

# Project On Government Oversight

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November 13, 2009

To [Kathleen.Sebelius@hhs.gov](mailto: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

Subject: Possible way to prevent deaths caused by H1N1 flu

Dear Secretary Sebelius:

The Project On Government Oversight is dedicated to achieving a more effective, accountable, open, and ethical federal government. In articles and in communications with you and your predecessor as DHHS Secretary during the past 20 months, we have expressed concern about the lack of transparency in the pandemic flu vaccine program and about the risk that defects in the program, undisclosed and thus uncorrected, might lead to vaccine shortages in a pandemic. We regret that DHHS failed to act on our concerns.

We now see a way in which prompt action by DHHS might benefit the country. In particular, we are writing about an unusual opportunity – a possible way to prevent many of the deaths caused by H1N1 influenza. It is an opportunity to establish whether these deaths can be prevented by treatment with a statin.

A clinical trial to examine the statin treatment of influenza has been authorized by the FDA and has already begun. However, many months may elapse before this trial can provide an answer. The long delay is caused by a lack of funding, but this problem can be overcome quickly. By exercising your unusual powers in the current public health emergency, you could speed up the pace of the trial by authorizing funds for the trial.

## Background

For several years scientists have speculated about the possibility that ordinary statins (like Lipitor, Crestor, Zocor, Pravastatin) may protect those who are the sickest with flu.

The possible use of statins in preventing deaths from H1N1 has just received support from a retrospective study whose results were announced (October 29) at a meeting in Philadelphia and reported in the press. By examining hospital charts of patients hospitalized with seasonal flu, researchers were able to learn which of those patients had been taking statins. The study showed that those on statins were *half* as likely to die.

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Were the statins responsible for cutting the death rate in half, or is there some other explanation? Only a direct (prospective) test of statins in flu patients will provide an answer. But no such test has ever been done, namely, a clinical trial with incoming statin-free patients randomly assigned to be given a statin or a placebo.

Fortunately, such a trial has just begun – “STIP: Statin Trial for Influenza Patients,” led by Dr. Gordon R. Bernard of Vanderbilt University. However, only one patient has been enrolled thus far. Hundreds will probably be needed to provide a clear answer on the effectiveness of the statin treatment.

Funding is the problem. The amount needed to complete the STIP trial may be in the range of \$2-4 million. Dr. Bernard is reportedly being assisted by an enthusiastic group of volunteer doctors and other volunteer medical personnel. But this level of support falls far short of enabling the trial to continue at a reasonable speed. An application for funding through a research grant could be submitted to the NIH, but approval and funding would take many months.

The timing of the funding is crucial – the sooner the better. The best time to recruit patients for the trial is obviously before or near the height of the pandemic, when many seriously ill patients are eligible for enrollment.

If the final results of the STIP trial show that the death rate is lower in patients treated with the statin, then this treatment, which is inexpensive and readily available, could be used elsewhere. Among the sickest patients – those requiring treatment in an intensive care unit – the saving of life might be considerable. In a study of patients hospitalized with H1N1 flu published in October in the *New England Journal of Medicine*, 28% of those admitted to the hospitals’ ICUs died.

### **Emergency funding**

We urge you to enable funding of the STIP trial through your enhanced powers as Secretary in the current public health emergency. These powers include the support of research on the treatment of the disease that created the emergency.<sup>1</sup>

Experts acquainted with the pros and cons of using statins for H1N1 flu are in a position to judge the merits of the STIP trial.<sup>2</sup>

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<sup>1</sup> The HHS Secretary’s emergency powers are described in a document entitled “Legal authorities,” dated April 26, 2009, signed by Acting HHS Secretary Charles E. Johnson and posted at <http://www.homeland1.com/biosecurity/articles/484390-HHS-Pandemic-Influenza-Plan/>

<sup>2</sup> Among those who might be consulted on this point are Dr. Roy Brower, Professor of Medicine, Johns Hopkins Medical School; Dr. B. Taylor Thompson, Associate Professor of Medicine, Harvard Medical School; Dr. Rajeev Venkayya, Director of Global Health Delivery, Gates Foundation; Dr. Bruce Gellin, Director National Vaccine Planning Office, DHHS. Some of them are associated with the STIP trial.

If a trial of statins is conducted and completed soon, near the height of the pandemic, then the results, if positive, could immediately be put to good use in hospitals everywhere. For this reason we hope that you will arrange to have the STIP trial funded without delay.

We would be glad to meet with you or Dr. Lurie.

Sincerely,



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