

August 26, 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

Subject: Greater transparency in the flu vaccine program is urgently needed

Dear Secretary Sebelius:

We are writing again to request that you deal quickly with a pressing issue: ensuring full transparency in the government's program for producing H1N1 swine flu vaccine. While recognizing the demands of your time-consuming focus on health care legislation, we nonetheless believe that the need for greater transparency in the vaccine program is urgent enough to require your prompt attention.

Vaccine will almost certainly be in short supply during the next few months of the flu pandemic. You and other government leaders must soon deal with those who demand vaccine but are not eligible to get it. If, for reasons outlined below, the planned supply of vaccine is interrupted, the problem of unmet demand for vaccine will worsen, and it could become a crisis. For this reason, the possibility of a severe vaccine shortage should be faced now. You and other senior members of DHHS should, at the very least, discuss this possibility frankly and openly.

In our July 20 letter to you, with its accompanying Commentary,¹ we urged you to deal promptly with the current lack of full transparency in the flu vaccine program. Specifically, we asked that you direct DHHS employees to post a broad range of information about flu vaccine production, information that is otherwise difficult or impossible to obtain from online government sites. This includes information about:

- o Contracts as well as performance evaluations of contractors
- o Pursuit of alternative vaccines
- o Foreign sources of vaccines for domestic use in the U.S.

¹ <http://www.pogo.org/pogo-files/alerts/public-health/ph-pfv-20090720.html>
<http://www.pogo.org/pogo-files/letters/public-health/ph-pfv-20090720-1.html>
A copy of the letter and the Commentary ("Flu Vaccine Shortage? The Whole Truth, Please") are attached to this letter.

Over a year ago the Project On Government Oversight, concerned about the lack of transparency in the flu vaccine program, raised precisely these points (and others) in its report of March 2008, *Pandemic Flu: Lack of Leadership and Disclosure Plague Vaccine Program*.² A series of POGO documents – its report of March 2008, two follow-up documents³ in 2008, another⁴ in April 2009, and our Commentary and letter to you last month – cover many topics for which full disclosure is overdue. The then-Secretary of DHHS, Mike Leavitt, ignored our request to seek the very same goals – full transparency, full disclosure – that we are now urging on you. Whatever the reasons for his failure to act, a likely result is an impaired ability by DHHS to ensure that enough swine flu vaccine is available to the public during the current pandemic. The vaccine shortages that are likely in the next few months can be traced in part to the failures, past and present, to disclose details of the government’s planning for vaccine production. We urge you and your associates, with this in mind, to read our report of March 2008 and our Commentary of July 20, 2009.

The Associated Press, in a recent article entitled “Fight for swine flu vaccine could get ugly,” cited flu experts who expressed concern about international competition for limited supplies of vaccine and added:

Public health officials are aware that so-called "vaccine wars" might break out if the swine-flu outbreak worsens, but are loath to even discuss the topic.⁵

Loath to discuss the topic! These public health officials – the AP is presumably referring here to your own officials in DHHS – won’t talk with journalists, evidently because the facts will alarm the public, as indeed they may. We think that you should be concerned about these efforts within your agency to shield the public from an unpleasant truth. Disclosing the truth right now is better than doing so later, during a crisis, when a vaccine shortage and its causes will become impossible to conceal.

² Released on March 6, 2008, at <http://www.pogo.org/pogo-files/reports/public-health/pandemic-flu-vaccine-program/pandemic-flu-vaccine-program.html>

³ April 6, 2008. We sent a message on the need for full transparency to Secretary Leavitt through his online blog. There was no response.

See http://archive.hhs.gov/secretarysblog/my_weblog/2008/03/pandemic-exerci.html
<http://www.pogoarchives.org/m/ph/secretarysblog-20080320.pdf>

June 2, 2008, an article in *Federal Times*. We again called on Secretary Leavitt to take action, again without apparent effect. See <http://www.federaltimes.com/index.php?S=3555398>
<http://pogoarchives.org/m/science/flu-vaccine/panflu-federaltimes-20080601.pdf>

⁴ April 28, 2009, “Pandemic Flu Threat Raises Question: Is U.S. Ready to Protect the Public?” posted on POGO’s website at

<http://www.pogo.org/pogo-files/alerts/public-health/ph-pfv-20090428.html>

⁵ The AP story by Maria Cheng was posted on July 16, 2009, at http://www.mercurynews.com/nationworld/ci_12850495 as well as on many other sites. Most of these printed “loathe” instead of “loath” as above.

The U.S. public may be the loser in a “vaccine war” if the government’s current optimistic plans for importing most of its vaccine fall apart. Michael Osterholm is one of the U.S.’s best-known non-governmental public health experts on pandemic influenza. According to the AP article, Osterholm said that about 80 percent of the United States’ pandemic vaccine supply will be coming from abroad. He added:

If there is severe disease, countries will want to hang onto the vaccine for their own citizens. . . . It’s easy to move vaccine around if the disease is relatively mild. But if it is more severe, countries may not be willing to let it go.

It’s a gamble. If swine flu remains a disease no more severe than the usual seasonal flu (about 30 or 40 thousand deaths per year in the U.S.), the federal government may be able to obtain the vaccine it needs – most of it from foreign suppliers. In that case, the DHHS may get away with its current policy of selective disclosure. But what if death rates go up, and the shipment of promised vaccine from abroad is blocked by foreign governments? Our government’s failure to level with the public by disclosing and explaining this possibility *in advance* will not quickly be forgiven or forgotten by a public already mistrustful of government pronouncements. Government leadership will be weakened in a time of crisis, when it’s most needed.


Even if this country weathers the storm during the swine flu pandemic, other epidemics undoubtedly lie ahead. In the SARS outbreak of 2002-2003, about 10% of those infected died; in human cases of H5N1 avian flu, about half of those infected during the past few years have died. This country, as well as the rest of the world, needs to be ready for outbreaks of viral infections that are both highly contagious and deadly. This will require the capacity for quick, large-scale manufacture of vaccines against newly emerging viruses.

The government’s planning for flu vaccine production in a pandemic was flawed, and the public will soon suffer the consequences, which could be either minor or severe, depending on unpredictable events beyond anyone’s control. The shortcomings of plans made by the government in the past should be displayed, not hidden, so that the same mistakes won’t be repeated. In addition, it is not too late to correct or ameliorate some of the current problems in vaccine production.

We hope that you agree with us on the urgent need for full transparency in the swine flu vaccine program.

We propose a meeting with you and your associates to discuss this important issue.

Sincerely,



Danielle Brian

Executive Director

Project On Government Oversight



Ned Feder, M.D.

Staff Scientist

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Attachments:

Letter of July 20 from Danielle Brian to Secretary Sebelius

Commentary of July 20 by Ned Feder

Project On Government Oversight

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July 20, 2009

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

Subject: Production of vaccine for H1N1 swine flu. Needed: greater transparency

Dear Secretary Sebelius:

The Project On Government Oversight, an independent, nonprofit organization, recognizes that your office must deal with the host of problems created by the H1N1 swine flu pandemic. Among these problems is the likelihood that adequate amounts of vaccine will not be ready in time – partly as a result of misjudgments and mistakes made in the past. A failure to disclose and examine these mistakes publicly – in other words, a lack of transparency – will almost certainly contribute to the shortage of vaccine in the months ahead.

The lack of transparency in the government's vaccine program is the subject of the attached Commentary by POGO's staff scientist. That Commentary is being posted today on POGO's website at <http://www.pogo.org/pogo-files/alerts/public-health/ph-pfv-20090720.html>. The Commentary gives three examples of a lack of transparency that ought to be corrected and also cites a March 2008 report by POGO for additional examples. As Executive Director of POGO, I am writing to call your attention to this Commentary and its recommendations.

POGO urges you to ensure full transparency in the government's flu vaccine program – public disclosure of all significant information except for that required by law to be kept confidential.

As Secretary of HHS, you alone have the power to make sure that not only the strengths, but the weaknesses of the present program for producing vaccine are made public. If you exercise this power, the weaknesses will be open to examination and criticism – and thus to correction or improvement. Unlike most other ways to speed up the manufacture of flu vaccine, a directive to ensure full transparency can be implemented quickly and at very low cost.

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I urge you to take this step. I would welcome meeting with you and your associates to discuss this important issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Danielle Brian". The signature is fluid and cursive, with the first name "Danielle" written in a larger, more prominent script than the last name "Brian".

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Attachment: Commentary of July 20 by Ned Feder, M.D., POGO Staff Scientist

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Flu Vaccine Shortage? The Whole Truth, Please.



July 20, 2009

Commentary

By Ned Feder, M.D., POGO Staff Scientist

As the H1N1 swine flu pandemic spreads, Americans who are counting on swine flu vaccine this fall are likely to be disappointed. President Obama recently said, according to the *New York Times*, that it is "our fervent hope" that, with good planning, a crisis can be averted.

¹ *The Times* also notes: "Vaccinations will begin in October only if tests scheduled to begin in August prove that it is safe and effective. Even then, officials expect only tens of millions of doses to be ready, so they will have to decide who gets vaccinated first."

Secretary of Health and Human Services Kathleen Sebelius should deal openly with flaws in the government's plans for manufacturing the swine flu vaccine. By disclosing the flaws, she will make it more likely they can be overcome. Danielle Brian, Executive Director of the Project On Government Oversight, wrote Secretary Sebelius today asking her to take action: "POGO urges you to ensure full transparency in the government's flu vaccine program – public disclosure of all significant information except for that required by law to be kept confidential." ²

The methods of manufacturing vaccine have improved steadily in recent years, thanks in large part to the initiatives and funding of the U.S. government. The current status of vaccine production is described on a government website, www.pandemicflu.gov.

Missing from www.pandemicflu.gov is the dark side of the government's vaccine program – an account of the lost opportunities, needless delays, insufficient funding, outright blunders, and other shortcomings that could contribute to a scarcity of vaccine in the months ahead. Many of the shortcomings are known to government scientists and administrators, but not to the public.

If the shortcomings had been disclosed quickly, they might have been corrected. In that case, the goal of producing large amounts of vaccine within a month or two of a pandemic outbreak instead of six months or more, as is now the case, might be closer to realization.

In the past, private organizations – the Infectious Diseases Society of America and the Trust for America's Health, among others – have exposed weaknesses in the vaccine program and pressed for improvements, often with success.³ Nonetheless, government leaders should themselves take the initiative in disclosing weaknesses. This will happen only if Secretary Sebelius decides that the benefits of full transparency outweigh the downside of disclosures that may prove embarrassing.

In this Commentary, the Project On Government Oversight (POGO) calls for full transparency

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in the government's vaccine program. We give here three examples of a lack of transparency that ought to be corrected and refer the reader to a [March 2008 report by POGO](#) for additional examples. [4](#)

A policy of full transparency in the vaccine program, if applied to contracts and to the performance of contractors, would expose flaws to the gaze of critics. Questionable judgment in the funding of novel, alternative vaccines would be dragged out of closed government offices into the light of day.

And decisions on vaccine from foreign sources, whether or not those decisions are sound, would at least be made openly. Of the three examples discussed here, the most surprising is the failure by the federal government to explain why this country may be dependent on foreign suppliers of vaccine – suppliers who may be unwilling or unable to provide the U.S. with the vaccine it needs.

Contracts

The public would benefit if specific information about contracts – and especially about contractors' performance – were made readily available for examination by interested parties outside of government. Since May 2006, the Department of Health and Human Services has awarded contracts totaling more than \$1 billion for the development and production of pandemic flu vaccines.

A determined person, by using the Freedom of Information Act (FOIA) and other means, can eventually discover the details of the contracts and perhaps learn, with difficulty, about the performance of the contractors. However, non-government experts who might have useful criticisms may not want to spend their time battling the federal bureaucracy in order to gather this kind of information.

The major contracts for vaccine production, without exception, should be posted online. There are precedents for the posting of contracts online soon after they are signed, without any requirement for a FOIA request. The U.S. Agency for International Development (USAID), for example, posts some of its contracts online.[5](#)

In addition to the contracts themselves, follow-up information should be posted, namely, the progress reports and evaluations of contractors' performance, updated periodically. Those writing the progress reports and performance evaluations should be identified, and their affiliations and possible conflicts of interest should be disclosed. If bonuses are awarded to manufacturers or contract changes are authorized, they should be disclosed promptly and explained.

Over the years there have been innumerable instances of government contracts that were poorly written or poorly enforced. Outright fraud in the vaccine program seems unlikely, but carelessness, overwork, and inadequate oversight can also result in contracts and contractor performance that fail to serve the public interest. The ready availability of contract information online would almost certainly strengthen the performance of manufacturers and improve the chances of faster production of effective vaccines.

Delays in pursuing alternative vaccines

More than five years ago, experts inside and outside government recognized the value of a particular kind of vaccine – so-called recombinant vaccine – in a pandemic. On June 23, 2009, Secretary Sebelius announced a contract with Protein Sciences Corporation for the development and manufacture of a recombinant flu vaccine.[6](#) The methods covered by the contract are particularly promising, for several reasons: the speed of vaccine production, the

relative ease of increasing the scale of production, and the potency and safety of the vaccine.

The government's contract with Protein Sciences ought to have been concluded much earlier – as much as two years or more earlier – thus markedly advancing the timetable for the production of this kind of vaccine. The apparent lack of a sense of urgency for this particular approach to vaccine production is unfortunate.

The delays were not explained publicly while they were occurring, but they should be explained now. This includes an explanation of the belated decision (in October 2007, rather than a year or two earlier) to solicit contract proposals (RFPs) for recombinant vaccines, as well as delays in the subsequent steps that finally led to the contract award.⁷

Similar questions about needless delays apply to other decisions – for example, those related to contracts for production of live attenuated vaccines as well as contracts for the testing of potency-enhancing additives (adjuvants). The government's decisions on the timing and size of these contracts should have been explained online. Dissenting views, if any, should also have been posted.

If there had been greater transparency, the government might now be closer to the goal of starting to produce flu vaccine for general use within a month or two after the onset of a pandemic. It is now worthwhile to disclose and examine the past mistakes in order to improve current plans for vaccine production. An online discussion of the pros and cons of producing large amounts of egg-based live attenuated vaccine (which could be made in a U.S. facility now in operation ⁸) should be posted promptly. Also, the role of patent rights and costs in the government's decisions on the testing and use of adjuvants should be explained online, along with the possibility of compulsory licensing of patents during the pandemic.

Domestic production of vaccine versus foreign sources of vaccine

The U.S. government is gambling that pandemic vaccine and vaccine components will be available from foreign sources. The gamble will probably succeed if the severity of the present pandemic remains at its present level, which resembles that of ordinary seasonal flu. But if the virus mutates into a more virulent strain and death rates rise significantly, foreign governments are likely to shut off exports of vaccine and vaccine components so that they can use their limited supplies to protect their own populations.

John Barry, an authority on the history of pandemic flu, recently commented in the *Washington Post* on the amount of vaccine available for the entire U.S. population. He wrote that "only about 30 percent of the supply will be made in the United States. The more virulent the virus, the more likely it is that foreign governments will refuse to allow export of the vaccine until their own populations are fully protected."⁹

As far as we know, this crucial *quantitative* estimate – 30 percent! – published in the *Washington Post* has not been posted on www.pandemicflu.gov, nor does the website contain any other quantitative estimate of the domestic supply of pandemic vaccine.

How much pandemic flu vaccine will be available in the U.S., both in the near term (the next four to eight months) and in the next year or two? A detailed answer to this question, including the two contingencies noted above (i.e., with and without foreign sources of vaccine included), should be posted online, and the information should be kept up to date. We are not commenting here on the wisdom of the initial decision, which was based on the premise that vaccine would continue to be available from foreign sources during a pandemic. Instead, we are saying that the facts and reasoning underlying that decision were not available on www.pandemicflu.gov. These should now be posted. Related issues ¹⁰ should also be discussed.

Furthermore, the U.S., among all countries, has made the largest monetary contribution to global efforts to prepare for a pandemic. The worldwide role of the U.S. in a pandemic should be described in greater detail online. The U.S. can contribute to world health by speeding up the timetable for flu vaccine availability around the world, a possibility that should be discussed online in much greater detail than at present.

There are other examples of facts and documents that we believe the government should make public. These are described in the POGO report of March 2008, *Pandemic Flu: Lack of Leadership and Disclosure Plague Vaccine Program*.

The operation and plans of the vaccine program should be described publicly in ways that do not obscure their uncertainties and shortcomings. Members of the public, experts on vaccine production, and journalists, as well as Members of Congress and advisors to the President deserve to have easy access to the facts. Senior government officials, both elected and appointed, must balance the need for protecting public health against the need to curb excessive costs. They should have all the relevant information readily at hand, whether that information is reassuring or troubling.

The present lack of full transparency in the vaccine program can be corrected easily. Secretary Sebelius should direct officials in the program to disclose information that is now being withheld. If information is made public as recommended in the present article and in our report of March 2008, some of the disclosures may reflect poorly on parts of the vaccine program.¹¹ For this reason, the person responsible for pursuing full transparency should be a senior official chosen for his or her independence and appointed by Secretary Sebelius herself. This person should report directly to the Secretary.

The federal government's preparations for pandemic flu are generally sound. Even so, it is likely that during the next year there won't be enough vaccine. Greater transparency in the vaccine program will make its shortcomings more apparent and also point the way to fixing them.

1 Donald G. McNeil Jr., "Obama Warns of Swine Flu Resurgence in Fall." *The New York Times*, July 9, 2009. <http://www.nytimes.com/2009/07/10/health/10flu.html>

2 The letter to Secretary Sebelius is posted on POGO's website at <http://pogoarchives.org/m/ph/pogo-letter-20090720.pdf>

3 "Experts Warn Nation's Pandemic Flu Preparedness Not Keeping Pace with Advancements in Science and Technology." News release by Trust for America's Health and Infectious Diseases Society of America. October 4, 2006. <http://www.idsociety.org/Content.aspx?id=3728>

4 On March 6, 2008, POGO issued a report on the need for greater transparency in the flu vaccine program at <http://www.pogo.org/pogo-files/reports/public-health/pandemic-flu-vaccine-program/pandemic-flu-vaccine-program.html> In the report, *Pandemic Flu: Lack of Leadership and Disclosure Plague Vaccine Program*, there were eight categories of information or documents for which we urged disclosure: government contracts for vaccine production, manufacturing capacity, domestic dependence on foreign production, material transfer agreements, intellectual property (patent rights, trade secrets, and know-how), foreign governments and the World Health Organization, alternatives to current vaccines, and size of budget.

We followed up with an online note of April 6, 2008, to Secretary Mike Leavitt, who ignored

our request for greater transparency. See http://archive.hhs.gov/secretarysblog/my_weblog/2008/03/pandemic-exerci.html ; <http://www.pogoarchives.org/m/ph/secretarysblog-20080320.pdf>

In the *Federal Times* of June 2, 2008, we again called on Secretary Leavitt to take action, again without apparent effect. See <http://www.federaltimes.com/index.php?S=3555398>; <http://pogoarchives.org/m/science/flu-vaccine/panflu-federaltimes-20080601.pdf>

5 USAID. "Assistance for Iraq: Contracts and Grants." www.usaid.gov/iraq/contracts/errsgi.html

6 "HHS Announces Advanced Development Contract for New Way to Make Flu Vaccine." News Release from HHS Press Office, June 23, 2009. <http://www.hhs.gov/news/press/2009pres/06/20090623c.html>

7 The delays were caused in part by unresolved legal issues between Protein Sciences and another biotech company, Emergent Biosolutions, Inc. The contract was finally awarded in part because of the good judgment and efforts of the director of the Biomedical Advanced Research and Development Authority (BARDA, a unit in DHHS). These issues were not explained on <http://www.pandemicflu.gov>, but they were discussed in the press. See Michael Bathon, "Protein Sciences, Vaccine Maker, Forced to Bankruptcy (Update1)," *Bloomberg.com*, June 22, 2009; Tom Hals and Santosh Nadgir, "Update 2-Creditors seek bankruptcy for H1N1 vaccine maker," *Reuters*, June 23, 2009; Vandana Sinha, "Contract aware may end dispute with EBS," *Washington Business Journal*, June 24, 2009; Andrew Pollack, "Vaccine Maker Facing Possible Bankruptcy Wins Contract," *New York Times*, June 23, 2009.

From the outset, a public airing of these problems, which included the government's auditing of Protein Sciences, would probably have led to a faster resolution and awarding of a contract. The activities of the vaccine program should be fully transparent unless there are legal constraints that prevent specific disclosures.

8 Bulk vaccine can be produced at an existing facility in Swiftwater, Pa. See "Sanofi Pasteur Receives Order from U.S. Government to Produce New Influenza A(H1N1) Vaccine." Press release, May 25, 2009. http://www.sanofipasteur.com/sanofi-pasteur2/sp-media/SP_CORP/EN/54/759/FLU%20A%20H1N1%20US%20ORDER%20ENG%20250509.pdf?siteCode=SP_CORP

9 John M. Barry, "Pandemic Reality Check: What Can Be Done – and What Can't – To Protect Against H1N1." *The Washington Post*, June 23, 2009. <http://www.washingtonpost.com/wp-dyn/content/article/2009/06/22/AR2009062202386.html>

10 The U.S.'s first cell-based flu vaccine manufacturing plant is now being built under contract in North Carolina by Novartis. The plant may be ready in 2010 or 2011 (news release from HHS press office, January 15, 2009, <http://www.hhs.gov/news/press/2009pres/01/20090115b.html>). The news release does not mention that Novartis already has a cell-based vaccine facility in Marburg, Germany. This plant, supported in part by contracts with the U.S. government, has just produced its first ten-liter batch of vaccine. ("Novartis successfully demonstrates capabilities of cell-based technology for production of A(H1N1) vaccine." Media release from Novartis, June 12, 2009. <http://www.novartis.com/newsroom/media-releases/en/2009/1322241.shtml> and "Novartis produces first batch of swine flu vaccine" By the Associated Press in *torontosun.com*, June 12, 2009. <http://www.torontosun.com/news/world/2009/06/12/9776301.html> (accessed July 17, 2009).

There is doubtless an explanation as to why the U.S. facility has not even been built, while the European facility is already producing vaccine. The explanation should be posted online. 11 We consider many of the current leaders of the vaccine program to be experienced, dedicated scientists and good administrators. Indeed, a requirement for full transparency may come as a relief to some of them. However, as we wrote in our report in March 2008: "The magnitude of the threat to the nation calls for a person of near-cabinet-level stature to lead the vaccine program, a person who commands respect in the business and public health communities – someone willing to blast through financial and bureaucratic roadblocks. But no such person has been appointed." We call on the Obama administration to recruit someone of the right caliber willing to lead the vaccine program. At this late date, this may be difficult.

Founded in 1981, the Project On Government Oversight (POGO) is an independent nonprofit that investigates and exposes corruption and other misconduct in order to achieve a more effective, accountable, open, and ethical federal government.

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