Congressional Budget Office in estimating the effects of the ACA.

However, the regulations provide that a section 36B Health Insurance Premium Tax Credit would be available if, among other conditions, the taxpayer or a member of the taxpayer's family is enrolled in a "qualified health plan through an Exchange established under section 1311 or 1321 of the Affordable Care Act." Section 1321(c) provides that if a State does not establish an Exchange, then the Federal government can establish a "Federally-facilitated Exchange." A section 1321(c) Federally-facilitated Exchange is not "an Exchange established by the State ...." and thus cannot satisfy the language of Code section 36B (b)(2)(A).

Even the relevant recent HHS proposed regulations recognize that a "Federally-facilitated Exchange" is different from an Exchange established by the State under section 1311: "Section 1321(c)(1) requires the Secretary [of Health & Human Services] to establish and operate such Exchange within States that ... Do not elect to establish an Exchange." That is, these HHS proposed regulations confirm that States may elect to not establish an

exchange, and that the HHS Secretary is required to establish an Exchange if the State does not do so.

Simply put, under current statutory law, there is no premium assistance amount, hence no section 36B Health Insurance Premium Tax Credit, to the extent that an Exchange is a Federally-facilitated Exchange. But contrary to the clear wording of the statute, the regulations suggest otherwise, extending the availability of premium credits to federal exchanges.

It is worth noting that even the grant of regulatory authority in section 1401 of PPACA does not authorize the extension of premium credits to the federal exchange. That section provides that "[t]he Secretary shall prescribe such regulations as may be necessary to carry out the provisions of this section." However, as discussed earlier, providing Health Insurance Premium Tax Credits based on Federally-facilitated Exchanges is not a "provision[] of this section."

In short, I believe the regulations inappropriately extended 36B health premium credits to purchases of insurance made via Federally-facilitated exchanges. Do you agree or disagree? Please thoroughly explain your answer.

For the reasons noted above, Treasury's Office of Tax Policy and the IRS have concluded that individuals who enroll in coverage through either a state-run or a federally-facilitated exchange are eligible for premium tax credits under section 36B. I recognize that some stakeholders have expressed a different legal view. In fact, this issue is subject to ongoing litigation in federal court. On September 19, 2012, the Oklahoma Attorney General amended an existing civil lawsuit in the Eastern District of Oklahoma to include claims challenging Treasury regulations promulgated under section 36B. Ultimately, I expect that the courts will determine the proper interpretation of section 36B, and I believe that any questions about the permissibility of Treasury's statutory interpretation should be resolved through the judicial process.

Opening Statement of William B. Schultz
Nominee to be General Counsel,
U.S. Department of Health and Human Services
Senate Committee on Finance
December 20, 2012

Mr. Chairman, Senator Hatch, and Members of the Committee, I am honored to appear before this Committee as the President's nominee to be General Counsel of the Department of Health and Human Services.

The Department of Health and Human Services has more than 65,000 employees whose mission is to assure that the American people have access to high quality and affordable healthcare, to support children and families, to assure the safety of food and medical products, and to support research that will improve health and save lives. The Office of General Counsel advises the Department on the legal authorities that Congress has given the agency and on the legal constraints Congress has imposed. It also works with components of HHS and the Department of Justice to ferret out fraud against the government, to assure compliance with the law, and to defend the government against legal challenges to its programs.

I believe my experience has prepared me for this position, and has equipped me with the relevant skills, as well as an understanding of the appropriate role of the General Counsel. I have worked in all three branches of government and in the private sector on litigation and regulatory matters. Since March 2011, I have served as the Principal Deputy General Counsel and Acting General Counsel of the Department. Prior to March 2011, I was a partner at the law firm Zuckerman Spaeder. Prior to that, I spent 11 years in government, including five years as counsel to the House Subcommittee on Health and the Environment, four years as Deputy Commissioner for Policy at the Food and Drug Administration, and two years as Deputy Assistant Attorney General at the Department of Justice, in charge of civil appellate litigation. I started my career as a law clerk to a federal district court judge here in Washington, D.C., and then worked for 14 years at Public Citizen Litigation Group, a public interest law firm.

I am fortunate that the HHS Office of General Counsel is populated by enormously talented and committed attorneys. I am also grateful to have the opportunity to work with Secretary Sebelius, Deputy Secretary Bill Corr and the other extraordinary officials at the Department. Throughout my career I have found public service and in particular government service to be both extremely challenging and rewarding, and I feel very fortunate to be nominated to this position. The mission of HHS could not be more important. If I am confirmed, I look forward to working with the members of the Committee, and will do my very best to ensure that the laws Congress has enacted are faithfully implemented.

Thank you for the opportunity to appear here today and I would be happy to respond to any questions.

SENATE FINANCE COMMITTEE
STATEMENT OF INFORMATION REQUESTED OF NOMINEE

A. BIOGRAPHICAL INFORMATION

1. Name: (Include any former names used.):

   William Barnett Schultz

2. Position to which nominated:

   General Counsel, Department of Health and Human Services

3. Date of nomination: *April 17, 2012*

4. Address: (List current residence, office, and mailing addresses.):

   Home:

   Office:

5. Date and place of birth:

   March 16, 1948; Bloomington, Indiana

6. Marital status: (Include maiden name of wife or husband's name.)

7. Names and ages of children:

8. Education: (List secondary and higher education institutions, dates attended, degree received, and date degree granted.)

Groveton High School
Fairfax County, Va.
September 1962 – June 1966
High School Diploma, 1966

Yale University
September 1966 – June 1970
B.A., 1970

University of Virginia School of Law
September 1971 – June 1974
J.D., 1974

9. Employment record: (List all jobs held since college, including the title or description of job, name of employer, location of work, and dates of employment.)

Law Clerk, Public Defender Service; Washington, D.C. (June-July 1972)

Law Clerk, Post Conviction Assistance Project; Charlottesville, Va. (July-August 1972)

Law Clerk, Wald, Harkrader & Ross; Washington, D.C. (June-August 1973)

Law Clerk, Judge William B. Bryant, U.S. District Court; Washington, D.C. (September 1974-September 1975)

Attorney, Cohen, Vitt & Annand; Alexandria, Va. (September 1975-December 1975)

Attorney, Public Citizen Litigation Group; Washington, D.C. (1976-1989)

Adjunct Professor, Georgetown University Law Center; Washington, D.C. Civil Litigation (1983-87); Food and Drug Law (1988-1993, 1996).

Counsel, Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives; Washington, D.C. (1989-1994)

Deputy Commissioner, Food and Drug Administration; Rockville, MD (1994-1999)

Deputy Assistant Attorney General, Civil Division, U.S. Department of Justice (Appellate Staff); Washington, D.C. (1999-2000)

Partner, Zuckerman Spaeder; Washington, D.C. (January 2001-March 2011)

Principal Deputy General Counsel and Acting General Counsel, Department of Health and Human Services (March 2011-Present)

10. Government experience: (List any advisory, consultative, honorary, or other part-time service or positions with Federal, State or local governments, other than those listed above.)

Worked as an intern at the U.S. Department of Labor during the summer of 1968

11. Business relationships: (List all positions held as an officer, director, trustee, partner, proprietor, agent, representative, or consultant of any corporation, company, firm, partnership, other business enterprise, or educational or other institution.)

As an attorney at Public Citizen Litigation Group from 1976 to 1989, I represented numerous nonprofit organizations, including Public Citizen, Center for Science in the Public Interest, Michigan Citizens for an Independent Press, Carolina Environmental Study Group, Community Nutrition Institute, National Council of Senior Citizens, Capitol Hill News Service, Center for Auto Safety, Convention Center Referendum Committee, Dade County Consumers Advocate Office, and American Public Health Association.

Between January 2001 and March 2011, I was a partner at Zuckerman Spaeder LLP.

To the best of my knowledge, I represented the following organizations during my time at Zuckerman Spaeder:

Actavis Inc.
Akorn Pharmaceuticals
Alliance for Community Health Plans
Alpharma, Inc.
American Academy of Pediatrics
American College of Obstetricians & Gynecologists
American Hospital Association
American Legacy Foundation
American Lung Association
Andrx Pharmaceuticals, Inc.
ApoPharma Inc.
Apotex Corporation
Arizona Attorney General
Association of Trial Lawyers of America
Axcan Pharma, Inc.

Azur Pharma Ltd.
Barr Laboratories
Ben Venue Laboratories, Inc.
BioPartners; S.R.A. - International, Inc.
Biotechnology Industry Organization
Blue, Lisa
Boehringer-Ingelheim
Capital Southwest Corporation
Catalent Pharma Solutions
Center for Science in Public Interest
CIBC World Markets
Cohen, Milstein, Hausfeld & Toll, PLLC
Concept Foundation
Consumers for Dental Choice
DAVA Pharmaceuticals, Inc.
Deephaven Capital Management
Doffermyre Shields Canfield Knowles & Devine
Dr. Reddy's Laboratories, Inc.
Elevance Renewable Sciences
Elizabeth Glaser Pediatric AIDS Foundation
Environmental Defense Fund
Ethypharm
Express Scripts
Fabre Kramer Pharmaceuticals, Inc.
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
FoxKiser Development Partners
Freedom Management Group, LLC
Freshfields Bruckhaus Deringer
Frost Brown Todd LLC
Generic Pharmaceutical Mfgs. Ass'n
Germiphene Corporation
Government Relations Writing
Impax Laboratories, Inc.
IntelliPharmaceutics Corp.
International Partnership for Microbicides
IVAX Corporation
Jerome Stevens Pharmaceuticals, Inc.
Kaiser Foundation Health Plan, Inc.
Kevin C. Stack
Klein-Becker LLC
Kleinfeld, Kaplan & Becker
Kohler's Drug Store
Labopharm, Inc.
Lavipharm Laboratories
Lifeminders, Inc.
Marwood Group
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, PC
Momenta Pharmaceuticals, Inc.
Mutual Pharmaceutical Company, Inc.

National Ass'n of Local Boards of Health
National Center for Tobacco-Free Kids
National Organization for Rare Disorders
New York City Board of Public Health
Otonomy, Inc.
P. Schoenfeld Asset Management LLC
PEW Charitable Trust (PCT)
Phillips & Cohen LLP
Praecis Pharmaceuticals Inc.
Ranbaxy Laboratories Limited
Respiratory Distributors, Inc.
Roxane Laboratories
Salem Pharmacy
Serono, Inc.
SkyePharma PLC
Spector Roseman & Kodroff, P.C.
State of Illinois
State of West Virginia
SUN Pharma Global Inc.
Teva North America
Teva Pharmaceuticals USA, Inc.
The Center for Alcohol Marketing & Youth
The George Washington University
The Sheridan Group
Theranos, Inc.
Topigen Pharmaceuticals, Inc.
TPG Capital, LP
TransCapital Corporation
Transkaryotic Therapies, Inc.
Trust for America's Health
Vanda Pharmaceuticals
Woodrow Wilson International Center for Scholars
World Health Resources
Yahoo, Inc.
Adams Nye Sinunu Bruni Becht LLP
Girardi & Keese
Goodwin Proctor LLP

I have held positions with the following nonprofit organizations:

Food and Drug Law Institute, Chair, Vice Chair and Board Member (2006-2010)
Food and Drug Law Journal, Chair and Editorial Advisory Board Member (Approx. 1983-87)
D.C. Circuit Historical Society, Treasurer and Board Member (2004-2011)
Center for Science in the Public Interest, President and Board Member (2005-2011)
Reagan-Udall Foundation, General Counsel (2008-2011)

Keystone Center, Board Member (Approx. 2002-2004)

12. Memberships: (List all memberships and offices held in professional, fraternal, scholarly, civic, business, charitable, and other organizations.)

In addition to the list below, please see response to question 11.

American Bar Association, member (Various years 2001-2010)
Trial Lawyers for Public Justice, member (Approx. 2002-2005)
D.C. Trial Lawyers, member (Approx. 2002-2005)
District of Columbia Bar Association, member (Approx. 2002-2005)
Woodley Park Community Association, President (Approx. 1984)

13. Political affiliations and activities:

a. List all public offices for which you have been a candidate.

None.

b. List all memberships and offices held in and services rendered to all political parties or election committees during the last 10 years.

Registered Democrat in Washington, D.C.

Presidential Election of 2008: member of Barack Obama Health Policy Committee; canvassed in Virginia for Barack Obama.

Presidential Election of 2004: canvassed and worked on phone banks for John Kerry. Drafted various policy papers for Howard Dean's presidential campaign.

c. Itemize all political contributions to any individual, campaign organization, political party, political action committee, or similar entity of $50 or more for the past 10 years.

Greg Bernstein for City Attorney, 2010:	*$250*
Obama for America, 2008:	*$2,300*
Hillary Clinton for President, 2008:	*$500*
Hillary Clinton for President, 2007:	*$500*
Hillary Clinton for President, 2007:	*$500*
Nathan Deal for Congress, 2007:	*$250*
Deval Patrick for Governor, 2005:	*$500*
Deval Patrick for Governor, 2006:	*$250*
Senator Ted Kennedy, 2005:	*$500*

Howard Dean for President, 2004:	*$250*
John Kerry for President, 2004:	*$500*
Democratic National Committee, 2004:	*$500*
Democratic National Committee, 2004:	*$750*
Senator Richard Durbin, 2001:	*$150*

14. Honors and Awards: (List all scholarships, fellowships, honorary degrees, honorary society memberships, military medals, and any other special recognitions for outstanding service or achievement.)

Champion, Legal Times/National Law Journal, 2010

The Best Lawyers in America, FDA Law, 2007, 2008, 2009, 2010, 2011

Super Lawyers 2007, 2008, 2009, 2010

Top Lawyers, Washingtonian, 2004, 2007, 2009

100 Most Influential Lawyers, National Law Journal, 2006

Leading Lawyers: Top Food and Drug Attorneys, Legal Times, 2005

Distinguished Service and Leadership Award, Food and Drug Law Institute, 2005

AV Peer Review Rated, Martindale-Hubbell

Nat'l Public Affairs Special Recognition Award, American Heart Ass'n, 1997

Secretary's Award for Distinguished Service, Department of HHS, 1997, 1999

Commissioner's Special Citation, Food and Drug Administration, 1995, 1997

50 Under 50 (Lawyers to watch under 50), National Law Journal, 1989

University of Virginia Law School Scholarship, 1972-1974

15. Published writings: (List the titles, publishers, and dates of all books, articles, reports, or other published materials you have written.)

"A Hard Pill to Swallow: Barriers to Effective FDA Regulation of Nanotechnology-Based Dietary Supplements" (Wilson Center 2009) (with Lisa Barclay).

"Generic Drugs: ANDAs, Section 505(b)(2) NDAs, Patents and Exclusivities," Chapter in

Food and Drug Law and Regulation (2008) (with Margaret Dotzel).

"Bolstering the FDA's Drug Safety Authority," 22 New England Journal of Medicine 357 (2007).

I Met The President Because of WordPerfect 6.1," in FDA: A Century of Consumer Protection (2006).

"A Modest Servant of Law and Life," The Washington Post, November 18, 2005, A23.

"How to Improve Drug Safety," The Washington Post, December 2, 2004, A35.

"The Leaderless F.D.A.," The New York Times, April 17, 2001.

"FDA Is Still Leaderless for Political Reasons", Arizona Daily Star, April 18, 2001.

"Tort Law Deference to FDA Regulation of Medical Devices," 88 Geo. L.J. 2119 (2000) (with Michael Green).

"The FDA's Decision to Regulate Tobacco Products," 18 Pace Law Review 27 (1997).

"The Food and Drug Administration's Regulation of Tobacco Products," 13 New England Journal of Medicine 988 (1996) (with David Kessler, et al.).

"Should Drug Firms Be Allowed to Give Doctors Peer-Reviewed Reprints on Off-Label Uses?" Physician's Weekly, vol. XIII, no. 12, March 25, 1996.

"Some Thoughts on FDA Reform," Tufts CSDD Newsletter, Tufts Center for the Study of Drug Development, vol. 21, no. 1, February 1996.

"We're Not Dragging Our Feet on New Drugs," The Washington Post, April 19, 1995.

"Food Drugs and Medical Devices" in Changing America: Blueprints for the New Administration (1992).

"Reforming the Civil Division of the Department of Justice", Changing America: Blueprints for a New Administration (1992) (with David Vladeck).

Panel Discussion on Expedited Drug Approval Process: Introduction: 45 Food, Drug, Cosmetic L.J. 327 (July 1990).

"On Good Authority from Reader's Digest," The Washington Post (August 19, 1989).

"Ban Red Dye to Protect our Health," USA Today (August 16, 1989).

Letter to the Editor on De Minimis and the Delaney Clause, The New England Journal of Medicine (April 6, 1989).

"An Obstacle to Public Safety," Health Magazine, The Washington Post (May 10, 1988) (with David Vladeck).

"Why the FDA's De Minimis Interpretation of the Delaney Clause Is a Violation of Law", 7 Journal of the American College of Toxicology 521 (1988).

The Judicial Record of Judge Robert H. Bork (August 1987) (coauthor of book and director of project), reprinted at 9 Cardoza L. Rev. 297 (1987).

"Don't Put the Sick at Further Risk," USA Today (March 24, 1987).

"But Which Red Dye?," The Washington Post (February 27, 1987).

"Contamination Reexamination," Letter to the Editor, The Wall Street Journal (July 14, 1986).

"Rent Control and the Post," Letter to the Editor, The Washington Post (November 24, 1985) (with Katherine A. Meyer).

"Public Citizen Fights for Initiatives in D.C., Public Citizen Magazine (September 1985).

"The Dyes and the Laws," Letter to the Editor, The Washington Post (August 1, 1985) (with Sidney Wolfe).

"Food Safety Laws Working Fine", At Home With Consumers (June 1985).

"Public Interest Law with Bread on the Table," ABA Journal (February 1985).

"The Bitter After-Taste of Saccharin", 40 Food, Drug, Cosmetic Law Journal 66 (Jan. 1985).

"Drugs," Chapter in Retreat From Safety (Pantheon Books, 1984).

"Contrary Signals from the FDA", U.S.A. Today Magazine (January 1984) (with Katherine A. Meyer).

"F.D.A.," The New York Times (February 3, 1983) (with Katherine Meyer).

"United States v. Generix: A Preview," 37 Food, Drug, Cosmetic L.J. 337 (1982).

"To Give Drug Industry Longer Patent Terms Is Just Aiding the Rich," Newsday (October 1, 1982).

"A Lot of Baloney about Delaney," Washington Post (November 21, 1981).

"How the Government Made Nuclear Accident Victims Subsidize Nuclear Power,"

Critical Mass Journal (June 1980).

Labels, Bans, and Consumer Preferences in Banbury Report 6: Product Labeling and Health Risks (Cold Spring Harbor Laboratory, 1980).

"Supreme Court Upholds Law Insulating Nuclear Industry From Liability for a Nuclear Accident," Critical Mass Journal (July 1979).

"An Industry Hiding from Liability," The Washington Post (April 28, 1979) (with Ralph Nader).

Drug Marketing Today: A Consumer View, 33 Food, Drug, Cosmetic L.J. 614 (1978).

The Myth of Swing Voting: An Analysis of Voting Pattern on the Supreme Court, 50 N.Y.U. Law Review 798 (1976) (with Philip K. Howard).

16. Speeches: (List all formal speeches you have delivered during the past five years which are on topics relevant to the position for which you have been nominated. Provide the Committee with **two** copies of each formal speech.)

- *Judge Bryant 100 Years (September 14, 2011)*

I have not given any other formal speeches during the past five years for which I have a written text.

17. Qualifications: (State what, in your opinion, qualifies you to serve in the position to which you have been nominated.)

Since March 2011, I have been the Principal Deputy General Counsel and Acting General Counsel of the Department of Health and Human Services (HHS), where I have been responsible for representing the Department, providing legal advice to the Secretary and to other senior officials, and managing the office of General Counsel.

Prior to March 2011 and for the past 30 years, I have worked as an attorney in government, public interest and private practice. During that time, I served in all three branches of government, as a law clerk to a federal district court judge, as counsel to the House Subcommittee on Health and the Environment, as Deputy Commissioner for Policy in the Food and Drug Administration (FDA), and as Deputy Assistant Attorney General, Civil Division, in the U.S. Department of Justice.

As counsel to the Subcommittee on Health and the Environment, I negotiated and drafted legislation involving health care, the FDA, and other public health

programs within the jurisdiction of HHS. I was responsible for representing the Committee on all legislation affecting matters within FDA's jurisdiction and was the principal drafter of legislation requiring nutrition labeling, upgrading the standards for medical devices, and improving the new drug review process through drug user fees.

My jobs in the Executive Branch have given me significant management experience. While at FDA, I served as Deputy Commissioner for Policy from 1994 to 1998. In this capacity, I oversaw all of the Agency's significant policy and regulatory decisions, including the Agency's tobacco rule in 1995. I was also the Agency's chief negotiator during the consideration of the Food and Drug Modernization Act of 1997 ("FDAMA"). While at the Department of Justice, I supervised all of the Department's civil appellate litigation and argued six cases in the U.S. Circuit Courts of Appeals. I also directed the Department's landmark lawsuit against the major tobacco companies. Over the past year, as Principal Deputy General Counsel and Acting General Counsel at the Department of Health and Human Services, I have gained considerable experience relevant to the job of General Counsel.

As a public interest litigation attorney, I brought numerous lawsuits against the federal government to enforce laws and to advance sound public policy. In addition to trial work, I argued approximately 25 cases in the federal courts of appeals and three cases in the United States Supreme Court.

Finally, in private practice I represented states, individuals, nonprofits, generic drug companies, and other commercial enterprises, which has given me another perspective on the importance of sound regulatory policy to states and businesses.

In order to be an effective General Counsel of the Department of Health and Human Services, it is necessary to have an understanding of health law, administrative procedure, litigation, and the legislative process. I believe that my experience has given me substantial knowledge in all of these areas. I have not only gained significant substantive expertise, but because I have worked in all three branches of government and also in private practice, I believe I have the ability to understand many different perspectives. In addition, it is necessary to work with members of the Executive Branch, Congress, and stakeholder groups. Again, because I have had the opportunity to work from within and with representatives of many organizations, I have gained a broad perspective and considerable experience working in all these areas as well.

B. FUTURE EMPLOYMENT RELATIONSHIPS

1. Will you sever all connections with your present employers, business firms, associations, or organizations if you are confirmed by the Senate? If not, provide details.

   Not applicable, as I am currently employed by the U.S. Department of Health and Human Services.

2. Do you have any plans, commitments, or agreements to pursue outside employment, with or without compensation, during your service with the government? If so, provide details.

   No.

3. Has any person or entity made a commitment or agreement to employ your services in any capacity after you leave government service? If so, provide details.

   No.

4. If you are confirmed by the Senate, do you expect to serve out your full term or until the next Presidential election, whichever is applicable? If not, explain.

   Yes.

C. POTENTIAL CONFLICTS OF INTEREST

1. Indicate any investments, obligations, liabilities, or other relationships which could involve potential conflicts of interest in the position to which you have been nominated.

   In connection with the nomination process, I have consulted with the Office of Government Ethics and the Department of Health and Human Service's designated agency ethics official to identify potential conflicts of interest. Any potential conflicts of interest will be resolved in accordance with the terms of an ethics agreement that I have entered into with the Department's Designated Agency Ethics Official and that has been provided to this Committee. I am not aware of any other potential conflicts of interest.

2. Describe any business relationship, dealing or financial transaction which you have had during the last 10 years, whether for yourself, on behalf of a client, or acting as an agent, that could in any way constitute or result in a possible conflict of interest in the position to which you have been nominated.

   In connection with the nomination process, I have consulted with the Office of Government Ethics and the Department of Health and Human Service's

designated agency ethics official to identify potential conflicts of interest. Any potential conflicts of interest will be resolved in accordance with the terms of an ethics agreement that I have entered into with the Department's Designated Agency Ethics Official and that has been provided to this Committee. I am not aware of any other potential conflicts of interest.

3. Describe any activity during the past 10 years in which you have engaged for the purpose of directly or indirectly influencing the passage, defeat, or modification of any legislation or affecting the administration and execution of law or public policy. Activities performed as an employee of the Federal government need not be listed.

The articles that I have written over the past 10 years, including articles related to public policy, are listed in response to question A.15.

Between January 2001 and March 2011, I represented the Campaign for Tobacco Free Kids in seeking the enactment of legislation to give the Food and Drug Administration (FDA) the authority to regulate tobacco.

While in private practice, I represented generic drug companies and other organizations in seeking legislation to authorize FDA to adopt a generic drug program for biological drugs. I also represented generic drug companies in seeking legislation that makes certain revisions to the generic drug approval process and patent system.

In private practice, I advised generic drug and other companies on obtaining approval of drugs under the standards of the Federal Food, Drug and Cosmetic Act. I have also worked on numerous comments to the FDA on various regulatory policies pertaining to generic drugs, including the rules for granting generic companies 180-day exclusivity and citizen petitions filed by the brand companies.

In private practice, I have also advised clients in connection with the following issues related to FDA: advertising on the Internet, FDA's Risk Evaluation Mitigation Strategies program, transparency of decisions pertaining to prescription drugs, antibiotic resistance caused by the use of antibiotics in animal feed, and the standards for approval of food additives.

I advised the American Academy of Pediatrics and the Elizabeth Glazer Pediatrics Foundation on legislation to require drug companies to test drugs likely to be used by children and on legislation that grants six months of exclusivity to encourage such research.

Between 2002 and 2004, I advised Consumers for Dental Choice on FDA's policies on the use of mercury in dental fillings. Between 2002 and 2004 I did

work for the American Hospital Association on the regulation of medical devices that are reprocessed.

In 2005 and 2006, I advised the Sheridan Group and Command Trust on the legal status of Silicone Gel Breast Implants and made presentations to FDA on these issues.

Between 2004 and 2008, I advised the State of Illinois on the rules that pertain to the importation of prescription drugs from Canada. In 2004 and 2005 I also worked with Illinois in an effort to obtain FDA clearance to import flu vaccine from Europe. (FDA clearance was not granted.)

In 2001 and 2002, I advised the Environmental Defense Funds on the law applicable to the use of antibiotics in animal feed.

In 2003 through 2005, I worked for the Center on Alcohol Marketing and Youth on legislation regarding advertising of alcohol products.

In 2001 through 2003, I worked for the Center for Science in the Public Interest on seeking legislation regarding allergenic food additives.

I testified before Congress (not on behalf of a client) on drug safety and on legislation that would authorize the importation of prescription drugs from Canada and other countries, under certain conditions.

4. Explain how you will resolve any potential conflict of interest, including any that may be disclosed by your responses to the above items. (Provide the Committee with **two** copies of any trust or other agreements.)

In connection with the nomination process, I have consulted with the Office of Government Ethics and the Department of Health and Human Service's designated agency ethics official to identify potential conflicts of interest. Any potential conflicts of interest will be resolved in accordance with the terms of an ethics agreement that I have entered into with the Department's Designated Agency Ethics Official and that has been provided to this Committee. I am not aware of any other potential conflicts of interest.

5. **Two** copies of written opinions should be provided directly to the Committee by the designated agency ethics officer of the agency to which you have been nominated and by the Office of Government Ethics concerning potential conflicts of interest or any legal impediments to your serving in this position.

6. The following information is to be provided only by nominees to the positions of United States Trade Representative and Deputy United States Trade Representative:

Have you ever represented, advised, or otherwise aided a foreign government or a foreign political organization with respect to any international trade matter? If so, provide the name of the foreign entity, a description of the work performed (including any work you supervised), the time frame of the work (e.g., March to December 1995), and the number of hours spent on the representation.

Not applicable.

D. LEGAL AND OTHER MATTERS

1. Have you ever been the subject of a complaint or been investigated, disciplined, or otherwise cited for a breach of ethics for unprofessional conduct before any court, administrative agency, professional association, disciplinary committee, or other professional group? If so, provide details.

   No.

2. Have you ever been investigated, arrested, charged, or held by any Federal, State, or other law enforcement authority for a violation of any Federal, State, county or municipal law, regulation, or ordinance, other than a minor traffic offense? If so, provide details.

   No.

3. Have you ever been involved as a party in interest in any administrative agency proceeding or civil litigation? If so, provide details.

   I received a uncontested divorce from my former wife in the Superior Court of Washington, D.C., in approximately October 1984.

4. Have you ever been convicted (including pleas of guilty or *nolo contendere*) of any criminal violation other than a minor traffic offense? If so, provide details.

   No.

5. Please advise the Committee of any additional information, favorable or unfavorable, which you feel should be considered in connection with your nomination.

   I am not aware of any additional information that the Committee should consider.

E. TESTIFYING BEFORE CONGRESS

1. If you are confirmed by the Senate, are you willing to appear and testify before any duly constituted committee of the Congress on such occasions as you may be reasonably requested to do so?

Yes.

2. If you are confirmed by the Senate, are you willing to provide such information as is requested by such committees?

Yes.

William B. Schultz Questions for the Record
Nominee to be General Counsel,
U.S. Department of Health and Human Services
Senate Committee on Finance
December 20, 2012

Senator Hatch

Q. Mr. Schultz, as you know I have long been a strong advocate for the over 150 million Americans who regularly consume dietary supplements as a means of improving and maintaining their health. In 1994, when you were counsel to Congressman Henry Waxman, we worked together to write the Dietary Supplement Health and Education Act (DSHEA). As you will recall, a tremendous amount of effort was put forth to carefully craft an appropriate regulatory structure that balances the risks and benefits to consumers with continued access and affordability. In fact, previous FDA Commissioners including Drs. Henney, McClellan, Crawford, and von Eschenbach, and the more recent former Deputy Commissioner, Dr. Sharfstein, all publically stated that they believed that the current laws provide for the right balance between government regulation and "access and affordability" for consumers. Can I count on you as General Counsel to continue efforts to maintain DSHEA and the delicate balance we struck together back in 1994?

Yes.

Q. The Department of Health and Human Services approved a demonstration program for the Medicare Advantage program, called the quality bonus demonstration, which effectively spent more than $8 billion beyond what Congress authorized, through what is called Section 402 demonstration authority. According to the Office of Management and Budget, these demonstrations are generally required to be budget neutral, and according to the law, they are supposed to test whether a new payment approach works. While I have always been a champion and supporter of the Medicare Advantage program, I do not believe that HHS had the legal authority to support this demonstration. In fact, the Government Accountability Office or G-A-O evaluated the demonstration to find that it was not designed in such a way as to test anything, and GAO has also said that HHS has not provided the legal justification for the M-A quality bonus demonstration. Based on your understanding of current law, what limits do you believe should be placed on future demonstrations under Section 402 authority?

There have been numerous demonstration projects of critical importance to the Medicare program over the years that have been authorized under section 402(a)(1)(A) of the Social Security Amendments of 1972, the authority under which the Medicare Advantage Quality Bonus Payment Demonstration Project is proceeding. The limits that must be placed on any future demonstration projects are contained in that provision, which authorizes the Secretary to develop and engage in demonstration projects but only if the purpose of the project is "to determine whether, and if so which, changes in methods of payment or reimbursement . . . for health care and services under [the Medicare program] . . . would have the effect of increasing the efficiency and economy of health services under" the Medicare program and only "through

the creation of additional incentives to these ends without adversely affecting the quality of such services." The authority that Congress granted to the Secretary under this provision has been deployed historically in ways that have led to significant improvements in Medicare payment policies (e.g., the advent of the prospective payment systems) and, under the statute, contains express limits. First, there must be a proposition to be tested and the means by which the results of the test can be evaluated; in other words, there must be a demonstration project. Second, there must be a change in a Medicare payment methodology to be tested, and there must be a reasonable hypothesis under which such a change would incentivize an increase in the efficiency and economy of the provision of services under the Medicare program (e.g., by decreasing cost, by increasing quality, by encouraging coordination). In addition, the demonstration project must reasonably ensure that such a change would not adversely affect the quality of the services provided under the Medicare program.

The job of the Office of the General Counsel is to provide legal advice to the Department so that it can comply with these and other requirements. While the question of whether the study is appropriately designed to answer a question is largely a matter for experts in the design of these types of studies, it is our job to oversee compliance with the statute and in particular with the requirement that the demonstration project will yield information that can be used to find out whether there are ways of increasing efficiencies (such as lowering costs or improving quality at the same costs) in the provision of health care through payment methodology changes.

Q. As you know, under Section 1115 waiver authority, Congress gave the Secretary of Health and Human Services some ability to help states experiment with better approaches to delivering care in their Medicaid programs. These waivers have achieved some very important policy innovation, but at the same time there are limits on how that waiver authority can be used. For example, some states have asked HHS for authority to spend Medicaid dollars on expenses that are not reimbursable under Title 19 of the Social Security Act. What do you believe are the limits on what expenses HHS can approve for state Medicaid programs under Section 1115 waivers?

The most important limit that section 1115 of the Social Security Act places on such projects is that the demonstration project must be likely to assist in promoting the objectives of the Medicaid program, which is to provide federal funding for state programs that pay for covered services provided to eligible individuals "whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396. The demonstration project costs for which federal matching payments are made may not be, for example, costs incurred in building roads.

There are many examples of demonstration projects involving costs that would not otherwise qualify for matching funds under the Act. This is how many states have provided Medicaid coverage for childless adults of designated income levels, even though, historically, such adults were not one of the statutorily specified groups entitled to Medicaid coverage (e.g., children, pregnant women, and disabled individuals of statutorily specified income levels).

Q. When Secretary Sebelius testified before this committee earlier this year, I asked her whether she or anyone else in HHS had conducted or requested any analysis of the constitutional or statutory religious freedom issues associated with the Administration's announcement of the contraception mandate. In response she said "Well, we certainly had our legal department look at a whole host of legal issues." Since my understanding is that you have been at the General Counsel's office HHS since March 2011, am I correct in assuming that you were part of the legal team that performed that analysis? What was your role and can you explain how you determined that this was an appropriate step for the Administration to take?

I was not at the Department when the Administration issued the initial preventive services coverage regulations in July 2010, but since March 2011, when I joined the Office of the General Counsel, I have worked with lawyers at the Department as they have carefully examined the Affordable Care Act and the constitutional and statutory protections for religious freedom in connection with the various Federal Register and other documents that the Administration has issued concerning the contraceptive coverage requirement.

As you know, the Administration has continued to refine how the requirement for providing contraceptive services coverage applies to religious organizations. In regulations issued on August 1, 2011, we exempted the health plans of religious employers as defined in the regulations. Subsequently, on February 10, 2012, we announced a temporary enforcement safe harbor for the health plan of any nonprofit organization that, on February 10, 2012 and since the announcement, has not provided contraceptive services coverage for religious reasons, consistent with any applicable state law. Any such organization that believes it qualifies for the safe harbor is required simply to certify that it meets the criteria and to provide a notice to plan participants.

Also on March 21, 2012, we issued an Advanced Notice of Proposed Rulemaking to establish alternative ways to fulfill the requirements of the contraceptive coverage requirement for objecting religious organizations that are not exempt under the final regulations announced on February 10, 2012.

The purpose of the safe harbor is to relieve the plans of these organizations from the contraceptive services coverage requirement while the Administration completes new rulemaking to exempt or otherwise accommodate the plans of additional employers from the contraceptive services coverage requirement. I anticipate that proposed rules will be issued in the coming months. I know that the Department will consider all comments very carefully and will do its very best to adopt a rule that is sensitive to religious concerns that also improves access to proven preventative care and is consistent with all constitutional and statutory religious protections.

Q. In your meetings with my staff, you committed to working with Congress to implement the various provisions of the Patient Protection and Affordable Care Act (PPACA) and to providing timely responses to questions posed about PPACA and other HHS related issues. While I appreciate that commitment, it stands in stark contrast to the

fact that many Congressional requests for information to your office and to HHS are not receiving timely responses. This ongoing failure to provide information relating to the implementation of the new law and respond to Congressional inquiries directly undermines Congresses' ability to conduct oversight and assess the impact that the law is having on patients, employers, states and taxpayers. To help ensure that Congress has the necessary information to make informed decisions about issues associated with implementation of PPACA and other pressing health care issues, will you commit to having your office respond to all Congressional requests, including letters and hearing questions for the record, within 21 days of the request?

I strongly support the important role of congressional oversight. As I am sure you understand, the Office of the General Counsel supports and advises the Secretary and other senior HHS officials, but we do not supervise those officials, nor do we have authority for communicating with Congress. As I stated during my hearing, I commit to you that I will do everything I can to make sure that the Department responds to your requests in a timely fashion and gets you the information you need to conduct your important oversight role.

Q. Mr. Schultz, I noticed from your Committee questionnaire that from 2005 through 2011 you were President and Board Member of a group call Center for Science in the Public Interest. Policies advocated by this group include higher taxes on tobacco products, sugared beverages, and alcohol.

In fact, Center for Science in the Public Interest is currently advocating increased taxes on sugared drinks and alcohol as a means of helping to avert the fiscal cliff. The group has a web page where visitors may send a pre-prepared message to lawmakers that reads in part "we urge you to consider a tax on sugary drinks and an increase in taxes on alcoholic beverages as revenue sources that would yield substantial new funds, improve the public's health, and help reduce health-care costs."

Traditionally, Health and Tax policy inhabit different policy spheres. If you are confirmed as General Counsel of HHS, will we see a merging of these issues?
Do you support the use of tax policy as a means to address public health concerns and the cost of health care in general, and specifically as advocated by the organization you were president of?

As President of the Center for Science in the Public Interest, I acted as Chairman of the Board. Although I supported many of the Center's projects, I had no responsibility for developing policy. As General Counsel for the Department of Health and Human Services, my responsibility would be limited to the laws that HHS administers, and I would have no responsibility for developing the Administration's tax policy.

Senator Roberts:

Q: I, along with the Senate HELP Committee, have been looking into the meningitis outbreak, the actions by NECC, and potential action by Congress in response to the

outbreak. However, we have made repeated requests for information related to the outbreak and have yet to receive adequate information and responses, hindering any progress. So I'd like to know when we can expect the FDA and HHS to respond to our requests?

Of particular interest to me is a timeline of events related to NECC and action by HHS and FDA, both prior to, and following the outbreak. We made this request in early October at the start of the meningitis crisis, and even after asking Dr. Hamburg about it during the HELP Committee Hearing, have yet to receive a response. When can I expect to receive the timeline?

I have been informed that FDA is working to respond to the HELP Committee's request for information and documents. To date, the Agency has provided more than 2,000 pages of documents to the HELP Committee, and will continue to provide additional documents on a rolling basis. In addition, FDA has provided four briefings to HELP Committee staff. FDA has been reviewing carefully contemporaneous documents so that it can develop an accurate timeline. I am informed that FDA expects to provide an historical timeline of events involving NECC and Ameridose to the Committee very soon.

Q: What do you believe are the scope and limits of FDA authority as it relates to compounding? And what's FDA's role and what is the appropriate role for state boards of pharmacy in oversight of this industry?

The states have been, and should continue to be, primarily responsible for the regulation of the practice of pharmacy, including traditional pharmacy compounding. The pharmacy compounding industry, however, has gone through significant changes in recent years, and the current legal framework is not the right fit for the FDA to provide appropriate and efficient oversight of this growing industry.

The courts have split on the issue of distinguishing traditional pharmacy compounding from other drug manufacturing. In the 5th Circuit, compounding must comply with the requirements set out in section 503A of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 353a), except for certain advertising and solicitation provisions, which the Supreme Court held unconstitutional. Nevertheless, the 9th Circuit has held that all the requirements of section 503A are invalid.

In the 9th Circuit, FDA has been following its Compliance Policy Guide (CPG), issued after the 9th Circuit decision but before the 5th Circuit decision. The CPG identifies factors that FDA uses to distinguish between traditional pharmacy compounding and other forms of manufacturing, and otherwise guides the agency's enforcement actions in the area of pharmacy compounding. However, as a guide, the CPG does not create any new legal requirements. In addition, courts outside of the 5th and 9th Circuits have not decided whether section 503A applies in their jurisdictions.

Moreover, neither the CPG nor section 503A provides the sufficient clarity or precision in drawing the line between traditional and non-traditional compounding to protect and promote the

public health. Other limits on FDA's authority over compounding relate to FDA's ability to effectively and efficiently regulate pharmacy compounding that exceeds the bounds of traditional pharmacy compounding. For example, compounders who claim that their practices are limited to selling and dispensing drugs at retail do not register with FDA, and when FDA attempts to inspect, these pharmacies have frequently sought to prevent FDA from viewing essential records, requiring FDA to go to court to obtain warrants and litigate as to the scope of FDA's authority. Similarly, there is a lack of clear authority to require these non-traditional compounding pharmacies to report adverse events associated with their products.

Q: In a Washington Post article you wrote in 1988, you were particularly critical of the Regan Executive Order which requires OMB review of all major federal regulatory decisions, more specifically you were censorious of OMB's cost-benefit analysis.

As I am sure you are aware while the OMB review process became more formalized in 1981 with President Reagan's Executive Order 12291, which was in effect from 1981 to September 1993 (the Reagan and Bush Administrations and the first nine months of the Clinton Administration). In September 1993, President Clinton issued Executive Order 12866, which retained the OMB review process in essentially the same form. And that Executive Order 12866 process remains in effect today.

I am very concerned about your previous comments on this issue, as I believe stakeholder input is essential to the regulatory process and as important is an analysis of the costs for regulations that this Administration and past Administrations have issued.

Does your position remain unchanged?

OMB review is an important part of the process of developing major rules. During the times that I have been in government, I have seen a significant number of instances where OMB's focus on the economic impact of regulations improved the quality of regulations and appropriately relieved business of regulatory burdens without diminishing the public health and safety goals of the particular regulation.

<u>For Mr. Schultz and Mr. Meade:</u>

Q: Recently HHS, Treasury and Department of Labor have issued regulations to implement provisions of the Patient Protection and Affordable Care Act (PPACA). These include the essential health benefits (EHB) mandate, actuarial value (AV) calculator, market rules and wellness provisions, as well as rules to implement provisions related to risk programs, cost-sharing, the federally-facilitated exchange (FFE) user fees, and medical loss ratio (MLR).

I would like to ask several questions related to these rules, rules that have been issued since then, and future rules:

a. **Many of the initial rules implementing the PPACA statute were interim final rules which allowed little or no stakeholder input. Of the most recently issued rules, while none of them were IFRs, many of these only provided 30 day comment periods. This is after the Administration took over 18 months to draft the regulations and OMB was allowed 4 months for their review.**

We have already heard from many stakeholders that a lot of them fear they will be unable to meet the timelines for comments, that comments will not represent a thorough review of the new policies, and that this Administration does not value stakeholder input in the process, to the point that many stakeholders are considering whether the time, effort and expense is worthwhile, when they believe their comments are not even considered, but instead treated more as a 'check the box' exercise to comply with existing Executive Orders and statute related to stakeholder input.

So aside from voicing my strong concern with these developments, I would like to know what value you put on stakeholder involvement in the regulatory process? What is a reasonable and standard amount of time for review and comment on regulations issued by this Administration?

I can assure you that HHS does value stakeholder involvement in the regulatory process. It is essential to developing regulations that are effective and do not impose unnecessary burdens on the public. We have worked to engage patients, health care providers, insurers, employers and many other stakeholders since the enactment of the Affordable Care Act, and have received comments on various guidance documents, which inform the polices in the proposed and interim final rules.

The reasonable amount of time for review of and comment on a regulation depends on the complexity of the regulation, the deadline for implementing it, and the amount of stakeholder input that has been allowed in other ways. Consistent with the Administrative Procedure Act the usual amount of time for commenting on CMS regulations, such as those issued under the Affordable Care Act, is 30 or 60 days.

b. **PPACA implementation represents novel legal and policy issues. Many of the regulations implementing the PPACA statute have been considered 'significant' which requires additional review, transparency, and allowance for stakeholder input among other requirements. However many of the regulations being issued are only outlining the options for being considered significant without defining which of the reasons make those rules significant. We have been unable to get clarification on this issue.**

Isn't this an important consideration when drafting and issuing regulations? And if the folks drafting the regulations don't know what is in a rule after 18

months of drafting, and 4 months of OMB review, how can you expect stakeholders to know such things and provide valuable feedback in a much shorter timeframe.

The Office of Management and Budget reviews regulations with an economic impact greater than $100 million and that raise novel legal and policy issues. The preamble to significant regulations identifies the various options available to policy-makers in drafting the regulations and describes why an option was chosen in preparing the proposed regulations. An economic analysis is often prepared simultaneously with the drafting of the proposed regulations and, in many cases, it is not clear whether a proposed regulation will exceed the $100 million threshold for being treated as a significant regulation until the economic analysis is completed. I agree that when a proposal is issued, it is necessary to inform the public of the economic impact of the various options and whether that impact would make the rule significant. I have been informed that HHS will focus on more clearly articulating the economic impact in future regulations.

c. **Similar to the previous question, many of the regulations recently issued have been labeled by OMB as 'economically significant'.**

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any 1 year).

For many of these rules the Departments have been unable to define how they reached the $100 million threshold, expressed disbelief, concern, or disagreement with OMB's determination, or have been unresponsive to requests for further clarification.

I, along with many of my colleagues expressed concerns to the Departments in a letter that "the RIA in each of these rules seem to lack consistency, or accuracy without any methodical standards. The estimates of the costs are minute considering the rules will be implementing reforms that will establish an entirely new market and create new regulatory standards and definitions."

Considering the potential cost implications of the PPACA implementation don't you think knowing and understanding the costs are important? Can you assist us in getting clarification on the 'economically significant' rules and the $100 million threshold?

Yes, I agree that gaining knowledge and understanding of the costs of regulations under the Affordable Care Act is very important. I will pass along your concerns, which we regard as important, to the appropriate officials in our agencies and at OMB.

Senator Burr

Q: In your testimony before the Subcommittee on Health and Environment, Committee on Energy and Commerce in 1988, you wrote that FDA has great discretion in interpreting the Food, Drug, and Cosmetic Act, stating that "...the FDA is not even obligated to adopt the best or most natural construction of a statute." In your opinion, what are the limits to the Department of Health and Human Services', including its Agencies, ability to interpret the laws passed by Congress, including with respect to enforcement?

I believe I was referring to the Supreme Court's decision in *Chevron v. NRDC*, 467 U.S.837 (1984), which discusses the deference that courts should give agencies that have issued regulations to construe statutes. The Court has issued numerous decisions on this subject since and they have not always been consistent. As General Counsel of the Department of HHS, I believe it would be my duty to interpret laws to faithfully implement the intent of Congress.

Q: What are your views on federal pre-emption?

The federal system of government contemplates that state laws will exist along with federal laws. As a general matter, as determined by the courts, state laws that conflict with federal laws are preempted. Congress, however, may enact a statutory provision that expressly preempts state law. An example of where Congress did expressly preempt state laws is in the Nutrition Labeling and Education Act of 1990, where Congress first enacted section 403A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343-1).

Q: Are there products or areas that FDA does not regulate today that you believe they should? If so, what?

The FDA struggles to find the resources to regulate the products within its jurisdiction. I am not aware of any additional product areas for which FDA jurisdiction needs to be expanded.

Q: In the wake of the meningitis outbreak, Commissioner Hamburg testified before Congress that FDA's authority over compounding is "limited, unclear, and contested," and attributed this uncertainty to a regulatory patchwork as a result of a split among federal appellate court decisions. When a Court decision creates uncertainty with respect to the law, do you believe the Agency or Department charged with implementing that law has a responsibility to inform Congress of such developments? If confirmed to serve as General

Counsel for HHS, do you personally commit to informing Congress of developments, including judicial decisions, which create uncertainty or identify shortcomings with respect to the laws HHS and its Agencies are charged with implementing?

Yes, I do believe that the Executive Branch should inform Congress where it needs legislation in order to carry out its mission, which in the case of FDA is vital to the public health. I am not the official at the agency responsible for communicating HHS positions to Congress, but I will work to inform Congress where information comes to my attention, such as judicial decisions, which Congress should be aware of as it considers potential revisions in the law.

Q: In your questionnaire, you cite your perspective on the importance of "sound regulatory policy to states and businesses" as part of your qualifications to serve as the Department of Health and Human Services General Counsel. You also highlight your extensive work in public and private capacities to advance FDA regulation of tobacco. Do you believe FDA's steadily increasing backlog of tobacco products under review by the Agency represents a sound regulatory approach? Are you concerned about the impact lengthy review times, regulatory inaction, and the increasing backlog will have on consumers' access to modified risk tobacco products?

I believe that federal agencies including the FDA certainly should act on product applications and petitions within a reasonable period of time and within the time prescribed by statutory deadlines, and I have spent much of my career working to improve the timeliness of responses by agencies. I am not aware of delays in acting on applications for modified risk tobacco products, but I certainly agree that FDA should act on such applications in a timely manner.

Q: Under current law, the biosimilar pathway provides 12 years of data exclusivity for branded biological products. As you implement current law, will you commit to working with your Administration colleagues to ensure that we secure and defend robust intellectual property rights for biologics, including the 12 years of data protection as found in U.S. law?

I will work to defend all legal standards contained in federal statutes including the biosimilar exclusivity provision.

Q: Title 42 US Code requires the Agency for Toxic Substances and Disease Registry within HHS' Centers for Disease Control and Prevention to conduct investigations and issue reports on EPA's National Priority List sites, formerly known as Superfund sites. In recent years, much attention has been paid to ATSDR's investigation of an over thirty year contamination of the drinking water system at Marine Corps Base Camp Lejeune, possibly the worst environmental exposure incident in the nation's history. Just last month, ATSDR released one of its most critical reports on the contamination, but it did so without any of the over fifteen hundred supporting documents provided by the responsible party for Camp Lejeune, the Department of Navy. ATSDR told my staff that it could not post any of these documents on its website because they were not made compliant with the

Rehabilitation Act of 1973, which requires Federal reports to be accessible to persons with disabilities. I have asked HHS why such an important and long awaited report would not be readily available. To date, HHS has not responded. I'm interested to know your thoughts on this matter and what you think of HHS's apparent position that the public's right to know in this case was superseded by ATSDR's inability to comply with Federal law.

The report mentioned in your question is available on the CDC website. HHS and CDC take very seriously the responsibility to make both the report and supporting materials available to the public. As you know, Section 508 is an amendment to the Rehabilitation Act of 1973 which requires that Federal electronic and information technology be accessible to people with disabilities. This includes files on websites. CDC is in the process of determining how to best address section 508 requirements with respect to the supporting documents. In the meantime, however, I have been informed that CDC is continuing to make the supporting documents available upon request on a disk.

Q: According to the Milwaukee Journal Sentinel's reporting earlier this month, The Administration on Children and Families (ACF) announced that, despite promising to release the results of the Head Start recompetition required under the Head Start Readiness Act of 2007 in the Fall, they would be delaying until sometime in 2013. Will you commit to finding out why this delay has occurred?

It is my understanding that ACF is currently evaluating grant applications in connection with this recompetition. On December 7, ACF posted information about the status of the competition on its blog (http://www.acf.hhs.gov/blog/2012/12/reform-continues-head-start-grant-applicants-under-review). As noted in this post, in the spring of 2013, ACF will release information to the public about the results for the competition.

Q: Chairman Kline and Senator Alexander sent a letter to ACF requesting more information regarding the competition so that the process would remain transparent, but no information has been made public on this competition that will impact many Head Start centers across the country. Will you commit to releasing all information, transcripts, discussions, e-mails, and other relevant documents to the public if confirmed General Counsel?

The Department of Health and Human Services established the Designation Renewal System through regulation that became effective on December 9, 2011. This regulation specifies seven conditions that HHS considers when determining whether a grantee is delivering a high-quality and comprehensive program and, thus, whether the grantee may be renewed without having to compete for continued funding. Approximately 200 funding opportunity announcements have been released as of May 2012, and those announcements detail the criteria that will be applied to evaluate applications. As noted above, it is my understanding that ACF is currently evaluating grant applications in connection with this recompetition. On December 7, ACF posted information about the status of the competition on its blog

(http://www.acf.hhs.gov/blog/2012/12/reform-continues-head-start-grant-applicants-under-review). As noted in this post, in the spring of 2013, ACF will release information to the public about the results of the competition.

Q: In 1998, Congress mandated HHS to conduct a national evaluation of Head Start. The first Head Start Impact Study, released in 2010, examined the academic and developmental outcomes of a group of Head Start participants from preschool through the first grade. In 2006, HHS initiated a follow up to the Head Start Impact Study, tracking outcomes of the same group of children through the end of third grade. Will you commit to releasing this report within the first month of being HHS' General Counsel?

This report was released on December 21 and can be accessed at the following link: http://www.acf.hhs.gov/press/new-study-examines-impact-of-head-start-through-third-grade.

Senator Coburn:

Q: FDA Regulating Off-Label Drug Use. In a December 2004 piece of writing ("How to Improve Drug Safety"), you said "The FDA should actively intervene when physicians misuse drugs. It is almost gospel at the FDA that the agency doesn't interfere with the "practice of medicine." This means that once a drug is approved for a single use, physicians are free under federal law to prescribe it for any use. Sometimes these unapproved uses can become widespread and dangerous." However, on December 3rd of this year, the Second Circuit, invoking the First Amendment protection of speech, reversed a criminal conviction for a drug salesman's promotion of a drug beyond its FDA-approved uses. So, for the moment, off-label use continues. As a matter of policy, do you think the FDA should have the authority to police off label use?

I believe, that the FDA should not interfere with the practice of medicine. Once a drug has been approved by the FDA, healthcare professionals may use or prescribe that product for uses or treatment regimens that are not included in the product's approved labeling.

Promotion of off label uses by pharmaceutical companies is far more complicated. Over the years, FDA has had various policies allowing drug companies to give physicians articles about off-label uses under certain conditions. In the FDA Modernization Act, Congress allowed distribution of such articles under other conditions (principally the condition that the company commit to undertaking clinical studies to determine whether the off label use is valid). This statutory provision has since sunset. I also do not believe there is any dispute that in appropriate circumstances, FDA has the authority to require that information about the safety and effectiveness of off-label uses, including adequate directions for use, be disclosed on a drug label, and that this is appropriate. We are still assessing the Second Circuit's decision, but I

would note that the decision did not contest FDA's authority to take action where promotion of an off-label use is false or misleading.

Q: FDA's Authority of Abuse-Deterrent Formulations of Opioids. I strongly believe FDA should not allow generic opioids, without abuse-deterrent formulations, to come to market. Unless FDA intervenes, Opana ER generic and Oxytocin generic –without abuse-deterrent formulations -- come to the market in January. Does FDA have sufficient legal authority to prevent this? Why or why not? If FDA does not have the authority to prevent this under current law, why didn't the FDA inform Congress of this in 2010 when the question was first formally raised with the agency?

FDA scientific staff is reviewing recently submitted data to determine whether the new opioid formulations you reference actually deter abuse. If FDA determines that the new formulations significantly deter abuse, we have concluded that FDA has legal authority, under the drug approval and drug safety provisions of the Federal Food, Drug, and Cosmetic Act, to require generic versions of Oxycontin and Opana ER to have abuse-deterrent formulations as well.

Q: HHS's Lack of Responsiveness to Congressional Inquiries.

a. **As you well know as a former Congressional staffer, one of the Constitutional responsibilities of Congress is to conduct oversight over programs and spending in the Executive Branch. One of the severe frustrations I share with my colleagues is not receiving timely or meaningful responses from HHS to simple inquiries or oversight letters I send. In a recent meeting with Senate Finance Committee staff, you said you thought a month was too long for a Member of Congress not to have received a reply from HHS on a letter. Yet, I have often waited many months for replies, and sometimes those replies are less than responsive. No agency is above oversight or review. So, what concrete, specific commitment can you make to me regarding HHS's responsiveness to letters and inquiries from the Hill?**

I strongly support the important role of congressional oversight. As I am sure you understand, the Office of the General Counsel supports and advises the Secretary and other senior HHS officials, but we do not supervise those officials, nor do we have authority for communicating with Congress. As I stated during my hearing, I commit to you that I will do everything I can to make sure that the Department responds to your requests in a timely fashion and gets you the information you need to conduct your important oversight role.

b. **In the questionnaire you submitted to this (Finance) Committee, there was this question: "If you are confirmed by the Senate, are you willing to provide such**

information as is requested by such committees [of jurisdiction]?" You answered "yes" to this question. So, do I have your commitment that you will not only appear before Congressional committees when asked, but respond to Congressional enquiries from me and other members of those committees in a timely and responsive manner?

Yes, I will do my very best to provide responses to you and other members of those committees in a timely and responsive manner.

Q: Recusal from Certain Policy Considerations.

a. **As I understand it, HHS' recusal process for senior appointees is that they recuse themselves from specific matters impacting former clients for two years. However, they are not required to recuse themselves from general policy matters which may have a direct impact on the issue area occupied by their former clients. For example, you would have to recuse yourself from a grant or lawsuit involving a generic drug company you represented, but would not have to recuse yourself from a policy changing drug pricing. Since you have strong philosophical views on generic drugs and have represented them or their viewpoint, how can you reassure me you will be legally objective on changes to drug policy, such as drug pricing?**

I understand that my role at the Department is as a lawyer and not as a policymaker, and that I am not the decisionmaker on HHS policies. I would like to note I have worked on the opposite side of attorneys for brand companies over the years, and I believe that they would tell you that I have a reputation for being fair and objective. As General Counsel, I intend to do my best to advise the Department of what applications of the law are permissible under the statute written by Congress.

b. **When you are recused from a particular issue due to a potential conflict, who registers or tracks that conflict of interest? Is it recorded anywhere internally for perpetuity? Is that conflict of interest posted on any public website? Why or why not?**

In handling recusals, I have sought advice from the career ethics attorneys at the Office of General Counsel, and I have followed that advice. I have a list of former clients and when a specific matter regarding such a client comes to my attention (as has happened approximately three times since March 2011), I inform the Deputy General Counsel responsible for the matter and I am shielded from any involvement in the matter. If there are any questions about whether a recusal is appropriate, I consult with the appropriate ethics attorneys.

Recusals are not required to be in writing. However, as a nominee for a Presidential appointee position subject to Senate confirmation, my ethics agreement, which describes the particular matters from which I am recused, is posted on the public website of the U.S. Office of Government Ethics and provided to this Committee. My OGE 278 public financial disclosure

report is also available to the public pursuant to the Ethics in Government Act and OGE regulations.

Q: HHS OGC Commenting on Legal Rationale for Pending Legal Matter. I understand the General Counsel's Office, as a general matter, considers its advice it gives to the Secretary and senior HHS officials to be confidential and subject to attorney-client privilege. This means that your office is not likely to share memos it wrote with the Hill. However, in a meeting with staff, you indicated that the GC's office *should* be able to share with the Hill an operative *legal rationale* underlying a particular issue. Will you commit to me and this Committee that, as general rule, you will always offer us your underlying legal rationale behind a particular conclusion?

I commit that I will always do my very best to provide appropriate responses, including legal explanations, to you and other members of the Committee.

Q: Legal Ability of Medicare to Pay Bills When It is Insolvent. Does the Medicare program have any legal ability to make outlays from the Part A trust fund when that trust fund becomes insolvent? Would legal options would HHS have then regarding the status of pending hospital claims if insolvency occurred?

We do not expect the Medicare Part A trust fund to become insolvent. If the trust fund were to become insolvent, HHS would seek a supplemental appropriation or otherwise work with the Congress to find a solution so that claims could be paid. If claims could not be paid, we expect claimants would avail themselves of legal remedies through the courts, which could lead to judgments against the United States that could then be paid out of the judgment fund.

Q: Interpreting the Law in Promulgating Regulations. Let me ask about how you interpret law when promulgating regulations. This is very important, since, as you once wrote, "regulations issues by agencies have the force of law, yet do not have to be approved by Congress." You once wrote that "the FDA is not even obligated to adopt the best or most natural construction of a statute," but suggested the statute would be upheld if it's "construction is reasonable or rationale." In a meeting with staff, you said an agency must implement the intent of Congress, but there are times when the intent of Congress is not in the statute. So, how do you – as the top attorney for HHS – decide what is *the intent of Congress*? What in the text tells you if it contains the intent of Congress or note? Since the "intent of Congress" can be a very elastic and subjective term, how do you ensure the agency does not go beyond its authority?

In order to determine the intent of Congress, our attorneys and I look at the text of the particular statutory provision involved, the legislative history and often the entire statute. The history of how the agency has interpreted the statute can also be important.

Q: Interpreting the Health Law and Exchange Subsidies. Let me ask you about subsidies and exchanges under the health care law. More than 30 states have decided not to set up an exchange, so the federal government will establish a federally-facilitated exchange in those

states. Based on a strict interpretation of the statute, it appears that HHS and the IRS are denied to the power to distribute tax credits and subsidies in these federally-facilitated exchanges. That is a literal textual reading of statute. Yet, the IRS and HHS are attempting to issue those subsidies — and penalize employers — where they don't appear to have authority to do so. Oklahoma's attorney general has filed suit to protect its employers from this tax. What is your read of the "intent of Congress" and the letter of the law on this matter?

Because this is a tax issue, the Department of the Treasury has the lead on interpreting the statute. As described in the preamble to the final rule promulgated by the Department of the Treasury on May 18, 2012, implementing the premium tax credit provision, the statute clearly provides for the availability of the premium tax credits in both state-based and federally facilitated exchanges. The premium tax credits are available in state-based exchanges, and that the purpose of the federally facilitated exchanges is to fill the gap where there is no state-based exchange by performing the functions of an exchange.

Q: Impact of Medical Device Tax on Innovation. Starting in January, the President's health care law levies a $20 billion tax on medical device manufacturers who develop and import products –such as pacemakers, artificial joints, surgical tools, and ultrasound equipment. This 2.3 percent tax affects revenue, not profits – so regardless if a company makes a profit, must pay the federal tax each year. On average, profits compose less than 4 percent of industry wide sales. Companies may respond to this by increasing the price on products, shifting product manufacturing and distribution outlets overseas, trimming their workforce, or investing less in R&D. You have been Deputy Commissioner of FDA and clearly are knowledgeable about many aspects of the medical device industry. Don't you worry about this onerous tax hampering innovation and development?

I have not analyzed this particular topic, but I understand the importance of the medical device industry to our nation's economy and public health. As General Counsel, my role would be to interpret the law for the Secretary and not to weigh in on tax policy.

Q: Risk Benefit Analysis at the FDA. One of the challenges inherent in FDA's review work is assessing the relative risks and benefits of a particular application pending for review. Too often reviewers can be prodded to consider risk on the one hand, or benefit on the other. The only way to eliminate all risk is to not approve any products, which also ensures there are no benefits. FDA reviewers already have many tools to mitigate potential risk associated with the use of a certain product. What can FDA do – from a management and culture perspective—to better systematize and routinize reviewers' adoption of an approach that appropriately balances risks and benefits?

This question raises issues outside my role as General Counsel; however I believe that the FDA has made great strides in making timely decisions on new drug applications. Whereas decisions once took 2-3 years, the agency now almost always reaches decisions on drug applications

within 10 months for standard drugs and 6 months for priority drugs. In FY 2012, the majority of novel drugs were first approved in the United States.

It is important to note that, as part of the 2012 reauthorization of the Prescription Drug User Fee Act, FDA has committed to developing a five-year plan to implement a structured benefit/risk assessment in the drug review process. I am informed that the agency will develop, publish, and implement a plan that includes: (1) a description of FDA's intended approach to build on FDA's current efforts to integrate a structured benefit/risk framework throughout the lifecycle of human drug development; (2) a plan to conduct two public workshops on benefit/risk considerations from the regulator's perspective; and (3) an evaluation plan to ascertain the impact of the benefit/risk framework in the human drug review process. FDA also intends to revise drug review templates and internal procedures to incorporate this structured benefit/risk assessment into the review process, and initiate a public process to nominate disease areas that could benefit from a more systematic and expansive approach to obtaining the patient perspective on disease severity or unmet medical need.

Q: Consequences When HHS Does Not Comply With Federal Law. As you may know, the Small Business Jobs Act of 2010 mandated HHS produce a report examining the results of the Medicare Fraud Prevention System (FPS) which uses predictive analytics to screen claims on a pre-pay basis. Federal statute required the report be shared with Congress and public on October 1, 2012. Yet the report was not public until last week –more than two months late. Did your office review this report? When did your office receive it and how long did it take you to review it? In this case, is currently there any penalty on HHS for not complying with federal law? In your *personal* view, should there be a penalty for any agency or official when an agency does not comply with federal law? Why or why not?

HHS takes very seriously its responsibility to prepare statutorily mandated reports to Congress, and works diligently to meet required deadlines. HHS regrets the two-month delay in issuing this report. OGC, along with other components of the Department, typically reviews such reports before they are issued, but I did not personally review this particular report.

In answer to the final question, while there are some situations where federal employees can be penalized for violations of law (such as certain ethics laws), I do not believe that federal employees should be personally penalized for not complying with this type of requirement. Typically, the preparation of a federal report requires work from multiple employees and is often not within the control of a particular employee. For this reason, I do not believe that a penalty would be appropriate.

Q: HHS Grantees' Violation of The Anti-Lobbying Act. The Anti-Lobbying Act, which is codified at Section 1913 of the Title 18, United States Code, bans the expenditure of federal funds to engage in various lobbying activities. In 2002, the Congress amended the Anti-Lobbying Act to prohibit all expenditures of federal funds to lobby or urge state and local governments to change their laws and restricted all exceptions to that general ban to communications between federal Executive Branch officers and employees and the Congress. You are seeking to be confirmed as the top attorney for HHS which administers

hundreds of millions of dollars in grants to private organizations and state and local agencies. There is substantial evidence that taxpayer dollars under some of these grant programs, including HHS and Centers for the Disease Control's Communities Putting Prevention to Work program, have been used to urge state and local legislatures to adopt new legislation. This activity is detailed in a letter from Senator Collins to Secretary Sebelius, which is available here: http://goo.gl/ajfSL. If confirmed, you will take on a solemn responsibility to help ensure HHS grant programs are designed in a manner that does not tolerate a grantee's violation of the law. In light of this:

a. Does the Anti-Lobbying Act prohibit the use of funds granted by HHS to private organizations and State and local government agencies to urge state and local legislatures to adopt or change laws? If you believe that the Anti-Lobbying Act permits some of this activity, please specifically identify what activity is permitted and explain the reasons for your conclusion.

The Office of Legal Counsel (OLC) at the Department of Justice has interpreted 18 U.S.C. §1913 to prohibit only large scale, high expenditure, "grass roots" lobbying campaigns conducted by federal agencies that expressly encourage members of the public to contact their elected representatives with regard to legislative matters *Constraints Imposed by 18 U.S.C. § 1913 on Lobbying Efforts*, 13 Op. O.L.C. 361, 362-65 (1989). While other legislative means and executive policies, such as appropriations riders and OMB circulars, have been employed to proscribe federally funded lobbying activities by government contractors and grantees, section 1913 has not been interpreted to apply directly to their activities.

The Centers for Disease Control also includes a funding restriction, AR-12, as part of all of its grant awards. AR-12 prohibits CDC grantees from using grant funds to engage in any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body.

It is important to note, however, that applicable lobbying restrictions do not prohibit awardees from all interaction with policymakers or the public. Federal law allows many activities that are not considered lobbying and that community awardees may decide to pursue, such as the dissemination of information about public health problems and science-based solutions or evidence-based educational materials. However, it would not be permissible for awardees to use federal funds to influence a specific piece of pending legislation through direct lobbying of legislators or by engaging in grass roots lobbying that encourages members of the public to contact those legislators. CDC has provided extensive guidance and training to its grantees to ensure that they do not engage in lobbying with Federal funds. *See, e.g.,* http://www.cdc.gov/od/pgo/funding/grants/Anti-Lobbying_Restrictions_for_CDC_Grantees_July_2012.pdf

b. What actions would you take, if confirmed as HHS General Counsel, to ensure that HHS grantees are complying with the Anti-Lobbying Act? Will you

provide definitive guidance to Department employees and grantees regarding what conduct is prohibited by the Anti-Lobbying Act?

If confirmed, I will continue to work with Department components to ensure that they understand applicable anti-lobbying restrictions and accurately convey such restrictions to grantees and contractors.

c. What steps will you take to make sure that Department officials have thorough and accurate legal advice regarding the meaning of the Anti-Lobbying Act? If you determine that the meaning of the Anti-Lobbying Act was unclear or ambiguous, will you commit now to seeking an opinion from the Department of Justice's Office of Legal Counsel interpreting the Anti-Lobbying Act? Would you regard such an opinion as binding on HHS?

If confirmed, I will continue to work with Department components to ensure that they have thorough and accurate legal advice on the applicable anti-lobbying restrictions. Where appropriate we will confer with the Office of Legal Counsel and work with whatever guidance they may provide.

Q: HHS' Ability to Offer "Premium Assistance Tax Credits" Through Federal Exchanges. Did you or your office produce any legal memos, analysis, or other written products for Secretary Sebelius or other Administration personnel regarding whether the IRS has the legal authority to offer "premium assistance tax credits" through federal Exchanges? If so, please explain the underlying legal rationale, including the legal citations, for your interpretation of Congressional intent in this matter.

Neither my office nor I produced any legal memoranda regarding the authority of the IRS to make premium tax credits available in federally facilitated exchanges. Because this is a tax issue, the Department of the Treasury has the lead on interpreting the premium tax credit provision of the Affordable Care Act.

Q: Passage of the Patient Protection and Affordable Care Act. Article I, Section 7 of the Constitution states "All Bills for raising Revenue shall originate in the House of Representatives; but the Senate may propose or concur with Amendments as on other Bills." In June of this year, the Supreme Court upheld the individual mandate as a tax, which raises revenue. However, the Patient Protection and Affordable Care Act (PPACA) originated in the Senate, not in the House. As you know, while the House passed a health overhaul in November 2009 and sent it to the Senate, the Senate amended another bill the House had recently passed, struck out the text of the existing bill, and inserted the PPACA as an amendment. This version of health care reform passed the Senate on Christmas Eve 2009. A few weeks later, the House passed a reconciliation bill which made changes to the Senate-originated health overhaul. Was it unconstitutional for the Senate to use a "shell bill" to pass the health overhaul? Why or why not?

No, it was not unconstitutional for the Senate to do so. An explanation of the Administration's position is contained in legal briefs filed by the Department of Justice. As those briefs explain,

the Supreme Court has never invalidated an Act of Congress based on a violation of the Origination Clause of the Constitution, and the Affordable Care Act was enacted in compliance with the Origination Clause's requirements. The Origination Clause provides that "[a]ll Bills for raising Revenue shall originate in the House of Representatives. U.S. Const. art. I, § 7. The Affordable Care Act originated in the House and is not a "Bill for raising Revenue" within the particular meaning of the Origination Clause.

Q: Judicial Review of HHS Actions. What is your position on judicial review of agency actions? Under what circumstances would your office welcome judicial involvement in settling a dispute with an external stakeholder?

Judicial review of agency actions is an important part of the administrative process and particularly of the process for issuing regulations. A principal goal of the agency should at all times be to take actions that will withstand judicial review, but I strongly endorse the right of external stakeholders to challenge agency actions in court.

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