Project On Government Oversight
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October 30, 2009
To Kathleen.Sebelius@hhs.gov

The Honorable Kathleen Sebelius
Secretary, U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Sebelius:

Summary: The vaccine shortage may be an inevitable result of DHHS's mistakes of the past. Those mistakes should be disclosed so they won't be repeated. The lack of disclosure is a problem that is easy and inexpensive to fix.

Thank you for asking Dr. Nicole Lurie to reply to our letter or letters (of September 30, August 26, July 20). However, we are disappointed that Dr. Lurie's reply (October 19) fails to deal with the main issues we raised.

In her letter to us Dr. Lurie wrote: "We agree that transparency is essential to our H1N1 response and we work continuously to maximize transparency to the greatest extent possible."

For a government agency, "transparency" should not consist of trying to excuse a problem only after it becomes obvious to everyone. Now that a vaccine shortage is front page news across the country, your agency has no choice but to provide an explanation. As reported in detail in the press, agency officials have blamed the shortage:

- o On the unusual behavior of the virus (it grows much more slowly than had been expected)
- o On the manufacturers (they ran into problems loading the finished vaccine into vials, and they also provided DHHS with "overly rosy" predictions about their delivery of vaccine)
- o On state and local health officials and the news media (DHHS gave in to pressure from them when making predictions, prematurely, about the availability of vaccine)

But no one in DHHS has acknowledged any significant misjudgment by agency officials. No one has accepted a significant share of the responsibility for the vaccine shortage. No one has said, "We made a mistake."

Members of Congress concerned about the current shortage of vaccine are seeking an explanation in mistakes of the recent past – the last few months. But at the time the flu pandemic began last spring, the shortages we are experiencing now may already have been inevitable – a result of bad decisions made by DHHS long before that. These decisions should be disclosed and examined in order to guide DHHS in its future decisions.

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What should be done now? POGO's quest for greater transparency

The public would benefit from knowing DHHS's future plans for H1N1 flu vaccine production – not only its emergency plans for dealing with the current vaccine shortage, but especially the agency's longer-range plans if the pandemic persists beyond the next few months, as is likely.

POGO has repeatedly urged disclosure of the weaknesses in the flu vaccine program, for example in its 17-page report published in March 2008 and more recent documents, including our letters to you.

Below we describe three areas among several in the vaccine program that are in need of full public disclosure.

Disclosure needed: Government contracts for pandemic flu vaccine production

Every one of these multimillion dollar contracts for vaccine production should be posted online – on the initiative of DHHS and without the need to file Freedom of Information Act requests. If a contract (redacted when necessary) is obtainable through a FOIA request, then that contract can and should be posted online without such a request. (USAID routinely posts many of its contracts online.) In addition, any evaluations of contractors' *ongoing* performance should be posted online and updated periodically. Dr. Lurie wrote that DHHS contract officers share information about contractors' *past* performance with other agencies; this is certainly not the same thing. She also wrote that DHHS provides updates to Congress; this, too, is very different from posting online the agency's evaluations of contractors' ongoing performance.

Questions. Will the contracts be posted online? Will DHHS's evaluations of manufacturers' performance under their contracts be posted? If such disclosures are prohibited by law, will that prohibition be explained?

Disclosure needed: U.S. dependence on foreign sources of vaccine

Probably some 70 to 80 percent of the U.S. supply of H1N1 vaccine will come from abroad. The extreme dependence of the U.S. on foreign manufacturers should have been described, and *the decisions that led to the dependence should have been justified publicly long ago* by DHHS. This includes a disclosure of the decision processes in the past, under the previous administration, that led to the present dependence on foreign sources. In a Commentary sent with our September 30 letter we asked you to disclose this information:

> POGO asks Secretary Sebelius to lay out the facts. She should describe the current level of U.S. dependence on foreign sources of H1N1 swine flu vaccine, the status of partially completed and fully active U.S. manufacturing facilities, and the timetable for U.S. self-sufficiency. Visitors to the government's pandemic flu website, www.pandemicflu.gov or other readily accessible site – laymen and experts alike – should have ready access to the documents and decision processes in the government's program for production of H1N1 swine flu.

Dr. Lurie ignored this important point. Her letter made no mention of the subject of U.S. dependence on vaccine produced abroad, and she did not comment on our request that information on this subject be posted.

Questions: Will this information be provided online? In a congressional hearing on October 21, Senator Jon Tester asked about the possibility that foreign manufacturers on which this country is depending might provide vaccine to their own people first. You replied that orders for vaccine would be filled in priority terms and that the U.S. is "at the front of the line" in terms of getting vaccine as it is produced. Is this still true? Will DHHS publicly take notice of statements, made by respected public health experts, that a foreign government in need of H1N1 vaccine may simply direct its own manufacturers not to ship vaccine abroad until the needs of its own population are met, regardless of the manufacturer's previous contractual commitments to other governments? In fact, has any of the H1N1 vaccine made abroad and committed to the U.S. been diverted for local use in the country of origin, thus delaying shipment of that vaccine to the U.S.?

Disclosure needed: Alternatives to current vaccines

In our March 2008 report we wrote:

> Major increases in government support for the production of other kinds of vaccines, such as live-attenuated vaccines and hemagglutinin vaccines, should be considered and discussed online. Administrators and scientists in the government's vaccine program are undoubtedly well aware of arguments for and against investing more heavily in the production of these types of vaccines. . . . With the available resources and with adequate funding, billions of doses of vaccine *could be produced significantly faster than six months after the start of a pandemic.* [Emphasis added.]

In articles during the past few months (here and here) and our letters to you we have described in detail how poor planning led to a delay of *several years* before a contract to produce recombinant vaccine was finally awarded in June 2009. Thus the U.S. still lacks the capacity to produce large amounts of recombinant vaccine quickly. If the misjudgments or mistakes that led to this long delay had not occurred, it is quite possible that H1N1 vaccine would have been available in September or even in August of this year. The decisions that led to the delay in recombinant vaccine production should be disclosed publicly. On this issue – DHHS's past planning for recombinant vaccine production – there is a particularly strong case for transparency. But Dr. Lurie's letter does not mention the issue of recombinant vaccine production.

Government and nongovernment experts should now be asked to consider whether it is justified, even at this late date, to quickly enlarge the capacity to produce recombinant vaccine. This would require certain actions by the FDA and also a large increase in the current investment in facilities for manufacturing the recombinant vaccine. These are difficult decisions. For example, the expanded, more numerous facilities may either prove to be unnecessary (because by then

there may be an abundance of egg-based vaccine), or these facilities may not be ready if and when they are needed. On the other hand, if there's a late emergence of an antigenically different strain of H1N1, the ability to produce vaccine more quickly than six months is likely to prove useful. DHHS should solicit and post the opinions of experts on this issue.

Questions: Will an accurate history of the recombinant vaccine planning within DHHS be posted online – thus either confirming or refuting our assertion about the unnecessary delay of several years? Do you plan to seek expert advice on the desirability of enlarging the capacity to produce recombinant vaccine, and if so, will that advice be made public?

If you direct your staff to institute a policy of greatly increased transparency, it should be possible for them to carry out this policy quickly and at low cost to the government. In this letter we describe just a few of the areas of the program in need of more disclosure. We believe that such a policy will strengthen the agency's plans for dealing with the pandemic and lay the groundwork for more substantial changes. In addition, the public will have more confidence in an agency that deals promptly and openly with good news and bad.

Sincerely,

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cc: Dr. Nicole Lurie, Assistant Secretary for Preparedness and Response, DHHS