Project On Government Oversight

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September 30, 2009 To Kathleen.Sebelius@hhs.gov and by fax to 202-690-7203

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

Dear Secretary Sebelius:

The shortage of H1N1 swine flu vaccine will persist for several months at least, and we believe that certain steps should be taken to deal with this issue. Some of the steps are described in the attached article, "Flu Vaccine Shortage: Why Did It Happen? How Can It Be Overcome?" which was posted today on POGO's website at

http://www.pogo.org/pogo-files/alerts/public-health/ph-pfv-20090930.html The article states:

> Up to now there has been little outcry over the shortage of vaccine. But soon that is likely to change.

In the coming winter of 2009, as the pandemic spreads and as vaccine becomes available, but in insufficient amounts, some of those who want vaccine for themselves or their families will be unable to get it. The clamor for vaccine may grow louder as many illnesses and a few deaths – some of them preventable – occur among those denied vaccine because of the shortage.

If complaints about the shortage intensify, the White House and the Department of Health and Human Services may be pressed for an explanation.

There has been a long delay – six months – from the start of the pandemic last spring until adequate supplies of vaccine will finally become available in the late fall or winter of 2009. Why did it take so long? Was the long delay intrinsic to the production process and unavoidable? Or were there misjudgments and mistakes in planning within DHHS during the last few years that delayed the production of vaccine when a pandemic began?

We at the Project On Government Oversight believe that it was the latter – that vaccine could and should have been available far sooner. However, we also believe that the effects of the faulty planning can be mitigated and that similar deficiencies can be avoided in the future.

In the attached article we describe examples of faulty planning. As a result of past decisions, the U.S. is now dependent on foreign manufacturers for most of its vaccine. Unlikely events beyond anyone's control could lead to a shutoff of vaccine shipments from abroad and an immediate, severe worsening of the vaccine shortage.

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In addition, enough vaccine for the whole U.S. population won't be available until November or December or perhaps later. We believe this long delay after the start of the pandemic could have been avoided. The failure by DHHS to support the production of recombinant vaccine in a timely fashion was serious lapse that contributed to the present shortage.

In the attached article we discuss these instances of faulty planning and suggest certain steps to be taken promptly. The goal should be to disclose the mistakes of the past, examine them, learn from them, and take action to make sure they are not repeated.

We welcome the opportunity of meeting with you to discuss the flu vaccine shortage, and we await notification of your availability for a meeting, as indicated by Shelly Watson in your Office of Scheduling in her email of August 28.

Sincerely,

Danielle Brian
Executive Director

Project On Government Oversight

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Attachment: Article of September 30, 2009