ONE HUNDRED NINTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOE BARTON, TEXAS
CHAIRMAN

March 4, 2005

The Honorable Joe Barton
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

Pursuant to rule 4(c)(2) of the Rules of the Committee on Energy and Commerce, I request that the attached additional questions for the record from Reps. Allen, Rush, Gonzalez, Schakowsky, Markey, and me be forwarded to the Honorable Michael O. Leavitt, Secretary of the Department of Health and Human Services, who appeared before the Committee on Energy and Commerce at a hearing entitled: "A Review of the Administration's FY2006 Health Care Priorities" held on February 17, 2005. The attached questions from each member, along with the witness responses, should be included in the printed hearing record.

I would further ask that when the responses are received, a copy of each response be forwarded to Candy Butler (cb2000@mail.house.gov) of the Committee's Democratic staff. Ms. Butler will be responsible for forwarding the responses to the Members who originated the questions.

If any further information is required, please have your staff contact either Candy Butler (ext. 6-3400) or Sharon Davis (ext. 5-3641).

With every good wish.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER

Attachments (6)

cc: The Honorable Tom Allen
The Honorable Bobby L. Rush
The Honorable Charles A. Gonzalez
The Honorable Jan Schakowsky
The Honorable Edward J. Markey

Questions for the Honorable Michael O. Leavitt
Secretary for the U.S. Department of Health and Human Services
from the Honorable John D. Dingell
Committee on Energy and Commerce
Regarding the February 17, 2005, Hearing entitled:
"A Review of the Administration's FY 2006 Health Care Priorities"

1. The Medicaid program is facing pressure from three distinct areas:

   (1) The aging of our society resulting in a growing number of elderly in state Medicaid programs;

   (2) Loss of employer-sponsored coverage, especially due to increased unemployment caused by economic downturns; and

   (3) Rising health care costs, including prescription drug costs.

   Given the above pressures on states, would you support returning back to the states any Federal money gained from eliminating current state funding practices by legally increasing their FMAP?

   Would you support some other mechanism for making them whole? If yes, what?

2. Please provide additional information about the proposed changes in state financing that are included in the President's budget.

   INTERGOVERNMENTAL TRANSFERS (IGTs)

   a. Does the proposal to limit intergovernmental transfers (IGTs) require a statutory change, or can it be done under current law?

   b. Does your IGT proposal make illegal certain intergovernmental transfers that are currently legal?

   c. Please provide a list of the states that would be affected by this proposal. What amount of Federal funding is at stake in each state?

   d. Please provide a detailed description of the regulatory or legislative change, if any, that would be needed to implement this proposal.

PROVIDER TAXES

a. Does the proposal to change the allowable provider tax from six percent to three percent require a statutory change, or can it be done under current law?

b. Does your proposal make it illegal to use certain provider taxes that are legal today?

c. Please provide a list of the states that would be affected by this proposal and the amount of Federal funding at stake in each state.

d. Please provide a detailed description of the regulatory or legislative change, if any, that would be needed to implement this proposal.

HMO TAXES

a. Does the proposal to change the Managed Care Organization provider tax require a statutory change or can it be done under current law?

b. Does the proposal make it illegal to use HMO provider taxes that are legal today?

c. Please provide a list of the states that would be affected by this proposal, including the amount of Federal funding at stake in each state.

d. Please provide a detailed description of the regulatory or legislative change, if any, that would be needed to implement this proposal.

Does your proposal include a transition period for the states that will be affected by this change?

If the President's budget proposals are adopted, how will HHS re-base (i.e., recalculate the Federal funds available) in either section 1115 waivers or section 1915 waivers (or both)?

3. The Administration proposes to change the Medicaid administrative claims from "an open-ended financing framework" to "an allotment" or block grant. According to the budget, this proposal would cut $6 billion from Medicaid administrative costs.

We already know Medicaid administrative costs are quite low. A number of the President's proposals, however, would increase administrative costs on the states, for example:

- improving information technology (IT);
- administering the Medicare drug bill for the low income;
- "Cover the Kids" budget proposal which will require states to process more applications;
- new proposed improper payment regulations that will cost at least $1 million per year in each state.

Many activities are included under Medicaid administrative costs. Please identify which of the following administrative costs will be subject to capped funding under the administrative block grant:

- Survey and certification of nursing homes to protect beneficiaries from abuse;
- Immigration status verification;
- External quality review of managed care organizations to ensure HMOs are appropriately caring for children;
- Additional administrative costs imposed by the Medicare drug benefit for implementation of Part D;
- Outreach and enrollment spending;
- Improvements to program integrity efforts;
- Improvements in computer systems to improve quality of care, better facilitate electronic medical records, and improve program management;
- Medicaid fraud control units;
- Medicaid management information systems (MMIS);
- Quality improvement organizations;
- Claims processing;
- Managed care contracting;
- Drug utilization review to ensure prescription drugs are being used appropriately;
- Disease management to help chronically ill people manage their illness better.

Please describe how each state's "allotment" will be determined. How will the allotments increase over time? Describe how much money would be in a state's administrative allotment under your proposal. How much funding will be cut from each individual state?

4. Your budget submission makes no mention of pending cuts in Medicare physician payments. Physician payments remain well below the rate of inflation and cuts of four percent to five percent annually are predicted for 2006 through 2013. In that time, there are estimates that physicians' costs will increase by 19 percent while Medicare payments will fall by 31 percent.

   a. Do you agree with these estimates? If not, please provide your estimates with an explanation.

   b. Do you plan to take these or any other administrative actions to address this problem?

   c. According to the Congressional Budget Office (CBO), eliminating the overpayment to Medicare HMOs and paying them the same as fee-for-service would save Medicare $28 billion over ten years. Only 11 percent of seniors are in Medicare HMOs, but 89 percent of seniors are in fee-for-service Medicare. Would you support reducing HMO overpayments to help protect seniors' choice of doctor in fee-for-service? Please explain.

5. The President's budget proposes to make the Long Term Care Partnership Program permanent. The Partnership program would allow the elderly to protect some or all of their assets, yet still qualify for Medicaid nursing home coverage.

   According to a number of research publications, including the Robert Wood Johnson Foundation (RWJF) that partially funded these partnership programs, it is not yet evident whether this saves Medicaid money because many who have purchased their policies have yet to use them.

   The RWJF report notes:

   > "Because of the nature of long-term-care insurance C particularly the span of time between the purchase of a policy and the exhaustion of benefits C the ultimate effectiveness of the partnerships may not be known for more than 10 years."

   Yet the President's budget notes that these programs are "proven" to reduce Medicaid costs (p. 139).

   What empirical evidence is there to show that the Partnership programs have actually reduced Medicaid costs? How much state and Federal funding has the Partnership program saved in each of the four states that currently operate such programs?

   The four states participating in the Partnership program have adopted strong consumer protections for these long-term care (LTC) insurance policies. The current protections in the Federal tax code do not even include all the standards promulgated by the National Association of Insurance Commissioners for long-term care policies.

If the Partnership Program were to be expanded, would the Administration support additional consumer protection standards for policies sold under this program beyond those that currently exist in the tax code? Which additional standards would the Administration support to improve policies to protect middle-class families who purchase LTC insurance?

6. You propose to spend $2.9 billion to move people out of nursing homes and into the community. Coupled with the block grant on Medicaid administrative funding that could affect nursing home quality reviews, and the cuts to Medicare reimbursement for nursing homes in your budget, it seems that individuals with disabilities and the elderly who reside in nursing homes are at great risk of having their quality of care jeopardized. What steps will the Administration take to monitor payment adequacy, quality of care, and access to care if your proposals to cut available resources for nursing home payments and quality activities are implemented?

7. Your budget includes $1 billion to fund outreach efforts aimed at enrolling more low-income children in Medicaid and CHIP.

   a. How many currently uninsured children do you expect to enroll as a result of this national outreach initiative each year over the five-year period? Please provide a breakout by the number of additional children added in Medicaid and CHIP.

   b. Your estimate for the total 10-year cost of this initiative is $11.3 billion, yet only $1 billion is grant funding. Of the remaining $10.3 billion, how much do you estimate is attributable to new Medicaid spending, and how much is attributable to new SCHIP spending?

   c. How much additional state-only funds do you estimate states will spend to match your estimated $10.3 billion in federal spending?

   d. In the past 18 months, more than half of all states have implemented procedures to make it more difficult for families to enroll in coverage. A number even had waiting lists in CHIP. Does the Administration propose to take any action to force states to accept these children into their programs after their "outreach campaign" or would you let states continue to adopt procedural barriers to keep children out of the program? How will the Administration prevent procedural barriers from keeping children found as a result of this effort from gaining coverage?

8. The Administration's budget proposes to increase coverage among low-income individuals and families "without creating additional costs for the Federal Government." Please provide the following information:

   a. Does this proposal mean there will be caps or limits on the amount of Federal funds

states have to serve these populations? If not, how do you plan to ensure, and therefore get savings, without some enforcement mechanism?

b. If the Administration believes that "increases in coverage among low-income individuals and families" can be achieved without "creating additional costs for the Federal Government" or the states, how does the Administration define "coverage"? For example, does it mean coverage for primary care services only, with no coverage for hospitalization or specialty care, as under Utah's "HIFA" waiver?

c. It is highly unlikely that any state could substantially expand coverage using only the current level of Federal funds available without reducing benefits or increasing costs for those currently covered. Which benefits would you eliminate in order to provide expanded coverage? Please provide a list of those benefits.

9. Please provide answers to the following questions regarding the President's New Freedom Initiative:

a. This initiative is said to provide additional funding for states to move individuals with disabilities out of nursing homes and into community living.

In the past, the Administration has supported a block grant -- limiting Federal funding -- for so-called "optional" services and "optional" people. You have also alluded to this in public remarks. Does the Administration therefore support limiting the amount of Federal funding available for these services necessary for individuals with disabilities to live in the community?

b. Do you support converting the Home and Community Based Care waiver program into a state option that could be done without a waiver? Do you support requiring states to cover all eligible individuals who wish to live in the community? Or do you believe that states should be allowed to limit the number of people who can move to the community?

10. The Centers for Medicare and Medicaid Services (CMS) hired 100 auditors who are now in the States reviewing state financing mechanisms for Medicaid. What criteria are these auditors using to review state financing? Is there a uniform policy manual or set of protocols being used across all 50 states? Are these documents publicly available so that all states know the criteria by which they are being judged? Please provide the criteria the auditors are using to review state financing mechanisms, including upper payment limits, intergovernmental transfers, certified public expenditures, and provider taxes for each class of provider that is being reviewed.

Please outline the difference between a "Certified Public Expenditure" and an "Intergovernmental Transfer."

Please describe the difference between a "front end" IGT and a "back end" IGT. Are both acceptable IGTs for states to use? If not, please describe your rationale for not allowing one or the other.

11. According to an e-mail exchange between Governor Jeb Bush and Alan Levine that was released as a result of a Freedom of Information Act (FOIA) request in Florida, CMS left the state with the impression that the state would likely be able to keep its IGTs under its waiver proposal. Please describe how Florida's IGTs meet the standards CMS is currently using to evaluate whether an IGT is legitimate or not. Please list which other states have similar IGTs and the dollar values associated with them. Will all these IGTs be protected under the Administration's budget proposal to restrict IGTs?

12. The Administration's Medicaid baseline decreased by more than $70 billion over ten years. What caused this drop? Please provide the respective contributions to the baseline, revision of changed projections of enrollment, utilization, cost of services (hospital care, drugs, nursing homes, payments to Medicare, including clawback), and changes in Federal spending -- DSH, UPL, IGTs, provider taxes -- as a result of CMS's administrative efforts to clamp down on state Medicaid financing.

Questions for the Honorable Michael O. Leavitt
Secretary of the U.S. Department of Health and Human Services
from the Honorable Tom Allen
Committee on Energy and Commerce
Regarding the February 17, 2005, Hearing entitled:
"Review of the Administration's FY2006 Health Care Priorities"

1. The President's budget cuts - and in some cases completely eliminates - many important programs which bolster our health care infrastructure. This is at a time when we have a rising number of uninsured – and underinsured - Americans. Small businesses and large employers are struggling to afford health insurance for their workers. The President's "solution" is to trot out the same old proposals- association health plans, health savings accounts, and tax credits. To what degree to you believe that these proposals will provide affordable, quality coverage to the 45 million uninsured Americans? How do you view these proposals as providing meaningful assistance to employers who are trying to offer affordable coverage to their workers?

2. The President's budget cuts Medicaid by $45 billion over ten years. Reductions of this magnitude will cause lasting harm to current Medicaid beneficiaries and make the system less viable for health care providers. It also shifts costs to states: the state of Maine will lose $307 million in federal funding over the next ten years under this proposal. Won't cuts to Medicaid simply result in shifting costs to beneficiaries, providers, and states? And do you believe that this cost-shifting will reduce the rate of overall growth in spending?

3. The Administration is supportive of efforts to encourage our trading partners to pay more for research on innovative pharmaceuticals. There is a proposal before the World Health Organization (WHO) to negotiate a new global treaty on medical research and development. This proposal seeks to have all nations commit to spend a fixed percentage of their GDP on drug research. If implemented, this approach would dramatically expand global investment in medical R&D. I understand that the U.S. government, with HHS as lead agency, has opposed the discussion of this proposed at the WHO. Given the Administration's interest in increasing foreign drug research, will the Department of Health and Human Services allow discussion of this serious proposal at the WHO?

4. On May 20, 2004, I wrote a letter to Assistant Secretary Jennifer Young requesting information on HHS's analysis of the impact of the U.S.-Australian Free Trade Agreement on the Medicare and Medicaid programs. Despite repeated inquiries, I have not received the requested information. Given that negotiations on several free trade agreements are ongoing, some of which may also require analysis on the impact on U.S. federal health care programs, there is a timely need for Congress to have a better understanding of the issues involved. I respectfully request your assistance in responding to this request.

Questions for the Honorable Michael O. Leavitt
Secretary of the U.S. Department of Health and Human Services
from the Honorable Bobby L. Rush
Committee on Energy and Commerce
Regarding the February 17, 2005, Hearing entitled:
"A Review of the Administration's FY 2006 Health Care Priorities"

1. My home state of Illinois is an aggressive utilizer of both IGTs and provider assessment plans, and the result has been very beneficial to the citizens of Illinois: we have used each and every single dollar of additional leveraged Medicaid funds to provide health care to poor and under-served citizens. I am proud of how our state has expanded coverage to our most vulnerable populations, and I don't think we should apologize for anything.

   But many proponents of the President's budget call such financing mechanisms "abusive" or pejoratively call them "schemes". Your own Medicaid budget cuts purportedly target "questionable financing practices" and "misuse of funds" in order to protect the "integrity" of the Medicaid system. Again, these are all loaded terms that convey that states like Illinois are doing something wrong or abusive. My question to you, Mr. Secretary is: do you really think that Illinois's use of IGTs and provider assessments to expand low income health care services is abusive? Do you really look at these practices in such pejorative terms.

2. The initial complaints over IGTs were that federal dollars were being "misused" for non-health-care, general-fund spending matters. Again, this is clearly not the case in Illinois, where the state has used additional federal dollars purely for health care services for low income citizens. Is it still a problem that states are wrongfully diverting federal funds for non-health care purposes?

3. Mr. Secretary, the President's budget also calls for a $180 million cut in the Low Income Home Energy Assistance Program, also known as LIHEAP. At a budget briefing, your staff informed my staff that the rationale behind this cut was that the Department of Energy informed HHS that fuel prices would be lower for 2006. However, when I asked Secretary Bodman about this, he flatly denied that such a prediction was given to HHS. How do you respond to this? What is your rationale behind cutting funding for LIHEAP?

4. Mr. Secretary, the midwest and Illinois is almost entirely dependent on natural gas to heat their homes during the winters. In Chicago, we are known for particularly brutal winters, and many of my constituents on the South Side depend on LIHEAP to keep warm and even stay alive. Every indication is that natural gas prices will rise by November or December this year. Given this escalation in fuel prices, particularly in natural gas, are you amenable to reversing this cut and restoring funds to this important program?

Questions for the Honorable Michael O. Leavitt
Secretary of the U.S. Department of Health and Human Services
from the Honorable Charles A. Gonzalez
Committee on Energy and Commerce
Regarding the February 17, 2005, Hearing entitled:
"Review of the Administration's FY2006 Health Care Priorities"

1. Secretary Leavitt, I am deeply concerned about the potential impact of proposed reductions in federal Medicaid spending on children and on children's hospitals, since Medicaid pays for the health care of one in four children and nearly half of the patient care in children's hospitals. CHRISTUS Santa Rosa Children's Hospital in my district is the largest provider of Medicaid services in the state of Texas—more than 70% of all of its patients are covered by Medicaid. Additionally, Texas has the fastest growing child population in the nation. Please explain to me what the administration proposes to do to make sure that the $60 billion reduction in Medicaid spending won't jeopardize the ability of children to receive the care they need, particularly the sickest children in the country who rely on children's hospitals.

2. Secretary Leavitt, you have identified targeted case management as one area where states should cut their Medicaid expenditures, yet targeted case management is an extremely valuable service for many children. For example, a child in foster care who has asthma, depression from suffering abuse and learning disabilities may need his caseworker to coordinate treatment with his teachers, doctors, therapists, foster parents and birth family. This coordination is not waste, fraud or abuse, and in many states this targeted case management provides a critical service and a significant portion of the funds to serve these vulnerable special needs children. In the face of billions of dollars worth of additional tax cuts for millionaires, why are you suggesting cutting this support out from under these children?

3. Secretary Leavitt, the budget proposes investing an additional $1 billion in outreach efforts to enroll eligible children in CHIP. Yet the budget also proposes freezing CHIP funding at next year's level. Given that health care costs continue to rise and that many states have already cut back on services, reduced eligibility or increased co-pays because they have the funds to service children at current levels, isn't it disingenuous at best to spend money on enrollment without adding funds to actually serve the children enrolled?

4. Secretary Leavitt, the passage of the Medicare Modernization Act last Congress created a new program; Part D to provide prescription drug benefits for seniors. In regards to Part D benefits and Preferred Drug lists, what criteria are going to be used to determine the drugs available for Medicare beneficiaries? Will the limited Oregon-style Evidence based medicine approach be utilized or will the more complete EBM system, as originally described be the basis for medication reviews? How limited will the drug formularies be and how will inclusions or exclusions be determined?

5. Secretary Leavitt, how does the FY 2006 Health care budget address reimbursements for acute care health services that are mandated for hospitals to provide?

Questions for the Honorable Michael O. Leavitt
Secretary of the U.S. Department of Health and Human Services
from the Honorable Jan Schakowsky
Committee on Energy and Commerce
Regarding the February 17, 2005, Hearing entitled:
"Review of the Administration's FY2006 Health Care Priorities"

NURSING HOME RESIDENTS

1 Mr. Secretary, you have consistently made a distinction between the treatment of "mandatory" and "optional" beneficiaries. For nursing home residents, there is not a lot of difference – both groups have serious disabilities and multiple medical conditions. While mandatory residents are below 74 percent of poverty, optional residents above that income level could not conceivably afford nursing home care at $50,000 to $70,000 a year. How would your plan distinguish between the two groups of residents? Would states have additional "flexibility" in making distinctions between the two groups?

2 The President's budget includes $4.5 billion in 10-year "savings" from limitations on Medicaid asset transfers. I know that you are not responsible for the entire budget, but I have to admit to a little confusion here. Apparently, the President is really concerned that some beneficiaries are trying to hold onto their homes or hoarding their assets so that they can leave their families an inheritance. On the other hand, the President is fighting for permanent elimination of the estate tax even on the wealthiest estates (the Congressional Research Service reported last month that the 505 estates worth more than $20 million paid $5 billion in estate taxes in 2003). I guess we'll have to ask the President why his budget singles out nursing home residents and their families while rewarding families of billionaires. My question to you is whether and when you will be sending us specific proposals on this issue. Do you have evidence of violations of current law and, if so, are you asking for more enforcement dollars?

MANDATORY VS. OPTIONAL

Mr. Secretary, in a February 1 speech that you gave on Medicaid, you stated that "…mandatory populations must continue to receive the comprehensive coverage that they receive now….Mandatory populations need the help. They must receive the help. The optional populations, on the other hand, may not need such a comprehensive solution. Most of them are healthy people who just need help paying for health insurance."

The Kaiser Commission on Medicaid and the Uninsured has just published an article on optional beneficiaries. Let me read you just a few of the examples of optional beneficiaries they give:

- A woman with disabilities who earns less than $23,275 a year whose employer does not offer coverage and who needs Medicaid's coverage of physician services, personal care services and prescription drugs.
- A 50-year old man with multiple sclerosis with recurring drugs and physician costs that average $750/month and who "spends down" to Medicaid medically needy eligibility levels
- A pregnant woman who has a part-time job, no health insurance, and earns more than $12,382/year.

Do you really believe that the private insurance market is anxious to cover these "optional" beneficiaries? Do you have any evidence to show that it would be most cost-effective to cover these and other optional beneficiaries through subsidies for private insurance than Medicaid?

CADILLAC COVERAGE

Mr. Secretary, on February 1, you gave a speech, "Medicaid: A Time to Act," where you asked "Wouldn't it be better to provide health insurance to more people, rather than comprehensive care to a smaller group? Wouldn't it be better to give Chevies to everyone rather than Cadillacs to a few?"

I was struck by this statement for two reasons. First, there is the juxtaposition of health insurance vs. care. I know that Governor Bush has asked for a waiver to provide private health insurance for Medicaid recipients. Would it be part of your new "flexibility" to allow states to provide tax credits for the purchase of private insurance? Are we talking here about privatizing Medicaid?

Second, I was interested in the use of the term "Cadillac" to describe optional Medicaid benefits. Can you tell me which mandatory or optional services under Medicaid you think are "Cadillac?"

MEDICARE PRICE NEGOTIATION AUTHORITY

On February 11, CMS released a memo from Chief Actuary Richard Foster to Dr. McClellan on whether drug price negotiations by Medicare would lower drug prices. This is an amazing document. The conclusion is that price negotiation by the Secretary wouldn't achieve greater savings than reliance on the market. That conclusion was not reached by any kind of quantitative analysis. Instead, it relies on the judgment that, "The Secretary's ability to achieve price reduction would depend on the Federal government's willingness to use its large-purchaser power in a forceful way....we do not believe that the current Administration or future ones would be willing and able to impose price concessions that significantly exceed those that can be achieved in a competitive market."

In other words, I believe that this conclusion says more about the Bush Administration's willingness to lower drug prices than anything else. Your predecessor Tommy Thompson used his negotiating authority with Cipro – saving taxpayers $82 million – and Flu-mist (again getting

half the retail price). Those discounts were considerably higher than the 15-25% discounts the Foster memo said Medicare drug plans would achieve on average. Secretary Thompson also said that not having negotiating authority in the Medicare drug bill was his biggest regret.

Why was Secretary Thompson so successful in winning discounts and why are you so opposed to having the authority to negotiate?

Questions for the Honorable Michael O. Leavitt
Secretary of the U.S. Department of Health and Human Services
from the Honorable Edward J. Markey
Committee on Energy and Commerce
Regarding the February 17, 2005, Hearing entitled:
"Review of the Administration's FY2006 Health Care Priorities"

1. Mr. Secretary, I am very hopeful that your new leadership will inspire some much needed reforms at the Agency. I must say that I have been extremely disappointed by the lack of responsiveness from HHS and particularly from FDA to Congressional oversight. I have not received even partial responses to letters that the FDA agency has been promising me for months. Last week, my staff was told that I would be getting responses prior to this hearing, but yesterday they told my staff that the responses had been delayed. Mr. Secretary will you commit to me that I will receive responses to my outstanding inquiries within one week's time? If you need additional copies of the letters, my staff would be happy to forward them to you.

2. Mr. Secretary, at the hearing, I asked you why the FDA is allowing drug companies to get away with NOT conducting post-marketing studies that the Agency told them to perform as a condition of approving a drug through the accelerated approval process. You responded by talking about the FDA's passive collection of information on drugs that have been approved for market and your desire to move the agency towards active collection of safety data. My question was not about the agency's effort in collecting information about fully approved drugs but rather about the agency's efforts in ensuring that companies that receive conditional approval for drugs complete the required post-market confirmatory trials. I am concerned that some of these drug companies are failing to keep their commitments and the public may be buying and using products that they think are safe and effective but are no better than sugar pills or even dangerous. What is the FDA doing to ensure that companies complete these required post-marketing studies?

3. Mr. Secretary it is my understanding that the Secretary has the authority to withdraw the approval if the sponsor fails to conduct any required post-approval study of the fast track drug with due diligence. But to my knowledge the FDA has never used its authority to withdraw approval for any of these drugs. Do you know of any cases where the FDA has withdrawn approval for these reasons?

4. I understand that the FDA is under immense political pressure from both drug companies and patient advocacy groups to keep drugs that have received accelerated approval on the market despite company failure to complete post-marketing studies. Does the FDA need other enforcement mechanisms to ensure that companies complete post-marketing studies?

5. Along these same lines, if a company does not complete a required study, the FDA could revoke the approval. Would you agree that the withdrawing an approval could result in significant financial losses to the company that was selling the product?

6. Since a sudden withdrawal would have serious consequences, don't you think that that full and complete disclosure regarding the status and outcome of any federally-mandated post-approval studies would be material information for those who are investing in the securities of those companies?

7. Does the Department, or the FDA, have any mechanism for informing the Securities and Exchange Commission of the commitments that a drug company has made to the federal government with respect to carrying out post-marketing studies so that the SEC can be sure that investors are informed that:

    a. the drug has only received conditional approval;
    b. the safety and efficacy of the drug has not been confirmed through clinical trials;
    c. if the companies do not complete the post-marketing confirmatory trials the FDA may withdraw the approval through an expedited process?

8. Mr. Secretary, on February 16, 2005, Forbes.com released an article that quoted a medical officer[1] with the FDA's Center for Drug Evaluation and Research who reviewed all the available data on the class of drug that include Vioxx called cox-23 inhibitors. In the article she claimed that reviewing drugs for approval is difficult because the FDA does not have the authority to ask for certain studies. She claimed that although there was some confusion about the data that they had on cox-2 inhibitors, the FDA could not ask the company to conduct additional studies that would have clarified the situation. She is quoted as saying, "we don't have a legal mandate to ask that certain studies be done." If your medical officers feel that the law limits the information available to them and don't have all of the information that they need to make good decisions about safety and efficacy, I am sure that we would be happy to give it to you. Are you planning on asking for additional authority to require companies to conduct additional studies to clarify questions of safety and efficacy?

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[1] "Dr. Lourdes Villalba, medical officer with the FDA's Center for Drug Evaluation and Research, reviewed for the panel all the available data on cox-2s and then stressed the challenges the agency had faced when reviewing the drugs for approval. Villalba said that all the data and signals from them had not always been clear, and that the agency could only review what was given to them because 'we don't have a legal mandate to ask that certain studies be done'...'How puzzled we were with all the data as it came in,' she added." See http://www.forbes.com/lifestyle/health/feeds/hscout/2005/02/16/hscout524041.html

9. Mr. Secretary, Our committee recently conducted a bipartisan investigation of the safety problems associated with antidepressants and Cox2 painkillers and we found that pharmaceutical companies hid negative trials and important safety information from the public. Further, we found that the FDA knew about these drugs' potentially deadly side effects long before they said anything to the public. Do you agree that it is important for the clinicians, the research community and the public to know about negative results and have access to new information about drug safety and efficacy on a timely basis regardless of whether the information is regarding an approved indication or an off-label use?

10. In order to ensure that companies can not hide this information and that clinicians, patients and researchers know what trials have been conducted and how they turned out, Rep. Waxman and I introduced a bill in the last Congress to create a public, federal registry of clinical trials and their results. I plan on re-introducing that bill shortly to address this problem. Will you be willing to support this legislation?

11. Mr. Secretary, our committee has learned of several cases where the FDA prevented its own scientists from presenting data that contradicted the agency's pre-determined position on the safety or effectiveness of a drug, pressured scientists to change study conclusions and discouraged them from raising safety questions in advisory committee meetings. Apparently some at the agency believed that the advisory committee's ears were too sensitive to hear about negative results, or their minds to weak to make sense of conflicting evidence about drug safety or effectiveness. I am pleased to see that Graham was allowed to present his results at the cox-2 inhibitor committee, but I would like to know what are you going to do to ensure that in the future, scientists within your agency and particularly in the Office of Drug Safety are no longer gagged – so that they are encouraged to express their scientific opinions and raise questions about drug safety and effectiveness?

12. Mr. Secretary, I understand that you and Mr. Crawford have recently announced plans to make a number of reforms at the FDA. I am pleased that the FDA has finally admitted that it has failed the public when it comes to drug safety, transparency and communication with the public. Recognizing the problem is the first step to solving it. However, I am concerned that your proposal is long on rhetoric and short on real reform. You announced with Dr. Crawford that this new a drug safety oversight board will advise the FDA. This proposal sounds suspiciously similar to the already existing Drug Safety & Risk Management advisory committee whose role it is to advise the FDA on issues of drug safety. To me it sounds like an old program with a new name. How will this committee be different from the existing committee? Will this board have any real power? For example, will it be able to remove a drug from the market if it determines that there are serious safety concerns? Will it have the power to change a label? Will members of this new board have the authority to examine information in the New Drug Application (NDA)?

13. Mr. Secretary, our bipartisan investigations of the safety problems associated with antidepressants and Cox2 painkillers have shown that a drug company that submits data after approval can drag the process of revising the drug label for months or years by simply not agreeing to FDA requested changes. In the meantime, prescribers, patients and parents are unaware of the discovery of dangerous and in cases fatal side effects of these drugs. Will you be sending legislation to us that permits FDA to dictate timely changes in the label when safety problems are identified?

14. One of the startling announcements to come out of FDA during the antidepressant hearings last September was the revelation that it was FDA policy not to even request that the drug companies note the failure to show efficacy on their label. These firms received billions in the extension of monopoly status for doing pediatric studies. In this case, doctors were writing prescriptions for children for years not knowing that the powerful drugs with serious risks they chose had not been shown to work in clinical trials of adolescent populations. This policy was made by senior FDA officials behind closed doors. They just decided without public knowledge that the issue was under consideration. How is your new drug safety committee to even learn when policies like this are being made?