FOIA Number: 2008-1524-F

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Collection/Record Group: Clinton Presidential Records

Subgroup/Office of Origin: Office of Science and Technology Policy

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Subseries:

OA/ID Number: 13036

FolderID:

Folder Title:
Tobacco: DES [Donna E. Shalala]-Commerce Committee Questions and Answers

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DRAFT

RESPONSES TO QUESTIONS FOR SECRETARY SHALALA

Questions submitted by Mr. BURR

1. Has your department, in its submissions to the Office of Management and Budget for next year's budget, included any aspect of the proposed tobacco settlement? If so, what did you include? What will the baseline assume with respect to the spending and revenue aspects of the tobacco settlement? What are the assumptions you made in the submissions to OMB? If you did not make assumptions, why not? Won't the settlement have an impact on HHS's budget, and other aspects of the budget for Fiscal Year 1999 and beyond? What do you expect those impacts to be?

   RESPONSE: Our budget request to OMB is part of the internal, deliberative process required to produce the President's budget, now scheduled for release in early February. We are unable to discuss the contents of our request until after the President's budget is released.

2. Your department has sent a notice to the states that you expect the states to reimburse the federal government for its share of past Medicaid expenditures, as is required under current law. What has been the response from the states thus far? What share of total Medicaid expenditures is funded by the federal government? What will be the share of the total settlement that you expect the federal government to collect? Over what time frame do you plan to collect these funds, or withhold payments to the states?

   RESPONSE: In June 1996, HCFA sent letters to the five states -- Louisiana, West Virginia, Florida, Massachusetts and Mississippi -- that settled with Liggett in March 1996. The letters reminded the states of their statutory obligation to report Medicaid recoveries in their quarterly statements to HCFA. Three states have reported recoveries, and the amounts have been credited to the federal government. As of this November, Florida had credited $200,000 to the federal government, while Massachusetts and Louisiana have each reported $291,500. On a broader level, the National Governors' Association, several state Attorneys General and the National Conference of State Legislators have registered opposition to sharing tobacco revenues with the federal government.

   In all Medicaid recoveries, the federal share is based on the individual state's match rate (the percentage of its Medicaid costs paid for by the federal government). On average, the federal government pays about 57 percent of Medicaid expenditures for services. Therefore, the federal government will recover about 57 percent of the Medicaid-related share of the total settlement. The federal government also pays half of the administrative and litigation costs related to Medicaid, including those incurred by the states in recovering funds from liable third parties.

   The response should discuss the more recent letter sent to all 50 states, the state response to that letter, and the Potus letter to the govs.

At present, it is difficult to estimate exactly the Medicaid-related share of the total settlement. We believe most state suits were primarily based on Medicaid expenditures, though some may be related, in varying degrees, to state programs other than Medicaid. We expect states to credit us with the federal share whenever the state receives payment from the tobacco industry. In these tobacco settlements, HCFA will work with each state involved to determine the appropriate amounts. The 11/3/97 letter from HCFA to state Medicaid directors invites them to discuss this with us.

Questions submitted by MR. DINGELL

1. Madam Secretary, the President's proposal includes an element related to increasing the price per pack of cigarettes, up to $1.50 per pack over the next 10 years. You know there will be an argument that such a price increase will penalize adult smokers and, further, that a price increase of this magnitude or higher could result in destroying the American tobacco industry. This argument is extended to point out that such a result would be counter-productive, because it could mean that the agreed-on financial contributions could not be made by the tobacco industry and, therefore, the expected public health activities could not be undertaken. How do you respond to these arguments?

RESPONSE: The President called for a combination of industry payments and penalties to increase the price of cigarettes by up to $1.50 in the next decade, as necessary to meet youth smoking reduction targets of 30 percent in 5 years, 50 percent in 7 years, and 60 percent in 10 years. We have proposed this because we know that increasing the price of cigarettes is the most effective method of reducing underage smoking. Youth smokers are far more price sensitive than adult smokers, which means that price increases should disproportionately reduce youth smoking – our primary goal in this initiative. Although ~~these~~ price increases may reduce adult smoking as well, ~~we do not believe that increases of this magnitude would have any significant adverse impact on the ability of the tobacco industry to meet its financial responsibilities. Indeed, even if cigarette prices were increased by $1.50 per pack over the decade, many other countries would continue to have significantly higher prices for cigarettes than the United States.~~ we believe the tobacco industry will be able to meet its obligations.

The President's fundamental intent in this initiative is to focus on this historic opportunity to significantly reduce the use of tobacco among young people. Raising the price of tobacco products is a critical element in achieving that goal.

2. In discussing the need for international tobacco control, your testimony stated that American embassies and missions should not be taking actions or be involved in

activities that promote the demand for tobacco, especially among young people. What specific kinds of activities are you referring to? What activities should Congress and the administration be attempting to curtail?

RESPONSE: We are pleased that Congress acted favorably on an amendment to the FY 1998 appropriations bill for Commerce, Justice, State and Judiciary (Section 618 of P.L. 105-119) that incorporates Administration policies. First of all, the federal government should not take any action that may conflict with our firmly established public health objectives. For example, officials should not challenge or in any way undermine another country's efforts to enact and implement non-discriminatory health-based measures designed to reduce tobacco use. Nor should U.S. government officials take any action that promotes the sale, manufacture, or export of ~~tobacco or~~ tobacco products.

The United States should increase its commitment to the efforts of the international health community to reduce tobacco use abroad, particularly as it affects the health of children and youth especially in developing countries. This can be accomplished by improving training, surveillance, research, and education. To reach out to foreign countries, the U.S. should act either unilaterally, by initiating multilateral and bilateral collaborations, or by invigorating our involvement in already existing collaborations, such as the WHO's Tobacco or Health Plan of Action (1996-2000).

3. In talking about an enhanced research agenda, you emphasized in your testimony the need for a comprehensive approach that includes a whole spectrum of activities, from basic biomedical research and disease-specific studies to epidemiological and other research. What level of research funding are you envisioning? How does this future research agenda compare with what is going on already, funded by NIH, CDC, SAMHSA, and others?

RESPONSE: Tobacco use is our nation's leading cause of premature death and preventable illness. It is responsible for 30 percent of the cancer incidence, one-third of cardiovascular disease deaths and 90 percent of chronic obstructive pulmonary disease, taking the lives of 400,000 Americans each year and consuming $50 billion in medical expenditures to treat. Each year, work by the National Institutes of Health (NIH) and other Public Health Service (PHS) agencies identify additional diseases (SIDS, low-birth weight babies, miscarriage, and birth defects such as cleft lip and palate, and periodontal disease) where tobacco use is implicated.

The need for a significant and targeted infusion of funding to support a broad spectrum of tobacco-related research is critical if we are to take advantage of the many promising scientific opportunities that could reduce the toll of tobacco-related

preventing illness and addiction,

illness. To make significant progress in improving treatments and better understanding the causes of tobacco-related diseases, we should support a robust and comprehensive research portfolio. At a minimum, such a portfolio should examine tobacco's impact on health, disease, and quality of life, and include studies from ~~six~~ seven broad research categories: biomedical, clinical, behavioral, health services, public health, and community, surveillance/epidemiologic research. Research must address issues at the national, state and local levels and include studies of tobacco use among both youth and adults. While most tobacco-related research is currently funded through the NIH, significant research in this field also is conducted by the other PHS agencies. But despite our best efforts, each year important areas of tobacco-related research go under funded. For example-

product design,

- Research to insure that young people do not start using tobacco;
- Research to identify and test the most effective interventions for helping current users to stop use of tobacco with emphasis on special populations (especially children);
- Research to prevent disease in former smokers;
- Research to assess baselines and monitor trends in incidence and prevalence of tobacco use behaviors and exposures to tobacco smoke (including appropriate use of biomarkers);
- Research to definitively characterize the environmental and biobehavioral underpinnings of nicotine addiction in both children and adults;
- Research on health effects of tobacco smoke in the environment;
- Research to characterize all tobacco and combustion products (including those of newly-introduced tobacco products) and their health consequences;
- Scientific review of tobacco industry research and other information that has been released and that will be released. This would include work on product design, marketing strategies (especially youth-oriented strategies), and health research. The review will help us determine our future research priorities and enhance the development of technologies and products to reduce the adverse health effects of tobacco products.

To reduce the toll of tobacco use and addiction, research funding should be sufficient to assure progress without detracting from other important health-research commitments. Furthermore, we need to establish a structure that will assure funding for tobacco-related research will expand upon – and not supplant – our nation's existing commitment to basic biomedical and behavioral research. Such protections should be transparent and established in a manner that assures science based peer review and scientific objectivity in identifying and supporting research proposals of greatest merit.

1. I was pleased to note the Administration's concern about the impact of the tobacco settlement, and any related legislation, on the variety of interests that were not

- Research on non-addictive and reduced risk tobacco products;

involved in the settlement negotiations, such as tobacco farmers, retailers, vending machine companies, and others. What proposals is the Administration developing that will try to minimize adverse impact on tobacco farmers and others?

RESPONSE: The President made it clear that any tobacco legislation must protect tobacco farmers and their communities. Most tobacco farmers live and work on small family farms; in many cases, their families have been growing tobacco for generations. In some states, entire communities rely on income from the tobacco crop. The Administration is committed to working with Congress in a bipartisan fashion to protect the financial well-being of tobacco farmers, their families and their communities. As I mentioned in my testimony, there are several active proposals before Congress and there will be more to come. Secretary Glickman and I will continue to work with Congress to develop effective solutions.

Questions submitted by Mr. STUPAK

1. What are the public health ramifications of not approving the proposed settlement or some variation?

RESPONSE: Each day, nearly 3,000 young people in the United States become regular smokers. Almost 1,000 of those young people will have their lives cut short by diseases caused by their use of tobacco. In fact, 5 million young people alive today will die prematurely because of tobacco use. We must act now to prevent this terrible tragedy from continuing, and the President's five principles lay a strong foundation for congressional action on meaningful, comprehensive tobacco legislation in ~~1998~~ 1998.

2. Under current law, if a plaintiff is awarded a judgment against a state's Medicaid program, is the federal government responsible for paying its pro-rata share of the judgment?

RESPONSE: HCFA will match all court-ordered state Medicaid expenditures, as long as the payment falls within the parameters of Title XIX. The federal government will pay all *pro rata* shares of the judgment arising from proper operations of the Medicaid program. However, if the state is taking actions not permitted by the Medicaid program, or is sued for a non-Medicaid issue, HCFA will not participate.

3. Is it your understanding that current law would have to be amended to allow the states to keep 100 percent of the settlement?

RESPONSE: Yes. Section 1903(d) of the Social Security Act clearly states, *"(2)(B) Expenditures for which payments were made to the State under subsection (a) shall be treated as an overpayment to the extent that the State or local agency administering such plan has been reimbursed for such expenditures by a third party pursuant to the provisions of its plan in compliance with section 1902(a)(25)...."*

Since Medicaid's inception, the statute has mandated that the federal government share in any recoveries just as it shares in payment of Medicaid costs. To excuse states from sharing Medicaid-related tobacco recoveries would require specific statutory authority.

4. Does the Administration believe that the Health Care Financing Administration should be allowed to recoup the federal share of the judgment?

RESPONSE: As noted in question 3, current law requires that HCFA pursue recovery of the federal share of any settlement or judgment. With respect to the proposed legislation, on December 5, the President sent a letter to the National Governors' Association and to the National Association of Attorneys General indicating his desire that the allocation of funds between state and federal government be "resolved through legislation."

5. If changes to current law are required to allow the states to keep the settlement proceeds, does the Administration support such a change?

RESPONSE: The President stated in his December 5 letter that he "would prefer to see the allocation of tobacco funds resolved through legislation" and he "looks forward to working with the States and with Congress to find a mutually agreeable purpose for the funds generated by tobacco legislation."

6. Should the litigation in Minnesota, which is scheduled to go to trial in January, delay Congressional action on the settlement?

RESPONSE: Minnesota's lawsuit against the tobacco industry is currently scheduled to begin on January 20, 1998. If it proceeds, this trial could last for months. Consideration of comprehensive tobacco legislation, which can begin once the Congress reconvenes, does not have to interfere with that litigation. Both can take place at the same time. ~~Given the complexity of the legislation to be considered, the trial may actually be completed before any legislation is passed.~~

7. Why should states be allowed to recover the costs they spent treating tobacco related illness, but private insurance plans and union plans will not?

RESPONSE: There is nothing to prevent the Congress from considering ~~the~~ claims by private insurance plans and union plans in its deliberations on comprehensive tobacco legislation.

Questions submitted by Mr. Rush

1. The *Chronicle of Higher Education* has reported that African American scholars received less than one percent (0.4%) of the National Institutes of Health (NIH) research that was awarded by NIH in 1991. These rates have not improved significantly since then.

Although minority medical schools and educational institutions receive little federal assistance for minority health research, they continue to commit significant funds to this vital area.

Researchers at minority institutions are most likely to be familiar with the community resources needed to develop effective tobacco control programs in this community.

Therefore, what steps will the Administration take to use funds from the settlement to support effective public health programs?

RESPONSE: During our analysis of the proposed settlement, for which we sought input from many representatives of minority communities, the Administration concluded that ~~the settlement did not~~ adequately address these communities. Minority groups and other special populations suffer a disproportionate burden of tobacco-related disease and are among the greatest users of tobacco products. ~~We~~ would recommend that the tobacco legislation include provisions that would assure that the needs of minority groups and other special populations be included in prevention and cessation programs. ~~Tobacco~~ research ~~programs should explicitly address gender and racial differences in tobacco use. Representative researchers should be included. To be sure that happens,~~ we will include representatives of affected communities at all stages of planning and implementation for these research programs.

2. Several studies on reducing tobacco use, including the Department of Health and Human Services (DHHS) report, "Strategies to Control Tobacco Use in the United States: A blueprint for public health action in the 1990s" by Dr. Louis Sullivan

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NUMBER OF PAGES (INCLUDING COVER SHEET): 8

Bob - Here are Bruce & my edits. Please don't hesitate to call me if you need help deciphering any of them. Thanks.

DRAFT

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Cite damage rpts submitted by states instead

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3. In talking about an enhanced research agenda, you emphasized in your testimony the need for a comprehensive approach that includes a whole spectrum of activities, from basic biomedical research and disease-specific studies to epidemiological and other research. What level of research funding are you envisioning? How does this future research agenda compare with what is going on already, funded by NIH, CDC, SAMHSA, and others?

RESPONSE: Tobacco use is our nation's leading cause of premature death and preventable illness. It is responsible for 30 percent of the cancer incidence, one-third of cardiovascular disease deaths and 90 percent of chronic obstructive pulmonary disease, taking the lives of 400,000 Americans each year and consuming $50 billion in medical expenditures to treat. Each year, work by the National Institutes of Health (NIH) and other Public Health Service (PHS) agencies identify additional diseases (SIDS, low-birth weight babies, miscarriage, and birth defects such as cleft lip and palate, and periodontal disease) where tobacco use is implicated.

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Questions submitted by Mr. Strunk

1. What are the public health ramifications of not approving the proposed settlement or some variation?

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RESPONSE: Yes. Section 1903(d) of the Social Security Act clearly states, *"(2)(B) Expenditures for which payments were made to the State under subsection (a) shall be treated as an overpayment to the extent that the State or local agency administering such plan has been reimbursed for such expenditures by a third party pursuant to the provisions of its plan in compliance with section 1902(a)(25)...."*

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preference

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RESPONSE: There is nothing to prevent the Congress from considering such claims by private insurance plans and union plans in its deliberations on comprehensive tobacco legislation.

Questions submitted by Ms. Rush

1. The *Chronicle of Higher Education* has reported that African American scholars received less than one percent (0.4%) of the National Institutes of Health (NIH) research that was awarded by NIH in 1991. These rates have not improved significantly since then.

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Researchers at minority institutions are most likely to be familiar with the community resources needed to develop effective tobacco control programs in this community.

Therefore, what steps will the Administration take to use funds from the settlement to support effective public health programs?

RESPONSE: During our analysis of the proposed settlement, for which we sought input from many representatives of minority communities, the Administration concluded that the settlement did not adequately address these communities. Minority groups and other special populations suffer a disproportionate burden of tobacco-related disease and are among the greatest users of tobacco products. We would recommend that the tobacco legislation include provisions that would assure that the needs of minority groups and other special populations be included in prevention and cessation programs. Tobacco research programs should explicitly address gender and racial differences in tobacco use. Representative researchers should be included. To be sure that happens, we will include representatives of affected communities at all stages of planning and implementation for these research programs.

2. Several studies on reducing tobacco use, including the Department of Health and Human Services (DHHS) report, "Strategies to Control Tobacco Use in the United States: A blueprint for public health action in the 1990s" by Dr. Louis Sullivan

(1991), have argued that innovative strategies will have to be developed to operate effective education and cessation campaigns in the minority community.

In light of these studies, what types of efforts does the Administration feel DHHS and other agencies can have in designing and overseeing the types of extensive community-based measures that will be required to truly reduce tobacco use in the minority community?

RESPONSE: Public health studies of tobacco use and the incidence of tobacco-related death and disease are necessary to determine accurately the scope of this problem within minority communities. Many of these issues will be addressed in the upcoming Surgeon General's Report on *Tobacco Use among Minority Populations*. However, significant data gaps must be closed before we can be sure that effective measures to prevent and control tobacco use among minority youth are successful.

Culturally appropriate strategies are created through partnership and collaboration with members of the minority population. This collaboration promotes a sense of ownership, enhances receptivity, and elevates the impact of tobacco control messages to minority youth. The experience of the Department of Health and Human Services is extensive. For example, the Centers for Disease Control and Prevention (CDC) fund 32 states and the District of Columbia to ensure participation by diverse community groups, coalitions and leaders to strengthen tobacco control initiatives nationwide. NIH's National Cancer Institute (NCI) funds 17 states for tobacco control. NCI initiated a Multicultural Committee which seeks to address diversity issues in tobacco control programming. The Indian Health Service also reduces tobacco use through cessation programs and several policy efforts. The Health Resources and Services Administration maintains a medical care delivery system which includes treatment for nicotine addiction and provider training programs that reach many minority communities.

Building on this experience, the Administration will continue to work with Congress to make sure that the health research and tobacco control programs that result from this legislation are responsive to our minority communities.

3. In addition to research for effective prevention and cessations programs for minorities, there are a number of minority health issues related to tobacco use that require further research. For example, 76 percent of African Americans smoke menthol cigarettes compared with 23 percent of whites.

This is particularly discouraging since menthol cigarettes can be inhaled more deeply, and therefore, cause more damage to the lungs. However, most admit that

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Jerry —
Good catch.
Thanks —
BR

TO: Cathy Mays

PHONE NUMBER:

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FROM: Mande

NUMBER OF PAGES (INCLUDING COVER SHEET): 15

Cathy - I marked (*) the Q&A. I thought BNR would want to review.