

**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 Reagan 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.

For Mr. Schultz and Mr. Meade:

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 policies 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 Oxycotin 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 Oxycotin 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 not? 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.