



**House Committee on Energy & Commerce  
Joint Hearing on H1N1 Preparedness: An Overview of Vaccine  
Production and Distribution  
Testimony of Jeffrey Levi, PhD  
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Chairmen Stupak and Pallone, Ranking Members Walden and Deal, and members of the subcommittees: Thank you for the opportunity to speak with you today on issues related to the preparation and response to the 2009 H1N1 novel influenza A pandemic. I am here on behalf of Trust for America's Health (TFAH), a nonprofit, nonpartisan advocacy organization dedicated to saving lives by making disease prevention a national priority. For the past five years, TFAH has advocated for increased investments in preparedness and response to a potential influenza pandemic. We have published numerous reports focused on these issues, including two related to the current H1N1 pandemic.

While I understand that today's hearing is a result of considerable frustration with the current H1N1 vaccination program, I want to emphasize four critical points:

- The public health system at all levels of government has moved with remarkable speed in getting vaccines to as many Americans as supply has permitted. We have moved as fast as or faster than any other country in the world. The United Kingdom, for example, just began its vaccination campaign in late October -- even though there is more vaccine production capacity in the U.K. than in the U.S. Similarly, the French vaccination campaign did not begin until last week
- The vaccine is well matched to the circulating virus. It is proven to be safe and effective in clinical trials. The H1N1 vaccine offers the best protection against the disease available to the American public.
- Whatever our concerns with production capacity are today, had the federal government not made the multi-billion dollar investment in enhanced vaccine production capacity since 2005, we would be in far worse shape. The limits on supply we are experiencing today are the limits imposed by the science and technology. We are depending on an inherently unpredictable technology and we are, unfortunately, still a few years away from U.S. approval of newer, more reliable technology.
- The federal government has been remarkably transparent with the American people about this pandemic since it began last spring. The federal effort appears to be well coordinated with all cabinet and subcabinet officials working from the same playbook. Public health officials have leveled with the American people -- making appropriate adjustments in recommendations as our understanding of the

nature of the pandemic has evolved. The same has held true as supply issues have arisen. While I cannot speak to when senior Administration officials should have known about serious supply problems, when they did become aware of them, they adjusted policy and messaging appropriately. This has led to some understandable confusion among the public, but it has reflected an honest attempt to reflect the current state of knowledge.

### **Current production capacity reflects the pay-off of a multi-year investment.**

While there is understandable dissatisfaction with the current vaccine production levels, it is important to note that if this pandemic had hit in 2005, getting a vaccine to the American public within six months would likely have been nearly impossible. In 2005, only two manufacturers were licensed to produce influenza vaccine in the U.S.<sup>1</sup> The Department of Health and Human Services' (HHS) Pandemic Preparedness Plan, issued in November 2005, called for increasing domestic pandemic vaccine manufacturing capacity to inoculate 300 million persons within six months of the onset of an outbreak.<sup>2</sup> Government officials estimated that this capacity would take approximately five years to ramp up. According to a 2008 Congressional Budget Office (CBO) analysis, the maximum capacity for a 2006-2007 pandemic flu vaccine would have been 120 million doses (of which 50 million would have been produced domestically).<sup>3</sup>

Today, the Centers for Disease Control and Prevention (CDC) and HHS estimate there will be enough vaccine for every American, between domestic and foreign production. The near-term availability of sufficient pandemic vaccine, albeit slower than hoped for initially, is due to an investment that began in FY 2006, when Congress approved \$3.2 billion for advanced development, infrastructure building, and purchase of vaccines.<sup>4</sup> The federal government invested in retrofitting and expanding capacity in vaccine manufacturers that had domestic production facilities -- MedImmune and sanofi Pasteur - - and ensuring a year-round supply of eggs.<sup>5</sup> HHS also developed contracts with foreign-based facilities to develop vaccine for the U.S. market. By mid-September 2009, the U.S. Food and Drug Administration (FDA) had approved four companies to produce H1N1 vaccine for the U.S.,<sup>6</sup> earlier than any European country, and a fifth, GlaxoSmithKline, was licensed by the FDA last week. Six companies have also received advance development contracts for building U.S. cell-based vaccine production facilities, and the

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<sup>1</sup> *A Killer Flu?* Trust for America's Health, June 2006. p. 10. Available from: <http://healthyamericans.org/reports/flu/Flu2005.pdf>

<sup>2</sup> BARDA Influenza and Emerging Disease Program. Available from: <https://www.medicalcountermeasures.gov/BARDA/MCM/panflu/panflu.aspx>.

<sup>3</sup> Congressional Budget Office, U.S. Policy Regarding Pandemic-Influenza Vaccines, Sept. 2008. Available from: <http://www.cbo.gov/ftpdocs/95xx/doc9573/Frontmatter.1.2.shtml>.

<sup>4</sup> DHHS, Report to Congress: Pandemic Influenza Preparedness Spending, January 2009. Available from: <https://www.medicalcountermeasures.gov/BARDA/documents/hhspanflu-spending-0901.pdf>

<sup>5</sup> CBO, 2008.

<sup>6</sup> U.S. FDA, "Influenza A (H1N1) 2009 Monovalent." Available from: <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181950.htm>.

most successful companies should receive additional contracts to bring production online.<sup>7</sup>

**New technologies for vaccine production are not yet FDA-approved. Use of technologies that might be perceived as “experimental” could undermine public confidence in a pandemic vaccine.**

There has been some debate about whether the United States could have used emergency authorities held by the FDA to permit different vaccine technologies to be used during this pandemic campaign so as to speed production and/or increase the amount of vaccine available. To date, the FDA has not approved cell-based vaccines, a technology whose development the U.S. government is supporting and is the basis for production of some pandemic (and seasonal) vaccine in Europe. Cell-based vaccine is more stable and allows for a faster production process. Similarly, some countries are using vaccine that contains an adjuvant -- a chemical additive that permits use of smaller doses of the actual vaccine thus dramatically extending the supply. While swift assessment of these technologies by U.S. officials is certainly called for, use of these technologies during the current pandemic would have been unwise. Given the very high level of skepticism in the U.S. (and around the world) about vaccines in general and some of the concerns about the pandemic vaccine in particular, it has been critical for federal officials to reassure the public that this is the very same vaccine manufacturing process that hundreds of millions of Americans have taken safely to protect themselves against seasonal flu. Clinical trials for this pandemic vaccine were thorough and efficient, providing additional reassurance to the American people. Approval of cell-based vaccines against a novel influenza virus, when not currently approved for the seasonal virus, would have been considered experimental by many Americans. There may have been a misperception that the vaccine had not gone through the usual rigorous FDA approval process. This would have complicated efforts to encourage all Americans, especially those at highest risk, to receive a vaccination against the H1N1 virus.

With respect to the use of adjuvanted vaccine, which is currently not approved by the FDA for seasonal or pandemic flu, those nations using it have found it to be controversial due to public perceptions. In Germany, for example, there have been protests because government officials were given a non-adjuvanted vaccine, while the public is receiving an adjuvanted vaccine. Some German professional medical societies are now recommending against the use of an adjuvanted vaccine for anyone.

**The government has moved as rapidly as possible to move vaccine from production lines to vaccine clinics. Using a centralized distribution system has assured equitable geographic distribution of a limited supply.**

As vaccine supplies have become available, the federal government has assured that vaccines have moved as quickly as possible to local vaccination sites. The government could have waited until a sufficient amount of vaccine was on hand before beginning to distribute it to immunization sites. This *may* have reduced some of the confusion we

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<sup>7</sup> CBO, 2008.

have experienced as delivery expectations were repeatedly revised downward. But this would have resulted in delaying the protection of millions who are at risk.

The policy decision that the federal government should be the central purchaser and distributor of vaccine was wise from public health and ethical standpoints. Centralization has permitted the federal government to control the flow of the limited supply. Every state is receiving vaccine on a per capita basis, rather than based on private ordering, state budgets, population demographics, or political decision-making. An influenza outbreak does not acknowledge or respect state borders, and no American should be less protected based on where he/she lives. If the federal government had depended on a private distribution system, as the previous Administration had suggested, we likely would have seen a repeat of the 2004-2005 seasonal flu vaccine shortage scenario -- wherein some providers would have sufficient vaccine, while others would have little or none, depending entirely on which vaccine manufacturer had been contracted with to supply vaccine. Although all states are temporarily experiencing shortages, all states are suffering shortfalls equally. The situation is not always as clear on the local level, where distribution within states appears uneven in some cases.

This is not to say that there have not been glitches in this new, untested, centralized system. But as best TFAH can determine, federal health officials have moved as rapidly as possible to address the problems.

**Supply shortages, the recession, and a decentralized approach to administration of vaccines in each local community contributed to varying capacity at the local level and confusion among the public.**

While the federal government has assumed centralized responsibility for vaccine distribution to state and local health departments, each locality is then responsible for developing its own policies and systems for administration of vaccine as it becomes available. This has posed a number of important challenges, particularly in a context of changing messaging resulting from shortages of both seasonal and H1N1 vaccines:

- First, local officials received constantly shifting information about how much vaccine would be available and when. This makes setting parameters for vaccine administration very difficult. It is nearly impossible to know why the communications breakdown between federal officials and industry occurred with regard to the pace of production. But this is clearly an issue that has not only created confusion among the American people; it has also made the job of local health officials far more difficult in an already challenging situation.
- Second, the largest mass vaccination campaign in U.S. history is taking place during an economic recession and when state and local health departments are experiencing devastating losses. According to a survey by National Association of County and City Health Officials (NACCHO), 15,000 positions have been lost in local health departments since the beginning of 2008. While the federal government has rapidly pumped almost \$1.5 billion to state and local health departments for pandemic response, this does not address the underlying decline

in the core capacity of health departments. We are seeing the result of decades of under-investment in public health capacity. It cannot be rebuilt on an emergency basis.

- Third, public confusion may well have been exacerbated by the fact that each state and locality has determined how to distribute its supply once received from the federal government. While all jurisdictions have kept to the general prioritization of certain populations, they have often acted differently in terms of which individuals within the prioritized grouping would get vaccine first. This may well have been due to how supply was ordered by the states and/or distributed within the states. For example, some localities have prioritized health care workers, some have prioritized the vaccination of children, and still others have made pregnant women a top priority. Population demographics differ from state-to-state, so it is sensible to allow some flexibility between locales (for example, if the pandemic had targeted seniors, Arizona and Florida may have very different distribution plans than other states). However, the wide variation in distribution methodologies has created a fair amount of confusion among the public. Although each health department based their plans on a larger supply of vaccines, HHS may want to revisit this issue and consider some standardization in future emergencies since it is not unreasonable for the American people to expect some level of consistency in approach. Otherwise, they may think that the target population hierarchies articulated by the federal government are not science-based.

#### **Near-term and long-term next steps:**

It is our hope that this hearing will contribute to the public's understanding of the complexities of the current pandemic influenza vaccine campaign. Among the key initiatives TFAH maintains are critical to the success of the response to this and future pandemics are:

- An education campaign is needed to assure the American people about the safety and effectiveness of this (and other) influenza vaccines and all vaccines in general. It is important to remind Americans that even with the delays in vaccine availability, they should get vaccinated as soon as they can. It is not clear that the pandemic has peaked, and even if it has, many who might yet get sick are still at risk and could be protected by a vaccine. Moreover, historically there is always the danger of a third pandemic wave, which may or may not be more severe than the previous two waves. So being vaccinated now will be critical protection for those who have not become ill during the initial waves.
- FDA should move forward in assessing new technologies that are already in use in influenza vaccines in other countries -- including use of adjuvants and cell-based vaccines. If data from other countries do not meet FDA's standards, FDA should work closely with industry and the National Institutes of Health (NIH) to collect the data needed for decision making.
- Congress and the Administration should come to a consensus on what is an appropriate level of investment in new technologies. This pandemic has

demonstrated that the nation still has a long way to go, not just in vaccine technology, but with regard to diagnostics and antiviral treatments as well as personal protection equipment for those exposed to influenza in the workplace. The Biological Advanced Research and Development Agency (BARDA) has been chronically underfunded since its inception. Its support is critical to moving promising developmental technologies into mass production. Professional estimates suggest BARDA needs an annual appropriation of \$1.7 billion, rather than the current \$275 million, to achieve its mission.

- We need to provide ongoing support to state and local health departments in building capacity to respond to pandemics and other public health emergencies. As discussed previously, this emergency has occurred at a time of state and local level budget crises, with associated reductions in the public health workforce. Federal support for preparedness has been inconsistent at best. Until the emergency funds provided this summer to state and local health departments, no funds for pandemic preparedness had been appropriated since FY 2006. Underlying preparedness funding has been declining over the last several years as well, down 27 percent since FY 2005 in inflation adjusted dollars. Congress must assure a consistent level of preparedness capacity at state and local health departments on an ongoing basis. Just as we don't fund fire departments at the moment a fire breaks out, we must move away from the emergency funding mechanisms to respond to public health emergencies. This is one reason TFAH supports the mandatory funding for core public health functions that is part of the House health reform bill.
- Congress and the Administration must also address several other critical aspects of pandemic response capacity. These include:
  - Replenishment of the Strategic National Stockpile (SNS) for supplies that have been distributed to the states. This includes N-95 respirators, surgical masks, and antivirals. To our knowledge, to date only the depleted supply of pediatric formulation of Tamiflu has been ordered for restocking. We do not know what demand a future wave of this pandemic strain will require of the SNS; nor can we forget the potential for other pandemic strains emerging -- such as the H5N1 bird flu that was of primary concern until last spring.
  - Heretofore, most health system preparedness funding has been focused on a hospital-based response, whereas in this pandemic, we have seen significant overload in the ambulatory care system. We need to examine the impact this pandemic has had on hospital and ambulatory care systems and reassess whether our preparedness plans have provided an appropriate level of support to *all* aspects of the health care system.

## **Conclusion**

The 2009 H1N1 influenza pandemic has both shown our government at its best and highlighted many of the ongoing weaknesses in our public health system. As we continue to ramp up our response to this pandemic -- and provide the protection the American people rightfully expect their government to make available -- we must also

take the steps necessary to assure that when the next public health crisis occurs, a stronger system is in place and capable of responding quickly, effectively, and nimbly.