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REFLECTIONS ON PREPAREDNESS: PANDEMIC PLANNING IN THE BUSH ADMINISTRATION

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I. INTRODUCTION

It may seem hard to believe today, but there was a time when pandemic influenza was not a subject of much interest anywhere outside of public health agencies like the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). Indeed, the whole history of influenza preparedness can be summarized as decades of inactivity followed by months of anxiety and years of second-guessing. If the recent criticism of the World Health Organization (WHO) is any indication, H1N1 seems to be following this pattern.¹ It is almost as if Santayana had influenza in mind when he observed that “[t]hose who cannot remember the past are condemned to repeat it.”² And influenza has quite a past.³ The 1918 pandemic was the most lethal plague in human history—killing between fifty million and one hundred million people worldwide in a matter of months.⁴ If we are to avoid this magnitude of devastation from occurring again, we must learn from our experience with influenza. My analysis of the facts and my experience working on pandemic preparedness has taught me the following lessons:

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1. See Robert Roos, *Who Says H1N1 Pandemic is Over*, U. OF MINN. CTR. FOR INFECTIOUS DISEASE RESEARCH & POL’Y, Aug. 10, 2010, <http://www.cidrap.umn.edu/cidrap/content/influenza/swineflu/news/aug1010who.html> (summarizing WHO’s response to H1N1 and its defense against critics who have accused the agency of “exaggerating the pandemic threat”). In the case of H1N1, decades of inactivity were punctuated by roughly six years of concerted effort (including funding) to prepare for a pandemic.

2. GEORGE SANTAYANA, *REASON IN COMMON SENSE*, 284 (Dover Publ’ns, Inc. 1980).

3. See generally David M. Morens et al., *Pandemic Influenza’s 500th Anniversary*, 51 *CLINICAL INFECTIOUS DISEASES* 1442 (2010) (summarizing the history of pandemic influenza).

4. Jeffery K. Taubenberger & David M. Morens, *1918 Influenza: The Mother of All Pandemics*, 12 *EMERGING INFECTIOUS DISEASES* 15, 15 (2006).

- Serious and sustained pandemic preparedness can trace its roots to 2003/2004 at the earliest—one might argue 1997, since that is when H5N1 emerged in Hong Kong,⁵ but the attention to influenza following the first H5N1 outbreak was relatively short-lived.
- Pandemic preparedness has not been a part of the national dialogue long enough to be securely imbedded in the policymaking process—this means it is highly vulnerable to shrinking budgets and shifting priorities.⁶
- Global influenza surveillance is at the very heart of our national security and must be funded accordingly. If effective countermeasures, especially vaccines, are to be developed and distributed in time to save lives and prevent the type of chaos that was commonplace during the 1918 outbreak, a newly emerging pandemic strain must be identified as early as technically possible.
- Better vaccines, antiviral drugs, and diagnostics need to be discovered and licensed. This means consistently and aggressively funding the NIH and CDC influenza programs.⁷ A 1918-like pandemic cannot be contained or even modulated with a campaign vaccine⁸ or the current generation of antiviral drugs and diagnostics.⁹

5. Carolyn Buxton Bridges et al., *Risk of Influenza A (H5N1) Infection among Health Care Workers Exposed to Patients with Influenza A (H5N1)*, *Hong Kong*, 181 J. INFECTIOUS DISEASES 344, 344 (2000).

6. See Martin Matishak, *Former Senators Criticize Possible Cut to Bioshield Funds*, GLOBAL SECURITY NEWSWIRE, July 13, 2010, http://gsn.nti.org/gsn/nw_20100713_6726.php.

7. See *Flu (Influenza): 2009 H1N1, Seasonal, Avian (Bird), Pandemic*, NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES, <http://www.niaid.nih.gov/topics/flu/Pages/default.aspx> (last visited Nov. 17, 2010) (The NIH influenza programs include not only scientific research, but also public awareness information about understanding the flu.). *Flu (Influenza): NIAID Influenza Funding Opportunities*, NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES, <http://www.niaid.nih.gov/topics/Flu/Research/Pages/fundingOps.aspx> (last visited Nov. 17, 2010) (highlighting the funding opportunities available for influenza research); *Seasonal Influenza (Flu)*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/flu/> (last visited Nov. 17, 2010) (stressing that not only does the CDC influenza program offer research and information, but also provides flu surveillance and tracking).

8. By campaign vaccine, I mean a vaccine produced once per year (or season) according to specifications set for that year (or season). Each year (or season) requires a new vaccine with different specifications. In the case of influenza, the trivalent vaccine contains antigens effective against three influenza viruses that are judged by public health experts to be the viruses that will predominate that season. Influenza viruses rapidly mutate, so a vaccine effective one season must be modified to be effective the following season. The Influenza vaccine production process takes at least six months. There are two main types of influenza: influenza A and influenza B. Influenza A viruses are divided into subtypes identified by two surface proteins: hemagglutinin (H) and neuraminidase (N). There are sixteen hemagglutinin subtypes and nine neuraminidase subtypes. Influenza B viruses are not divided into subtypes.

- As an expression of self-interest, the U.S. and other developed countries need to provide substantial pandemic preparedness funding and technical expertise to the developing world, including assistance building disease surveillance systems, laboratory capacity, and vaccine production infrastructure.
- If we declare victory and move on after H1N1, we will be laying the foundation for a 1918-like catastrophe. H1N1 was not the event about which scientists and public health leaders have been warning—it was, at most, a dress rehearsal.

In the next few pages, I will outline a brief history of pandemic preparedness between 2001 and 2009. This period covers the development of today's pandemic preparedness and response plan in the United States, including building vaccine infrastructure, funding research and development, stockpiling vaccine and antiviral drugs, mobilizing international support, and establishing other elements of preparedness. While 1957, 1968, 1976/1977, and 1997 were all years of substantial influenza activity or anxiety,¹⁰ the flu has never had much luck capturing the attention of policymakers for any length of time and little from those years was integrated into a national pandemic preparedness plan. Indeed, it is probably not too much of an exaggeration to say that for most of the last fifty years or more, the flu has ranked just ahead of the common cold in terms of the perception of threat by policymakers. In 2001, the U.S. Department of Health and Human Services (HHS) pandemic preparedness

For the 2010/2011 season, the vaccine protects against H1N1 (Pandemic), H3N2, and influenza B. See Catherine Gerdil, *The Annual Production Cycle for Influenza Vaccine*, 21 VACCINE 1776, 1776-79 (2003); *Types of Influenza Viruses*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/flu/about/viruses/types.htm> (last updated Sept. 17, 2010); *Selecting the Viruses in the Seasonal Influenza (Flu) Vaccine*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/flu/professionals/vaccination/virusqa.htm> (last updated Oct. 6, 2010).

9. Michael T. Osterholm, *Preparing for the Next Pandemic*, 352 NEW ENG. J. MED., 1839, 1840 (2005). See Gardiner Harris, *After Delay, U.S. Faces Line for Flu Drug*, N.Y. TIMES, Oct. 7, 2005, <http://www.nytimes.com/2005/10/07/politics/07flu.html> (The Bush Administration strengthened both international and domestic disease surveillance programs. These programs included buying drugs like Tamiflu and investing in research to develop alternative methods of making flu vaccines.).

10. See Joel C. Gaydos et al., *Swine Influenza A Outbreak, Fort Dix, New Jersey, 1976*, 12 EMERGING INFECTIOUS DISEASES 23, 23 (2006) (detailing the swine flu outbreak in 1976-77); Lone Simonsen et al., *The Impact of Influenza Epidemics on Mortality: Introducing a Severity Index*, 88 AM. J. PUB. HEALTH 1944, 1949 (1997); René Snacken et al., *The Next Influenza Pandemic: Lessons from Hong Kong, 1997*, 5 EMERGING INFECTIOUS DISEASES 195, 195-97 (1999) (highlighting the emergence of avian flu and looking at the historical trends of new strains of influenza).

plan was still a draft—albeit a working one—and remained so until 2005.¹¹ Accordingly, this article will not focus on events and milestones that occurred prior to 2001.

II. MY BACKGROUND

From 1995 to 1999, I was counsel to Tommy G. Thompson, then-Governor of Wisconsin.¹² In addition to the usual duties of an in-house lawyer, I was responsible for emergency preparedness policy and planning in the Office of the Governor. As a consequence, I had been involved on the periphery in public health preparedness for the state, including biodefense—to the extent we were doing work in this area.¹³

In late 1997, I read an article in *The New Yorker* by Malcolm Gladwell about the 1918 influenza pandemic and an effort then underway to obtain DNA from the bodies of miners who died during the pandemic and were buried in the permafrost in Norway.¹⁴ Prior to reading the article, I really had little appreciation for the enormity of the 1918 outbreak and its impact on every corner of the globe. I had heard stories about one of my great aunts dying from the Spanish Flu,¹⁵ but beyond that I knew nothing. So, the

11. *HHS Pandemic Influenza Plan*, U.S. DEP'T OF HEALTH & HUMAN SERVS., <http://www.hhs.gov/pandemicflu/plan> (last visited Nov. 18, 2010). The work to finalize the HHS pandemic plan was ably led by Dr. Bruce Gellin, HHS Deputy Assistant Secretary and Director, National Vaccine Program Office. His contributions to pandemic preparedness are too numerous to list and his positive influence on U.S. vaccine policy extends well beyond influenza. It was a privilege collaborating with Dr. Gellin on pandemic preparedness.

12. WIS. LEGIS. REFERENCE BUREAU, *THE WISCONSIN BLUE BOOK* 301-53 (2009), available at <http://legis.wisconsin.gov/lrb/bb/97bb/ch6a.pdf>. See also *Tommy Thompson: Secretary of Health & Human Services (2001 – 2005)*, WHITE HOUSE, <http://georgewbush-whitehouse.archives.gov/government/thompson-bio.html> (last visited Nov. 18, 2010) [hereinafter *Tommy Thompson*].

13. This included a state effort to obtain funding from the CDC to build public health preparedness capacity in Wisconsin. In February 1999, CDC launched the Public Health Preparedness and Response to Bioterrorism Cooperative Agreement Program, which made approximately \$41 million available to states to build a public health preparedness infrastructure. See *Statement on Bioterrorism Before the Subcomm. on Tech., Terrorism, and Gov't Info., Subcomm. on Youth Violence, S. Comm. on the Judiciary*, 106th Cong. *passim* (1999) (statement of Dr. James M. Hughes, Director, National Center for Infectious Diseases, Centers for Disease Control and Prevention), available at <http://www.hhs.gov/asl/testify/t990420a.html>. I worked closely on this initiative with Dr. Jeffrey Davis of the Wisconsin Division of Public Health and Dr. Ronald Laessig of the Wisconsin State Laboratory of Hygiene. Dr. Davis and Dr. Laessig were the thought leaders for our proposal to the CDC and both taught me much about public health preparedness.

14. Malcolm Gladwell, *The Dead Zone*, *NEW YORKER*, Sept. 29, 1997, at 52, 52-54.

15. See ALFRED W. CROSBY, *AMERICA'S FORGOTTEN PANDEMIC: THE INFLUENZA OF 1918* *passim* (Cambridge University Press 1989) (describing the historical context of the 1918 pandemic, also known as the Spanish Flu). See also Taubenberger & Morens, *supra* note 4

Gladwell piece really captured my interest. In the article, he noted that public health authorities in the U.S. were always concerned about a 1918-like virus emerging.¹⁶ A few weeks later, I mentioned the Gladwell article to Governor Thompson and asked him what he knew about the 1918 pandemic. The Governor knew more about it than I had prior to reading the Gladwell piece, but, like me, he was interested in learning more—specifically, how well prepared we were for something like it today. The Governor suggested I do a little research on pandemic preparedness and give him a briefing on my findings.¹⁷ I have to admit this was more of an academic interest than anything else. We had so many other policy issues to work through (everything from Private School Choice in Milwaukee to Indian gaming to Truth-in-Sentencing) that I really did not think of pandemic preparedness as a pressing concern for the State of Wisconsin (or, for that matter, any state).

It was, however, interesting and so over the next few months I did some research at the University of Wisconsin Medical School library. Among the literature I read was Alfred Crosby's account of the 1918 outbreak in *America's Forgotten Pandemic*, which Gladwell had referenced in his *New Yorker* article.¹⁸ I learned a great deal about the flu and did, in fact, give the Governor an extensive briefing on the 1918 pandemic—probably much more than he wanted. While this project of mine had absolutely no impact on pandemic preparedness in Wisconsin in the late '90s, it did typecast me as the public health preparedness point-man when Governor Thompson was nominated to be President Bush's first Secretary of Health and Human Services. When it came time to brief the Governor for his confirmation hearings, I was the person responsible for preparing him for whatever influenza or biodefense questions he might get during the confirmation process. And I have to say that no one—including me—expected that he would get such questions. But I found this assignment interesting and the Governor—to his credit—was eager to learn all that he could about public health preparedness.

passim. There is no evidence that the 1918 pandemic emerged in Spain. But Spain was neutral during World War I and, unlike the combatant countries, did not censor the press. The 1918 disease became known as the Spanish Flu "very likely because newspapers were publishing accounts of the spread of the disease that were picked up in other countries . . . Spanish papers were filled with reports of the disease especially when King Alphonse XIII fell seriously ill." JOHN M. BARRY, *THE GREAT INFLUENZA: THE EPIC STORY OF THE DEADLIEST PLAGUE IN HISTORY* 171 (2004).

16. Gladwell, *supra* note 14, at 61-64.

17. Such assignments were a regular occurrence in Governor Thompson's office. During the more than twenty years that I have known him, he has always had an acute sense of intellectual curiosity. This was one reason I mentioned the Gladwell article to the Governor.

18. CROSBY, *supra* note 15.

A. *Pre-9/11*

Governor Thompson was sworn in as HHS Secretary on February 2, 2001.¹⁹ I had decided not to leave Amtrak, where I had been serving as Corporate Secretary and Counsel since 1999.²⁰ I agreed, however, to become a Special Government Employee (SGE) to work—without pay—on preparedness issues during Secretary Thompson's transition. After the transition, I joined HHS full-time as Deputy General Counsel, then became Special Counsel for Preparedness, and later was appointed Assistant Secretary for Public Health Emergency Preparedness.²¹

During the first seven months of the Bush administration, few in the political ranks of the department, other than Secretary Thompson and several senior aides, were particularly interested in public health preparedness.²² There were a number of U.S. Public Health Service (USPHS) officers and other career officials who were enormously dedicated to preparedness, but, with a few exceptions, it was not a priority for political appointees at HHS.²³ In fairness, it was the beginning of the Administration and so much was in play. At the time, the Bush stem cell policy was

19. *Tommy Thompson*, *supra* note 12.

20. OFFICE OF FED. REG., NAT'L ARCHIVES & RECORDS ADMIN., THE UNITED STATES GOVERNMENT MANUAL 476 (2004), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2001_government_manual&docid=188578tx_xxx-81.pdf.

21. GEORGE W. BUSH, 1 PUBLIC PAPERS OF THE PRESIDENTS OF THE UNITED STATES 1172 app. A (2004), available at http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?dbname=2004_public_papers_vol1_misc&page=1172&position=all. Following the events of September 2001, Secretary Thompson administratively established the Office of Public Health Preparedness (OPHP) within the Office of the Secretary, HHS. This office was led by a Director appointed by the Secretary. Dr. D.A. Henderson was appointed by Secretary Thompson to be the first Director of OPHP. See *D.A. Henderson to Direct New Office of Public Health Preparedness*, CTR. FOR INFECTIOUS DISEASE RES. & POL'Y, Nov. 6, 2001, <http://www.cidrap.umn.edu/cidrap/content/bt/bioprep/news/110601henderson.html>. In 2002, Congress created the position of Assistant Secretary for Public Health Emergency Preparedness, a presidential appointment. See 42 U.S.C. § 300hh-10 (2006). OPHP was merged into the Office of the Assistant Secretary for Public Health Emergency Preparedness. Several Acting Assistant Secretaries led the office (including Dr. William Raub) until 2004 when President Bush appointed me to be the first Assistant Secretary for Public Health Emergency Preparedness.

22. Ladd Wiley, HHS Deputy General Counsel and a former colleague of mine in the Governor's Office, and Sally Canfield, Counselor to the Secretary and a Thompson transition staffer, worked closely with me on preparedness policy development. In addition, Robert Wood, Thompson's Chief of Staff, assigned the department's White House Fellow, Lt. Cdr. Kathryn Allen, USN, to work on biodefense-related projects. See Kathryn Allen, *Experiencing the Transition*, 26 WHITE HOUSE FELLOWS, no. 2, 2001 at 1, 3.

23. See generally Marilyn Werber Serafini & Gia Fenoglio, *Health and Human Services Department Profiles*, 33 NAT'L J. 1948-52 (2001) (the lack of demonstrated interest by the HHS heads illustrates that influenza was not their priority).

emerging and there were a number of other highly charged issues on the department's agenda. Nevertheless, several times a week, I would leave Union Station and travel across the Mall to the Hubert H. Humphrey Building, HHS Headquarters, to spend a few hours on preparedness issues, including pandemic preparedness. Secretary Thompson had directed CDC to detail a senior physician to the Immediate Office of the Secretary to focus on public health preparedness full-time²⁴ and there were several career officials in the HHS Office of the Assistant Secretary for Planning and Evaluation working on preparedness. The Clinton Administration's Assistant Secretary for Planning and Evaluation, Dr. Margaret A. Hamburg, had done excellent work in developing preparedness plans and directing preparedness investments.²⁵ I sought to pick-up where Dr. Hamburg had left off, and Secretary Thompson was eager for me to do this. Indeed, he used to call me in for briefings on a fairly regular basis. While most political appointees in the department paid little or no attention to public health preparedness, Secretary Thompson was committed to it from the outset. From tornadoes to floods to forest fires, emergency preparedness and response is an everyday fact of life for a governor. Whether a governor's tenure is a success or a failure can turn on how an emergency operation is managed. Secretary Thompson saw public health preparedness in this context and the same can be said for his successor at HHS, Governor Michael O. Leavitt.²⁶

B. 9/11

As I indicated, Dr. Hamburg had been very effective in the Clinton Administration in making public health preparedness a priority. She and her staff made important, enduring contributions to pandemic planning and the product of this effort became the foundation for our work. Indeed, on the morning of September 11, 2001, a pandemic preparedness briefing was on Secretary Thompson's calendar.²⁷ Once the second plane hit the World

24. Dr. Scott Lillibridge was formally named Special Assistant to the Secretary with responsibility for bioterrorism preparedness on July 10, 2001. *HHS Names Physician to Coordinate Anti-Bioterrorism Initiatives*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (July 10, 2001), <http://archive.hhs.gov/news/press/2001pres/20010710a.html>.

25. Prior to her appointment as HHS Assistant Secretary for Planning and Evaluation, Dr. Hamburg was Commissioner of Health and Mental Hygiene for the City of New York. She was one of the pioneers in biodefense and public health preparedness. In 2009, President Obama appointed Dr. Hamburg to be Commissioner of Food and Drugs. Gardiner Harris, *Former New York Official Is Called Choice for F.D.A.*, N.Y. TIMES, Mar. 12, 2009, at A20.

26. Gardiner Harris, *Fear of Flu Outbreak Rattles Washington*, N.Y. TIMES, Oct. 5, 2005, at A23.

27. This briefing was to be led by Dr. William Raub, then-Principal Deputy Assistant Secretary for Planning and Evaluation. Dr. Raub had been Dr. Hamburg's principal deputy and he played an important role in providing continuity on public health preparedness matters

Trade Center, the schedule was cleared and the pandemic preparedness briefing was put on hold until later in 2001 or the beginning of 2002.

C. Post-9/11

Following the events of 9/11 and the anthrax letters later that month,²⁸ Congress focused on improving public health preparedness in the United States. Billions were sent to the states, through CDC and the Health Resources and Services Administration (HRSA), to build public health infrastructure and substantial funds were appropriated to NIH to catapult biodefense basic research forward—and this included work on influenza.²⁹ But in 2001—another virus was in the headlines: smallpox.³⁰ At the time, I was focused almost exclusively on leading the contracting effort to accelerate development of the second-generation smallpox vaccine.³¹ This

between administrations. He later served as Dr. Henderson's deputy in the newly created Office of Public Health Preparedness and later Acting Assistant Secretary for Public Health Emergency Preparedness. Earlier in his career, Dr. Raub had been a Deputy Director of NIH. See *The NIH Almanac – Historical Data*, NAT'L INSTS. OF HEALTH, U.S. DEP'T OF HEALTH & HUMAN SERVS., http://www.nih.gov/about/almanac/historical/deputy_directors.htm (last updated Nov. 9, 2010). He was a respected adviser to both Secretary Thompson and Secretary Leavitt.

28. *The Anthrax Letters*, COUNCIL ON FOREIGN RELATIONS, http://www.cfr.org/publication/9555/anthrax_letters.html (last updated Jan. 2006). See also Sheryl Gay Solberg & Alison Mitchell, *A Nation Challenged: The Overview; Letter Containing Anthrax Sent to U.S. Senate Leader*, N.Y. TIMES, Oct. 16, 2001, <http://query.nytimes.com/gst/fullpage.html?res=9C05EFD81F3FF935A25753C1A9679C8B63&scp=2&sq=anthrax%20letters%20a%20nation%20c%20challenged%20overview&st=cse>.

29. See *HHS Provides \$1.4 Billion More to States and Hospitals for Terrorism Preparedness*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Sept. 2, 2003), <http://archive.hhs.gov/news/press/2003pres/20030902.html>.

30. See, e.g., Jonathan Rauch, *Countering the Small Pox Threat*, 288 ATLANTIC MONTHLY 50, 50-51 (2001).

31. The contract to accelerate development of the second-generation smallpox vaccine was awarded on November 28, 2001, to Acambis of Cambridge, Massachusetts. ACAMBIS, INC., ACAM2000: SMALLPOX VACCINE: VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE (VRBPAC) BRIEFING DOCUMENT 7 (Apr. 18, 2007), available at <http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4292B2-02.pdf>. This contract was essentially the continuation of the smallpox vaccine research and development project that Dr. Hamburg launched in 1999. See *Statement on Bioterrorism Before the S. Appropriations Subcomm. on Labor, Health & Human Servs., Educ., & Related Agencies*, 106th Cong. *passim* (1999) (statement of Dr. Margaret A. Hamburg, Assistant Sec'y for Planning & Evaluation, U.S. Dep't of Health & Human Servs.), available at <http://www.hhs.gov/asl/testify/t990316a.html>; Donald A. Henderson et al., *Smallpox as a Biological Weapon: Medical and Public Health Management*, 281 JAMA 2127, 2136 (1999); James W. LeDuc & Peter B. Jahrling, *Strengthening National Preparedness for Smallpox: An Update*, CTRS. FOR DISEASE CONTROL & PREVENTION (last updated Mar. 5, 2009), <http://www.cdc.gov/ncidod/eid/vol7no1/leduc.htm>.

project was guided by a core group of scientists, including Dr. D.A. Henderson,³² Dr. Anthony S. Fauci,³³ Dr. John LaMontagne,³⁴ Dr. Philip K. Russell,³⁵ Dr. James LeDuc,³⁶ Dr. William Raub,³⁷ and Dr. Scott Lillibridge.³⁸

During one of the early meetings of this group, I recall a side discussion with Dr. Fauci and Dr. LaMontagne about influenza. Dr. LaMontagne told me that if anything would get us, it would not be smallpox, but the flu.³⁹

32. Following the events of 9/11, Secretary Thompson personally recruited Dr. Henderson to lead the newly created Office of Public Health Preparedness. He became the architect of the post-9/11 HHS public health preparedness program and a mentor to many in the department, including me. Dr. Henderson was precisely the type of leader this new office needed in the dark days following 9/11. Earlier in his career, Dr. Henderson directed the successful WHO-led effort to eradicate smallpox, one of mankind's greatest achievements. Following this, he was appointed Dean of the Johns Hopkins School of Public Health. D.A. Henderson: *Professional Profile*, U. OF PITTSBURGH MED. CTR., <http://www.upmc-biosecurity.org/website/center/staff/henderson.html> (last visited Nov. 18, 2010). See also D.A. HENDERSON, *SMALLPOX: THE DEATH OF A DISEASE* 290-92 (2009).

33. Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health.

34. Late Deputy Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health.

35. Secretary Thompson, Dr. Henderson, and I recruited Dr. Russell to lead the countermeasure Research and Development (R&D) program, within the Office of Public Health Preparedness. Earlier in his career, Dr. Russell served as the Commanding Officer, U.S. Army's Medical Research and Materiel Command. By the Fall of 2001, Dr. Russell had long since retired from the Army and was serving on the faculty of the Johns Hopkins School of Public Health and the board of the Sabin Vaccine Institute. When it became clear how much HHS needed him, Dr. Russell put aside his personal wishes and returned to government service. His contributions to public health and biodefense are too numerous to list. See Philip K. Russell, MD, SABIN VACCINE INST., <http://www.sabin.org/about-us/executive/philip-k-russell-md> (last visited Jan. 28, 2011). See also HENDERSON *supra* note 32, at 289-90.

36. Dr. James LeDuc, then-Director, CDC Division of Viral and Rickettsial Diseases, led the CDC project team responsible for developing the second-generation smallpox vaccine. He later served as the CDC influenza coordinator. See *Influenza Coordination Unit Organizes to Meet Pan Flu Threat*, CCID SPECTRUM, Sept. 2006, http://www2.cdc.gov/spectrum/vol1no4/CCID_influenza_coordination_unit.html. Today, he is Director of the Galveston National Laboratory, University of Texas Medical Branch. See Garland D. Anderson, Message from the Provost, available at http://www.som.utmb.edu/news/031510_GNL_IHLL_Leadership.pdf. He is one of the finest public servants with whom I have had the privilege to serve.

37. Then-Principal Deputy Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services

38. Special Assistant to the Secretary, U.S. Department of Health and Human Services. In addition to these individuals, the successful effort to accelerate the development of the second-generation smallpox vaccine benefited substantially from the expertise of the late Joseph Gilchrist, Lorenzo Falgiano, Charlotte Flitcraft, Debra Yeskey, John Beecher, and George French all of the CDC, and Katherine Drews and Jonathan Baker of the HHS Office of General Counsel.

39. Dr. LaMontagne died in November 2004. Joe Holley, *NIH Administrator John LaMontagne Dies*, WASH. POST, Nov. 8, 2004, at B6. To honor Dr. LaMontagne and recognize

And what I subsequently learned about the history and properties of the influenza virus corroborated Dr. LaMontagne's statement. It should be noted that both Dr. Fauci and Dr. LaMontagne were integral to our work to accelerate development of the second-generation smallpox vaccine and their positive influence can be seen in everything we accomplished in building a biodefense research and development program at HHS.⁴⁰

But even with such staunch advocates, only modest progress had occurred over the years in improving the U.S. licensed inactivated flu vaccine. Today's licensed influenza vaccine is made using 1950s technology.⁴¹ Essentially, embryonated chicken eggs serve as little bio-reactors.⁴² Hundreds of thousands of chickens producing millions of eggs are needed every year.⁴³ Depending on how well the strains selected for that year grow, vaccine production can take between six and nine months.⁴⁴ And the process is vulnerable to any number of perils—including influenza itself, which can kill the chickens producing the eggs needed to make the vaccine.⁴⁵

The events of September 2001 made bioterrorism our principal focus and not influenza. And no one—then or now—thinks influenza is a serious bioterror threat. Smallpox, anthrax, and other bioterrorism agents were our top priority. But, pandemic influenza preparedness benefited in at least two important ways from the heightened attention directed at bioterrorism. First and foremost, NIH received a substantial increase in funding for bioterrorism-related basic research and influenza research was included in

his lifelong commitment to influenza research and pandemic preparedness, HHS sponsored, in 2005, the John R. LaMontagne Symposium on Pandemic Influenza Preparedness. The LaMontagne Symposium was convened by the Institute of Medicine for the purpose of identifying gaps in influenza research. See *John R. LaMontagne Symposium on Pandemic Influenza Preparedness*, INST. OF MED. OF THE NAT'L ACADS., <http://www.iom.edu/Activities/Disease/LaMontagneFluSymp.aspx> (last updated Oct. 11, 2009).

40. Dr. Fauci's influence reached far beyond biodefense research and development. During my five years at HHS, I consulted with Dr. Fauci on all manner of issues. Secretary Thompson and Secretary Leavitt similarly relied on Dr. Fauci's excellent judgment. He spent a great deal of time teaching me--and other appointees--about emerging and reemerging infectious diseases as well as about science policy and interagency diplomacy. But most importantly, Dr. Fauci taught me an enormous amount about how to be a good public servant. It was an honor to work with him.

41. Osterholm, *supra* note 9, at 1839.

42. Nell Greenfieldboyce, *New and Old Ways to Make Flu Vaccines*, NAT'L PUB. RADIO, Nov. 8, 2007, <http://www.npr.org/templates/story/story.php?storyId=16105360>. See Osterholm, *supra* note 9, at 1839-40.

43. Osterholm, *supra* note 9.

44. *Id.*

45. Greenfieldboyce, *supra* note 42.

this portfolio.⁴⁶ No amount of planning for a biological event like an anthrax release or an influenza pandemic can overcome the absence of effective medical countermeasures. The investment in biodefense basic research that occurred after the events of September 2001 has contributed to science's understanding of the influenza virus and funded work, which will surely lead to additions to the influenza armamentarium.⁴⁷

Second, Secretary Thompson increased international engagement related to public health preparedness by proposing that a group of health ministers meet periodically to coordinate efforts to prepare for bioterror events. In November 2001, health ministers from Canada, France, Germany, Italy, Japan, Mexico, the United Kingdom, and the United States joined representatives from WHO and the European Commission in Ottawa to establish the Global Health Security Initiative (GHSI).⁴⁸ The ministers pledged to strengthen public health preparedness and response planning for chemical, biological, radiological, and nuclear emergencies.⁴⁹ At the December 2002 GHSI ministerial meeting in Mexico City, Secretary Thompson argued successfully to broaden GHSI's mandate to include

46. See NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES, U.S. DEP'T OF HEALTH & HUMAN SERVS., FY 2010 BUDGET 7 (2010), available at <http://www.nih.gov/about/almanac/appropriations/index.htm> (2010) (In FY2002, the National Institute of Allergy and Infectious Diseases (NIAID) received over \$2.3 billion in funding, \$187 million of which was directed at biodefense. Today, NIAID receives more than \$4.7 billion in funding, \$1.6 billion of which is directed at biodefense. See *id.* at 19.). NIAID is the NIH institute responsible for research to "better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases." *Who We Are and What We Do*, NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES, U.S. DEP'T OF HEALTH & HUMAN SERVS., <http://www.niaid.nih.gov/about/Pages/default.aspx> (last updated Apr. 12, 2010). See also NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES, U.S. DEP'T OF HEALTH & HUMAN SERVS., OPEN LETTER IN *SCIENCE* REGARDING NIH BIODEFENSE FUNDING 3 (2005), available at <http://webcache.googleusercontent.com/search?q=cache:ZMUNHfPzDusJ:www.niaid.nih.gov/news/newsreleases/2005/pages/scienceletter.aspx+biodefense+budget+NIAID&cd=1&hl=en&ct=clnk&gl=us&source=www.google.com> (showing that remarkable increase in biodefense spending from \$42 million in FY2001 to \$187 million in FY2002 to nearly \$1.2 billion in FY2003); NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES, U.S. DEP'T OF HEALTH & HUMAN SERVS., FISCAL YEAR 2009 FACT BOOK: A YEAR IN REVIEW *passim* (2010), available at <http://www.niaid.nih.gov/about/whoWeAre/Documents/fy09FactBook.pdf>.

47. See *The Role of NIH-Supported Research in the Response to 2009 H1N1 Influenza*, Statement Before the Subcomm. on Labor, Health & Human Servs., Educ. & Related Agencies, H. Comm. on Appropriations, 111th Cong. *passim* (2009) (statement of Anthony S. Fauci, MD, Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health, U.S. Department of Health and Human Services), available at <http://www.niaid.nih.gov/about/directors/Documents/110409niaidstatementlhsh1n1.pdf>.

48. Overview: *Global Health Security Initiative (GHSI)*, GLOBAL HEALTH SECURITY INITIATIVE, <http://www.ghsi.ca/english/background.asp> (last visited Nov. 18, 2010).

49. *Id.*

pandemic influenza preparedness.⁵⁰ Since then, GHSI has included a pandemic influenza working group. Adding influenza preparedness to GHSI's mandate created a framework for close coordination in the nascent work of preparing for a pandemic.⁵¹

III. WHO INFLUENZA SURVEILLANCE

Each May, the principal governing body of the World Health Organization—the World Health Assembly—meets at the U.N. complex in Geneva, Switzerland, where delegations from 193 Member States listen more or less politely to a series of predictable speeches.⁵² In 2002 and subsequently, I served on the U.S. delegation to the World Health Assembly. In addition to the formal agenda for the Assembly, a number of side-meetings, informal conferences and bilateral discussions occur.⁵³ One such meeting was an influenza surveillance briefing by WHO staff for the then-HHS Assistant Secretary for Health and me.⁵⁴ We spent several hours discussing the global influenza surveillance network and its gaps. We also talked about readiness: how well prepared were Member States and what could be done to improve it. When I returned to Washington, I briefed Secretary Thompson on our pandemic discussions at WHO and he asked that I develop a plan to improve our pandemic preparedness posture.

IV. ALFRED CROSBY—AMERICA'S FORGOTTEN PANDEMIC

The first order of business in moving our pandemic preparedness effort forward was to put the threat in context—in other words, to understand the impact of the 1918 virus. As I noted, Professor Alfred Crosby's book, *America's Forgotten Pandemic*, was cited in Malcolm Gladwell's article. Since Crosby's book had made such an impact on me, I wanted to begin our pandemic preparedness effort with a talk by him. I contacted Professor

50. *Id.*

51. *Id.*

52. *World Health Assembly Opens*, WORLD HEALTH ORG. (May 19, 2008), <http://www.who.int/mediacentre/news/releases/2008/wha01/en/index.html>.

53. In May 2004, for example, Secretary Thompson convened a pandemic preparedness meeting with health ministers from Asia during the 57th World Health Assembly. This meeting included ministers from countries then most at risk from H5N1. In addition to Secretary Thompson and myself, U.S. participants included the following HHS officials: Dr. Bruce Gellin, Dr. Nancy Cox, Dr. William Steiger, Mary Lou Valdez, and David Hohman; and Dr. Robert Webster of the St. Jude's Children's Research Hospital, a world renowned influenza expert. See Meeting minutes from the National Vaccine Advisory Committee (NVAC) (June 1-2, 2004) (on file with author).

54. In May 2002, Dr. Eve Slater, then-HHS Assistant Secretary for Health, and I met with several WHO officials about global influenza surveillance: Dr. David Heyman, Dr. Klaus Stohr, Dr. Mike Ryan, and Dr. Ray Arthur (a CDC assignee to WHO).

Crosby at his home in New England and he agreed to come to Washington to spend a few hours with most of the senior HHS officials—both political and career—involved in influenza policymaking.⁵⁵ Everyone in the room knew about the 1918 pandemic and what—in general—it had done to the country (and the world). But the magnitude of the disruption shocked me (and others) then—as it still does today. What became clear to everyone present was that we were not ready for a 1918-like event, not even close. My colleagues and I left the Crosby talk with two priorities: (1) close gaps in global influenza surveillance and (2) dramatically improve our capacity to make influenza vaccine (both egg-based vaccine and, eventually, cell-culture vaccine).

V. THE INFLUENZA INITIATIVE—\$250 MILLION

Following a number of meetings and budget discussions, several HHS thought leaders⁵⁶ crafted a \$250 million proposal to begin work on creating a cell-culture influenza vaccine for the U.S. and to secure the egg supply for the licensed vaccine.⁵⁷ The idea was to launch a Research and Development (R&D) initiative with one of the vaccine makers to produce a cell-culture vaccine. At the time, there was no U.S. work of any significance going on in this area. There was at least one cell-culture influenza vaccine in pilot production in Europe,⁵⁸ but no pharmaceutical firms at the time were doing any influenza cell-culture work in the U.S. or for the U.S. market. So we thought we could enter into a contract with Sanofi Pasteur or Chiron (then the only makers of licensed inactivated flu vaccine for the U.S.) to begin an R&D effort for cell-culture influenza vaccine and build new capacity for cell-culture production. It is important to understand that there is nothing revolutionary about cell-culture vaccine. There are a number of

55. Dr. D.A. Henderson introduced Professor Crosby and moderated the discussion. Dr. Henderson was—and remains—a strong proponent for pandemic influenza preparedness.

56. This group included Lester Cash, William Beldon, and Kerry Weems of the HHS budget office, and Dr. William Raub, then of the Office of Public Health Emergency Preparedness.

57. The \$250 million influenza vaccine initiative was part of a larger proposal to improve the Nation's domestic vaccine production capacity. The proposal was developed at the request of Secretary Thompson and included what later became Project BioShield. See Ted Agres, *Bioshield Moving Forward: Unlimited Spending Authority and Industry Liability Remain Key Stumbling Blocks*, SCIENTIST, May 16, 2003, <http://cmbi.bjmu.edu.cn/news/0305/153.htm>.

58. *Baxter Receives European Commission Approval for CELVAPAN H1N1 Pandemic Influenza Vaccine*, BAXTER (Oct. 7, 2009), http://www.baxter.com/press_room/press_releases/2009/10_07_09-celvapan.html.

licensed vaccines in the U.S. made with cell culture technology.⁵⁹ But the consensus among vaccine experts at HHS was that a cell culture influenza vaccine would be more reliable than the currently licensed vaccine and it would be readily scalable because cell culture vaccine production does not require eggs. Instead, human cells or some other cell line are used in bioreactors to make the vaccine.⁶⁰ Cell-culture influenza vaccine would not solve our pandemic preparedness problems, but it would be faster—by a few months—and more secure.

In addition to developing a cell-culture vaccine for the U.S., we needed to secure the egg supply for the licensed vaccine. As I mentioned, there are hundreds of thousands of chickens producing millions of eggs each year for the U.S. licensed influenza vaccine, but these chickens are vulnerable to avian diseases, including influenza itself. If such a disease were to wipe out the egg supply for the vaccine makers, the vaccine manufacturing process would be set back a number of months, until the flock could be reconstituted. The chickens that produce the eggs for vaccine production are specialized—indeed, they have been bred for this work. So we needed a contingency or standby flock—ready to step in if something should happen to the primary flock.

The \$250 million vaccine proposal funded both of these projects. Since it was a relatively modest amount of money, we thought we stood a good chance of getting it funded in the President's 2004 budget request. But we also understood that it often takes a few years to get a new initiative approved and resourced. Each year, competing priorities run the budget gauntlet where some do better than others. In the Fall of 2003, we learned that the HHS influenza initiative fell into the latter category—it was not going to be funded in the President's 2004 budget. Initially we thought we would need to wait for the 2005 request, but then an alternate strategy emerged.

As is well known, Vice President Cheney was an effective advocate for biodefense and public health preparedness. During my five years at HHS, I cannot recall a single week that I—and many others at HHS—did not have contact with the Office of the Vice President.⁶¹ When we saw that the HHS influenza initiative was not going to be funded in the President's 2004

59. See generally STANLEY A. PLOTKIN, WALTER A. ORENSTEIN & PAUL A. OFFIT, *VACCINES* 5, 7 (5th ed. 2008) (noting that the "golden age of vaccine development" occurred in 1949, using cell culture).

60. Greenfieldboyce, *supra* note 42.

61. Our principal interlocutor in the Office of the Vice President was Carol Kuntz, Ph.D., a Department of Defense career official who served as the Assistant to the Vice President for Homeland Security. See OFFICE OF FED. REG., NAT'L ARCHIVES & RECS. ADMIN., *THE UNITED STATES GOVERNMENT MANUAL 2004/2005 90* (2004), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2004_government_manual&docid=198805tx_19-19.pdf.

budget, Secretary Thompson gave me permission to approach the Office of the Vice President and seek their assistance in obtaining funding in the 2004 budget. I have a very specific recollection of a telephone conversation between Secretary Thompson and an official at the Office of Management and Budget (OMB) about the pandemic vaccine initiative which concluded with the Secretary saying: "I'll have to go to the Veep on this." Following that conversation, I went to the White House and briefed Vice President Cheney's staff on the HHS influenza initiative.⁶² Vice President Cheney had been President Ford's Chief of Staff during the 1976 swine flu scare⁶³ so he already knew about the influenza threat in some detail. When he was briefed on the HHS initiative, he signed on right away. Shortly thereafter, Vice President Cheney and Secretary Thompson met with President Bush in the Oval Office where they obtained the President's approval for putting \$100 million into the President's 2004 budget request.⁶⁴ It was not what we had requested, but it was a very good start. Unfortunately, as often happens with new programs, Congress only partially funded the President's request and the result was a \$50 million initiative—not enough to do anything meaningful with cell-culture vaccine, but more than sufficient to secure the egg supply for the licensed vaccine.⁶⁵

The year 2004 turned out to be an inflection point for influenza preparedness in the United States. In addition to the HHS vaccine being launched, two events outside the U.S. persuaded policymakers to address pandemic preparedness in earnest: following several years of apparent

62. This briefing included I. Lewis (Scooter) Libby, Chief of Staff to the Vice President; Dr. Carol Kuntz, Assistant to the Vice President for Homeland Security; Capt. Bruce Miller, USN, Deputy Assistant to the Vice President for Homeland Security; Dr. Noreen Hynes, USPHS, an HHS assignee in the Office of the Vice President.

63. STEPHEN F. HAYES, CHENEY: THE UNTOLD STORY OF AMERICA'S MOST POWERFUL AND CONTROVERSIAL VICE PRESIDENT 78 (2007). See David J. Sencer & J. Donald Millar, *Reflections on the 1976 Swine Flu Vaccination Program*, 12 EMERGING INFECTIOUS DISEASES 29, 29 (2006).

64. U.S. DEP'T OF HEALTH & HUMAN SERVS., FY 2004 BUDGET IN BRIEF 91 (2004). Secretary Thompson invested substantial amounts of political capital in pandemic preparedness well before influenza was recognized outside of the public health community as much of a threat. During his tenure at HHS, he consistently advocated for more resources to be invested in pandemic preparedness. In his farewell press conference, Secretary Thompson identified pandemic influenza as one of the greatest public health challenges facing the U.S. See William Branigin, Mike Allen & John Mintz, *Tommy Thompson Resigns from HHS*, WASH. POST, Dec. 3, 2004, <http://www.washingtonpost.com/wp-dyn/articles/A31377-2004Dec3.html>.

65. *Secretary Thompson Announces Contract to Secure Future Egg Supply for Flu Vaccines*, U.S. DEP'T OF HEALTH & HUMAN SERVS., Nov. 9, 2004, <http://archive.hhs.gov/news/press/2004pres/20041109a.html>.

dormancy, H5N1 reemerged in Hong Kong⁶⁶ and in the very midst of the 2004 election, the Chiron seasonal influenza vaccine failed—resulting in a loss of approximately half of the licensed U.S. influenza vaccine supply.⁶⁷

VI. H5N1 REEMERGES (2003/2004)

Following the Hong Kong control effort in 1997, H5N1 did not show itself again until the end of 2003—beginning of 2004: first in Hong Kong and then Vietnam.⁶⁸ This created sufficient anxiety within HHS and elsewhere in the federal government to enable HHS to take two important steps toward preparing for a pandemic. First, work began to develop a vaccine against H5N1. And second, HHS purchased an initial quantity of

66. J.S.M. Peiris et al., *Re-emergence of Fatal Human Influenza A Subtype H5N1 Disease*, 363 LANCET 617, 617-19 (2004).

67. CTR. FOR BIOLOGICS EVALUATION & RES., U.S. FOOD & DRUG ADMIN., BIORESEARCH MONITORING: WARNING LETTERS ISSUED TO EIGHT CLINICAL INVESTIGATORS CONDUCTING STUDIES WITH INVESTIGATIONAL PRODUCTS 8 (2005), available at <http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/EnforcementStoryArchive/UCM091058.pdf>; Andrew Pollack, *U.S. Will Miss Half Its Supply of Flu Vaccine*, N.Y. TIMES, October 6, 2004, at A20. See also *Flu Shot Shortage Looms*, CNNMONEY.COM, Oct. 6, 2004, <http://money.cnn.com/2004/10/05/news/midcaps/chiron>. The emergence of Severe Acute Respiratory Syndrome (SARS) in March of 2003 also played a role in focusing policymakers on pandemic influenza preparedness. Initial reporting about SARS even referred to the virus as a “killer flu.” See Thomas Crampton, *Killer Flu Is Traced to a Hotel in Hong Kong*, INT’L HERALD TRIBUNE, Mar. 20, 2003, at 9. Concern about the spread of SARS also led President Bush in April 2003 to amend the list of quarantinable diseases to include SARS. The last time a disease was added to the list had been in 1983 when President Reagan amended the list to include Ebola and other hemorrhagic fevers. Exec. Order No. 12,452, 3 C.F.R. 224 (1983), as amended by Exec. Order No. 13,375 (2005), available at <http://www.archives.gov/federal-register/codification/executive-order/12452.html>. President Bush amended the list again in April 2005 to include influenza viruses with pandemic potential on the list of quarantinable diseases. See Exec. Order No. 13,375 (2005), available at http://edocket.access.gpo.gov/cfr_2006/janqtr/pdf/3CFR13375.pdf.

68. Peiris et al., *supra* note 66, at 617; Y.L. Lau, Editorial, *Avian Influenza*, 9 HONG KONG J. PAEDIATRICS 101, 101 (2004), available at <http://hkjpaed.org/details.asp?id=61&show=1234>. The successful effort to contain H5N1 in Hong Kong in 1997 was led by Dr. Margaret Chan, Hong Kong’s health officer. Following the death in 2006 of Dr. J. W. Lee, WHO Director General, Dr. Chan was elected Director General and remains in that post today. Prior to her election, she was Assistant Director General for Communicable Diseases and the Director General’s Special Representative for Pandemic Influenza. EMMA CHANLETT-AVERY ET AL., CONG. RESEARCH SERV., RL 33871, FOREIGN COUNTRIES’ RESPONSE TO THE AVIAN INFLUENZA (H5N1) VIRUS: CURRENT STATUS 6 (2007); Dr. Margaret Chan, WORLD HEALTH ORG., <http://www.who.int/dg/en/> (last visited November 19, 2010); Former Director-General Dr. LEE Jong-wook, WORLD HEALTH ORG., <http://www.who.int/dg/lee/en/> (last visited Nov. 19, 2010).

Tamiflu for the Strategic National Stockpile.⁶⁹ But this later action was not without controversy. Several officials outside of HHS questioned the need for acquiring influenza antiviral drugs and even wondered about whether the Strategic National Stockpile⁷⁰ had legal authority to make such purchases. These objections made it perfectly clear that there was no consensus within the Bush Administration about the severity of the pandemic threat. To address this problem, I hosted a series of presentations on influenza in the Secretary's Conference Room at HHS, including discussions on the 1918, 1957, and 1968 pandemics, the 1976 swine flu affair,⁷¹ and the 1997 emergence of H5N1 in Hong Kong.⁷² In addition to HHS officials, these sessions were attended by individuals from OMB, the Office of the Vice President, the Homeland Security Council, and the Office of Science and Technology Policy. The purpose was to educate colleagues about the virus and the potential threat. But while the sessions were generally successful and a broader understanding of the pandemic threat resulted, there remained little consensus on how much should be invested in preparing for a pandemic.

VII. 2004 CHIRON VACCINE CRISIS

By 2004, there were only two makers of U.S. licensed inactivated flu vaccine: Sanofi Pasteur and Chiron.⁷³ Medimmune was licensed to make the live attenuated Flumist vaccine⁷⁴—but their capacity was fairly modest. Approximately one-half of the inactivated vaccine was made in the U.S. by Sanofi Pasteur⁷⁵ and one-half made in Liverpool, UK by Chiron.⁷⁶ Late in the Summer of 2004—an election year—we learned that the Liverpool plant had been inspected by the United Kingdom's Medicine and Healthcare Products Regulatory Agency (MHRA), the British equivalent to the FDA, and the MHRA had concluded that the Chiron plant had major deficiencies in

69. Tamiflu® (Oseltamivir) and Relenza® (Zanamivir) were the only licensed antiviral drugs effective against H5N1. See Anne Moscona, *Neuraminidase Inhibitors for Influenza*, 353 NEW ENG. J. MED. 1363, 1373 (2005).

70. See DEP'T OF HEALTH & HUMAN SERVS., HHS PANDEMIC INFLUENZA PLAN 8 (2005), available at <http://www.hhs.gov/pandemicflu/plan/pdf/HHSPandemicInfluenzaPlan.pdf>.

71. See RICHARD E. NEUSTADT & HARVEY V. FINEBERG, *THE SWINE FLU AFFAIR: DECISION-MAKING ON A SLIPPERY DISEASE* *passim* (1978).

72. These sessions included presentations by Dr. D.A. Henderson, Dr. Jeffrey Taubenberger of the Armed Forces Institute of Pathology, Dr. Michael Osterholm of the University of Minnesota, Dr. James LeDuc, and Dr. Nancy Cox, Chief of the CDC Influenza Branch.

73. *Flu Shot Shortage Looms*, *supra* note 67.

74. *Id.*

75. *See id.*

76. *See id.*

regulatory compliance.⁷⁷ The result was that the MHRA would not release the Chiron vaccine.⁷⁸ Suddenly the U.S. had lost half of its flu vaccine and just in time for the first presidential debate. So, for a time, the influenza vaccine became a rather hot political topic—even then-Governor Rod Blagojevich got into the act by purchasing a number of lots of un-licensable influenza vaccine from Europe.⁷⁹ Luckily, the flu was not particularly severe in 2004⁸⁰ and Sanofi Pasteur, the remaining supplier of licensed inactivated flu vaccine, did excellent work to make up for the loss of the Chiron vaccine. In fact, at the end of the 2004/2005 flu season, thousands of doses had gone unused.⁸¹

The reemergence of H5N1 and the loss of the Chiron vaccine together signaled the beginning of the end of influenza's time in the political wilderness. Suddenly, it became a political liability to ignore influenza preparedness. Accordingly, the President's 2005 budget submission again requested \$100 million for the HHS pandemic vaccine initiative and this time Congress funded the total amount.⁸² We also substantially increased

77. *Flu Vaccine License is Suspended*, BBC NEWS, Oct. 5, 2004, <http://news.bbc.co.uk/2/hi/health/3717726.stm>.

78. *Id.*

79. *FDA Yet to Deal with Many Details of States Importing Flu Vaccine*, FDA WEEK, Nov. 12, 2004, at 1, 9; David Bernstein, *Mr. Un-Popularity*, CHICAGO MAG. (2008), <http://www.chicagomag.com/core/pagetools.php?pageid=7444&url=%2FChicago-Magazine%2FFebruary-2008%2FMr-Un-Popularity%2F&mode=print>.

80. CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., AVIAN INFLUENZA: CURRENT H5N1 SITUATION (2007), available at <http://www.cdc.gov/flu/avian/outbreaks/pdf/current.pdf>; 2004-2005 U.S. Influenza Season Summary, CTRS. FOR DISEASE CONTROL & PREVENTION (July 7, 2005), <http://www.cdc.gov/flu/weekly/weeklyarchives2004-2005/04-05summary.htm>; *Influenza Pandemics*, HIST. OF VACCINES, <http://www.historyofvaccines.org/content/articles/influenza-pandemics> (last visited Nov. 19, 2010).

81. SARAH A. LISTER, CONG. RESEARCH SERV., RL 32655, INFLUENZA VACCINE SHORTAGES AND IMPLICATIONS 6 tbl.1 (2004); Lon McQuillan et al., *Impact of the 2004_2005 Influenza Vaccine Shortage on Pediatric Practice: A National Survey* 123 PEDIATRICS e186, e188 (2009); *Strengthening the Nation's Influenza Vaccination System: An NVAC Assessment*, U.S. DEP'T OF HEALTH & HUMAN SERVS., <http://www.hhs.gov/nvpo/nvac/influenzareportfinal1204.html> (last visited Nov. 19, 2010). Had more vaccine been needed, it could have been lawfully imported from foreign sources. Following the loss of the Chiron vaccine, HHS created a special program that granted Investigational New Drug (IND) status to certain foreign-made influenza vaccines so that these products could have been imported to the U.S. under an IND protocol through a system developed by the Office of the Secretary, CDC, FDA, NIH, HRSA, and the Centers for Medicare & Medicaid Services (CMS). See *Influenza Vaccine Supply, Statement Before the H. Comm. on Energy and Res.*, 109th Cong. *passim* (2005) (statement of Jesse L. Goodman, Director, Center for Biologics, Evaluation, and Research), available at <http://www.fda.gov/NewsEvents/Testimony/ucm161669.htm>.

82. FY2004 BUDGET IN BRIEF, *supra* note 64, at 102. See also *HHS awards \$97 Million Contract to Develop Cell Culture-Based Influenza Vaccine*, U.S. DEP'T OF HEALTH & HUMAN SERVS., Apr. 1, 2005, <http://archive.hhs.gov/news/press/2005pres/20050401.html>.

our stockpiling of influenza antiviral drugs known to be effective against H5N1.⁸³

VIII. THE GREAT INFLUENZA

But the push to prepare in historic, sustainable terms began with the publication of John Barry's magnificent book, *The Great Influenza*.⁸⁴ As I noted, the 2005 budget made a meaningful investment in cell-culture vaccine. Thanks to this funding, a contract was awarded to Sanofi Pasteur to begin serious R&D work on a cell culture influenza vaccine.⁸⁵ But in the world of vaccine development, \$100 million does not go very far.⁸⁶ If we were going to drastically change our vaccine production infrastructure to keep pace with the emergence and reemergence of pandemic strains, the U.S. would need to invest billions.

At the end of 2004, Secretary Thompson left HHS for the private sector and was replaced by Michael O. Leavitt, the former Governor of Utah and, more recently, Administrator of the Environmental Protection Agency (EPA).⁸⁷ It was not a foregone conclusion that Governor Leavitt would retain me as an Assistant Secretary. Like all HHS division and office heads, I went to EPA to brief Governor Leavitt about my office and our mission. This meeting was framed as a substantive discussion, but it was also an audition.⁸⁸ I gave him

83. HHS PANDEMIC INFLUENZA PLAN, *supra* note 70, at F-38.

84. BARRY, *supra* note 15. Since the release of *The Great Influenza*, Barry has continued his research on the 1918 outbreak and made important contributions to pandemic preparedness. See generally John M. Barry, Cecile Viboud & Lone Simonsen, *Cross-protection Between Successive Waves of the 1918-1919 Influenza Pandemic: Epidemiological Evidence from US Army Camps and from Britain*, 198 J INFECTIOUS DISEASES 1427 (2008); JOHN M. BARRY, WHITE PAPER ON NOVEL H1N1: PREPARED FOR THE MIT CENTER FOR ENGINEERING SYSTEMS FUNDAMENTALS *passim* (2009), available at <http://esd.mit.edu/wps/2009/esd-wp-2009-07-072709.pdf>; John Barry, *5 Things You Didn't Know About the Flu*, Sept./Oct. 2010, http://www.foreignpolicy.com/articles/2010/08/16/the_flu.

85. HHS Awards Contracts Totaling More than \$1 Billion to Develop Cell-Based Influenza Vaccine, U.S. DEP'T OF HEALTH & HUMAN SERVS., May 4, 2006, <http://archive.hhs.gov/news/press/2006pres/20060504.html>.

86. SANOFI AVENTIS, SANOFI PASTEUR AWARDED \$97 MILLION HHS CONTRACT TO ACCELERATE CELL-CULTURE PANDEMIC INFLUENZA VACCINE DEVELOPMENT (2005), available at http://en.sanofi-aventis.com/binaries/050405_PDF_Cell_Culture_media_tcm28-14866.pdf.

87. *Biography of Mike Leavitt*, HHS.GOV, <http://www.hhs.gov/secretary/dhhssec.html> (last visited Nov. 19, 2010); *Tommy Thompson, Secretary of Health & Human Services (2001-2005)*, WHITE HOUSE, <http://georgewbush-whitehouse.archives.gov/government/thompson-bio.html> (last visited Nov. 19, 2010).

88. This meeting included Rich McKeown, Governor Leavitt's Chief of Staff at EPA; Natalie Gochnour, EPA Associate Administrator for Public Affairs; and Kerry Weems, Acting Assistant Secretary for Budget, Technology and Finance, HHS. McKeown and Gochnour (who accompanied Governor Leavitt to HHS) and Weems were instrumental in developing and

an in-depth briefing on the department's preparedness mission—for both bioterrorism and naturally occurring threats. At the conclusion of the meeting, I gave Governor Leavitt a copy of *The Great Influenza* and suggested he read it. I told him it was a good primer on the pandemic threat. Once he had been confirmed and in office a few weeks, I asked Secretary Leavitt if he had had a chance to read the book. He said he was about half way through and that what he had read thus far was sobering—to say the very least. About a month after this, the Secretary called me to his office and asked how long it would take me to prepare a highlighted and tabbed version of *The Great Influenza*. I told him I could have it done by the end of the day. A week or so later, I was in the Secretary's outer office and there was an assembly line of people tabbing and highlighting the book according to my template. The Secretary told me that he intended to give a tabbed and highlighted copy of the book to members of the various Congressional committees with jurisdiction over HHS. I have to admit I was skeptical that this would amount to much, but nothing else had worked so it seemed worth a try. Over the course of several months, Secretary Leavitt met (individually or in groups) with dozens of Senators and Members of Congress. He distributed tabbed and highlighted copies of *The Great Influenza*, described the pandemic threat, and told them HHS needed an immediate, substantial infusion of resources to deal with it. Following one of Secretary Leavitt's closed-door sessions about the pandemic threat, Senator Harry Reid remarked that the briefing "scared the hell out of me."⁸⁹ Shortly thereafter, Congress included approximately \$3.3 billion for pandemic preparedness in the Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2006.⁹⁰ In May 2006, HHS announced that it had entered into contracts totaling more than \$1 billion with five pharmaceutical firms to develop cell-culture influenza vaccine.⁹¹ Less than two years before, \$100 million for cell-culture vaccine was out of the question. But in the fall of 2005, pandemic influenza was finally getting the attention it deserved.

IX. INFLUENZA: THE MAIN ATTRACTION

Once pandemic influenza captured the attention of political leaders and policymakers, a number of changes occurred in the way the influenza policy

executing Leavitt's pandemic preparedness strategy. All three made meaningful and enduring contributions to pandemic preparedness.

89. Harris, *Fear of Flu Outbreak Rattles Washington*, *supra* note 26.

90. Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2006, Pub. L. No. 109-148, 119 Stat. 2783, 2786.

91. See *HHS Awards Contracts*, *supra* note 85.

was developed and executed. Thanks in large part to Secretary Leavitt's advocacy, The White House focused like a laser on pandemic preparedness.⁹² The White House Homeland Security Council (HSC) led a major effort to develop a national pandemic plan, which covered all departments and sectors of critical infrastructure.⁹³ The HSC also established an uncommonly productive interagency process, which ensured a coordinated and rational approach to addressing pandemic preparedness on a national scale, including liability related to pandemic vaccines and other countermeasures.⁹⁴ Few would dispute that domestic public health resilience benefited mightily from the Bush Administration's commitment to pandemic preparedness and biodefense.⁹⁵ The truth of this assertion can be seen in the response to H1N1.⁹⁶

92. Secretary Leavitt's leadership on pandemic preparedness was exemplary. Had he not made pandemic preparedness a personal priority, I doubt whether the U.S. would have been in much of a position to respond to H1N1.

93. See U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-07-781, INFLUENZA PANDEMIC: FURTHER EFFORTS ARE NEEDED TO ENSURE CLEARER FEDERAL LEADERSHIP ROLES AND AN EFFECTIVE NATIONAL STRATEGY 2 (2007). The HSC influenza effort was ably led first by Dr. Ken Bernard, then by Dr. Rajeev Venkayya, and finally by Dr. Robert Kadlec. All three made important contributions to pandemic preparedness.

94. Liability is a perennial issue in emergency preparedness, especially when a vaccine or other countermeasure is involved. The Administration worked with Congress to address this obstacle to pandemic preparedness in the Public Readiness and Emergency Preparedness Act, which was signed into law by President Bush on December 30, 2005. See 42 U.S.C. § 247d-6d (2006). See also *Public Readiness and Emergency Preparedness Act (PREP Act) for Pandemic Influenza Medical Countermeasures Utilization Protocol & Decision Tools*, FLU.GOV, http://www.flu.gov/professional/federal/prep_act.html (last visited Jan. 28, 2011).

95. For example, Secretary Leavitt convened officials from all fifty states and relevant federal departments (i.e., HHS, USDA, and the Department of Homeland Security) on December 5, 2005, to begin the process of developing integrated pandemic preparedness plans for each state. Pandemic planning summits were then held in all fifty states. See *Pandemic Planning: A Convening of the States*, FLU.GOV, <http://www.flu.gov/professional/states/convening.html> (last visited Jan. 28, 2011). An important element of the Bush Administration's biodefense agenda was the Project BioShield Act of 2004, which, among other things, created the Emergency Use Authorization (EUA). EUAs were used to make available influenza countermeasures. *Emergency Use Authorization Granted for BioCryst's Peramivir*, BIOCRYST PHARMACEUTICALS, INC. (Oct. 23, 2009), <http://investor.shareholder.com/biocryst/releasedetail.cfm?releaseid=417887>. See also Stuart L. Nightingale, Joanna M. Prasher & Stewart Simonson, *Emergency Use Authorization (EUA) to Enable Use of Needed Products in Civilian and Military Emergencies*, *United States*, 13 EMERGING INFECTIOUS DISEASES 1046, 1046-51 (2007); HHS PANDEMIC INFLUENZA PLAN, *supra* note 70, at S6-1, S6-3, S6-12.

96. Indeed, President Obama complimented the Bush Administration's effort to prepare for an influenza pandemic. See President Barack Obama, News Conference by the President (Apr. 29, 2009) (transcript available at *Speeches and Remarks*, WHITE HOUSE, Apr. 30, 2009, http://www.whitehouse.gov/the_press_office/News-Conference-by-the-President-4/29/2009/).

The Administration's focus on pandemic preparedness included international public health engagement on a historic scale. Until 2005, influenza planning at the federal level was almost entirely the responsibility of two agencies: HHS and the U.S. Department of Agriculture (USDA). Since influenza is a disease of animals that can affect humans, USDA and HHS share responsibility for influenza-related policymaking. Other agencies like the Department of Defense (DoD), Department of Homeland Security (DHS), and Department of Veteran Affairs (VA) were engaged in influenza decision-making to the extent such decisions affected them, but national contingency planning and international engagement were largely left to HHS and USDA. In 2005, this changed. The continuing spread of H5N1 combined with the publication of *The Great Influenza* galvanized national interest in the pandemic threat and the need for serious planning. The HSC-led interagency process focused on the development of President Bush's National Pandemic Plan.⁹⁷ The Bush Administration also recognized that like all of nature, influenza operates outside of the control of human institutions and political jurisdictions. So, international engagement was essential if any meaningful progress was to be made in planning for the next pandemic. Accordingly, the State Department was tapped to lead an effort to build international support for pandemic planning.

Three multilateral international organizations have subject matter jurisdiction over influenza: WHO, the UN's Food and Agriculture Organization (FAO), and the World Organisation for Animal Health (OIE).⁹⁸ Prior to 2005, HHS dealt with WHO on influenza-related matters with little or no oversight from the State Department or any other agency of the U.S. government. The same can largely be said for USDA and its influenza related work with FAO and OIE. Furthermore, in ministerial meetings, influenza rarely surfaced on the agenda or during informal discussions. But, this changed in September 2005 when President Bush announced in a speech to the UN General Assembly the formation of the International Partnership on Avian and Pandemic Influenza (IPAPI).⁹⁹ The objective of IPAPI was to develop a consensus on ten core principals that would govern pandemic preparedness.¹⁰⁰ More than eighty countries and eight international organizations participated in the IPAPI process.¹⁰¹ And while

97. See HOMELAND SEC. COUNCIL, NATIONAL STRATEGY FOR PANDEMIC INFLUENZA (2005), available at <http://www.flu.gov/professional/federal/pandemic-influenza.pdf>.

98. See U.N. FOOD & AGRIC. ORG., WORLD ORG. FOR ANIMAL HEALTH & WORLD HEALTH ORG., THE FAO-OIE-WHO COLLABORATION 2 (2010), available at <http://www.fao.org/docrep/012/ak736e/ak736e00.pdf>.

99. U.N. GAOR, 16th Sess., 2d plen. mtg. at 8, U.N. Doc. A/60/PV.2 (Sept. 14, 2005).

100. HHS Pandemic Influenza Plan, U.S. DEP'T OF HEALTH & HUMAN SERVS., <http://www.hhs.gov/pandemicflu/plan/appendixh.html> (last visited Nov. 19, 2010).

101. *Id.*

there was nothing particularly novel about the core principals or the process, IPAPI raised the profile of influenza preparedness and ensured that it would remain an element of international dialogue for the remainder of the Bush administration and beyond. The State Department's involvement in pandemic international engagement went well beyond IPAPI. In November 2005, the State Department and HHS co-led the U.S. delegation to a special WHO meeting on pandemic preparedness.¹⁰² In 2006, the Secretary of State, Condoleezza Rice, named Ambassador Nancy Powell as the State Department's first Special Representative for Avian and Pandemic Influenza¹⁰³ and she was succeeded by Ambassador John Lange in 2007 as Special Representative.¹⁰⁴ Under President Obama and Secretary Clinton, the State Department has remained at the center of pandemic international engagement. In March of 2009, the Administration designated Ambassador Robert Loftis as the Special Representative for Avian and Pandemic Influenza.¹⁰⁵

Beginning in 2005 and continuing through the end of the Bush administration, HHS sought to improve global influenza surveillance by building capacity at WHO as well as partnering with the Institut Pasteur, which operates a network of thirty-two laboratories in Europe, Asia, Africa, Latin America, and other international public health institutions.¹⁰⁶ At WHO, HHS established a fund to defray the cost of shipping influenza specimens from poorer countries to one of WHO's influenza collaborating laboratories.¹⁰⁷ My HHS colleagues and I had been told by WHO that the cost of shipping such samples was a major impediment to closing the gaps

102. See *Meeting on Avian Flu and Human Pandemic Influenza*, WORLD HEALTH ORG., http://www.who.int/mediacentre/events/2005/avian_influenza/meeting_avian_influenza/en/index.html (last visited Nov. 19, 2010); *Meeting on Avian Flu and Human Pandemic Influenza: Provisional List of Participants*, WORLD HEALTH ORG., http://www.who.int/mediacentre/events/2005/avian_influenza/LOP_AvianInfluenza2.pdf (last visited Nov. 19, 2010).

103. *2006 Homeland Security Medal Recipient*, SERV. TO AM. MEDALS, http://servicetoamericamedals.org/SAM/recipient/profiles/hsm06_powell.shtml (last visited Nov. 19, 2009).

104. Vivian Keller, *Coming to America?*, STATE MAG., June 2006, at 22, 24.

105. *Biography: Robert Geers Loftis*, U.S. DEP'T OF STATE, <http://www.state.gov/r/pa/ei/biog/124222.htm> (last visited Nov. 19, 2010).

106. *Missions*, INSTITUT PASTEUR, <http://www.pasteur-international.org/ip/easysite/pasteur-international-en/institut-pasteur-international-network/missions> (last visited Nov. 19, 2010).

107. WORLD HEALTH ORG., *TERMS OF REFERENCE FOR WHO H5 REFERENCE LABORATORIES* (2006), available at <http://www.who.int/csr/disease/influenza/torh5reflab2006.pdf>. See also Michael O. Leavitt, Sec'y, U.S. Dep't of Health & Human Servs., Remarks at WHO Plenary Session (May 22, 2006) (transcript available at <http://www.hhs.gov/news/speech/2006/060522.html>). The UK Secretary of State for Health, Rt. Hon. John Reid, announced a major contribution to this fund at the 2004 GHSI ministerial meeting in Paris. Dr. David Harper, Chief Scientist, UK Department of Health, was instrumental in directing this contribution to the influenza specimen transport fund.

in the global influenza surveillance program. HHS also assigned HHS scientists to work at the WHO influenza program in Geneva and provided funding to WHO for an array of influenza preparedness activities, including logistics planning and policy development.¹⁰⁸

Establishing a partnership between HHS and Institut Pasteur turned out to be a more sensitive undertaking than I had anticipated when I first proposed it. The relationship between HHS and Institut Pasteur had been strained for years as a result of a dispute related to the discovery of HIV.¹⁰⁹ The initial overture to Pasteur was somewhat controversial within HHS. But, if we were to make any real progress on closing the gaps in influenza surveillance, the Institut Pasteur network had to be part of the solution. In places at greatest risk from H5N1, like Cambodia, Institut Pasteur operated the only laboratory capable of isolating the virus.¹¹⁰ So, my HHS colleagues and I worked long and hard to build a partnership with Institut Pasteur.¹¹¹

108. Dr. Stuart Nightingale, Deputy Assistant Secretary and Chief Medical Officer, HHS Office of Public Health Emergency Preparedness, led an effort to gain adoption of a resolution from the 58th World Health Assembly supporting expedited pandemic influenza planning. This resolution was adopted by the Assembly on May 23, 2005, and formed the legal foundation for much of what WHO did to prepare for a pandemic. G.A. Res. 58/5. ¶ 2, U.N. Doc. A/RES/58/5 (May 23, 2005). It would be difficult to overstate Dr. Nightingale's contribution to pandemic preparedness, but his service at HHS reached well beyond influenza and touched every corner of public health. Collaborating with Dr. Nightingale was one of the high points of my tenure at HHS.

109. See *Institut Pasteur v. United States*, 814 F.2d 624 (Fed. Cir. 1987) (Pasteur claimed that the National Cancer Institute (NCI), an HHS agency, had breached express and implied contracts to share research and recognition related to AIDS virus samples provided by Pasteur to NCI. *Id.* at 626. Pasteur alleged that NCI scientists used these samples to acquire information which enabled the U.S. to file patent applications for an HIV diagnostic kit. *Id.*). The Court of Appeals reversed the decision of the U.S. Court of Claims and remanded the case for further proceedings. But an out of court settlement was reached following negotiations between high-ranking U.S. and French officials. An agreement signed by President Reagan and Prime Minister Jacques Chirac provided that credit for the discovery would be shared between the NCI and Pasteur scientists and that income derived from the diagnostic kit patents would be divided between the U.S. and Institut Pasteur (both would, in turn, contribute a percentage of their share of the royalties to a newly created international AIDS research institute). See Howard L. Singer, *Institut Pasteur v. United States: The AIDS Patent Dispute, the Contract Disputes Act and the International Exchange of Scientific Data*, 25 AM. J.L. & MED. 439 (1989). See also Lawrence K. Altman, *U.S. and France End Rift on AIDS*, N.Y. TIMES, Apr. 1, 1987, <http://query.nytimes.com/gst/fullpage.html?res=9B0DE0DF1231F932A35757C0A961948260>.

110. INSTITUT PASTEUR, INSTITUT PASTEUR INTERNAT'L NETWORK & WORLD HEALTH ORG., PARTNERSHIPS 4 (2009), available at <http://www.pasteurfoundation.org/pdf/IP-WHO%20Collaborations.pdf>.

111. The following HHS officials were instrumental in developing the partnership with Institut Pasteur: Dr. H. Clifford Lane, Dr. Carole Heilman, Dr. Stuart Nightingale, Dr. Amar

Thanks to supportive leadership at Pasteur¹¹² and a genuine desire on both sides to close the book on the HIV dispute, HHS and Institut Pasteur executed a memorandum of understanding creating a partnership on influenza surveillance.¹¹³ During this period, HHS also funded influenza surveillance projects in Vietnam,¹¹⁴ reestablished a relationship with the Gorgas Memorial Institute (GMI) in Panama,¹¹⁵ and substantially increased funding for influenza surveillance at the International Centre for Diarrheal Disease Research in Dhaka, Bangladesh (ICDDR,B).¹¹⁶ These partnerships remain active today and form the basis for joint influenza surveillance projects worldwide.

X. THE FUTURE

During the eight years of the Bush Administration, an enormous amount of effort and political capital went into pandemic preparedness. Without this work, the U.S. would not have been in any position during the 2009/2010 season to produce both an annual trivalent vaccine and a special monovalent vaccine (H1N1).¹¹⁷ While the H1N1 pandemic turned out to be substantially less severe than either the 1957 or 1968 pandemics,

Bhat, Capt. Philip Budashewitz, USPHS, Dr. Bruce Gellin, Dr. Linda Lambert, Dr. James LeDuc, Dr. William Steiger, and Lily Engstrom.

112. The partnership with Institut Pasteur would not have been possible without the unwavering commitment of Prof. Alice Dautry, President, Institut Pasteur, Amb. Michele Boccoz, then-Executive Vice President, Institut Pasteur, Dr. Paul Brey, Institut Pasteur's Southeast Asia Regional Advisor and Caitlin Hawke, Executive Director, Pasteur Foundation.

113. *HHS and Institut Pasteur Partner on Pandemic Influenza Preparedness*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (February 6, 2006), <http://archive.hhs.gov/news/press/2006pres/20060206.html> (last visited Nov. 19, 2010). See also *HHS Partnership on Pandemic Preparedness*, PASTEUR FOUND., <http://www.pasteurfoundation.org/dhhs.shtml> (last visited Nov. 19, 2010).

114. *Agreement on Health and Medical Sciences Cooperation Between the Government of the United States of America and the Government of the Socialist Republic of Vietnam*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (July 28, 2009), <http://www.globalhealth.gov/news/agreements/ia072006.html>.

115. *HHS Secretary and Panamanian Health Minister and Gorgas Memorial Institute Agree to Expand Cooperative Public Health Efforts*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (April 14, 2006), <http://archive.hhs.gov/news/press/2006pres/20060414.html>.

116. *HHS Assistant Secretary Simonson Travels to Bangladesh and India to Enhance Planning for a Potential Influenza Pandemic*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (April 27, 2006), <http://archive.hhs.gov/news/press/2006pres/20060427.html>.

117. *Final Estimates for 2009-10 Seasonal Influenza and Influenza A (H1N1) 2009 Monovalent Vaccination Coverage – United States, August 2009 Through May, 2010*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/flu/professionals/vaccination/coverage_0910estimates.htm (last updated Oct. 7, 2010); *2001 H1N1 Vaccine Doses Allocated, Ordered, and Shipped by Project Area*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/h1n1flu/vaccination/vaccinesupply.htm> (last updated Mar. 4, 2010).

imagine what would have happened if H1N1 had been even half as deadly as the 1918 pandemic. Thanks to investments in infrastructure and effective project management at HHS, a special H1N1 vaccine was ready in time to have an impact. But, this may not be the case next time. The fact is that a campaign vaccine made with 1950s technology and totally dependent on chickens is no way to prepare for a threat like the 1918 pandemic. Even with a contingency flock and extreme biosecurity, the current vaccine is vulnerable to catastrophic failure—that is, loss of the flocks that lay the eggs that make the vaccine. And yield remains a major variable that can be better controlled with cell-culture production. But the only way to take influenza off the table as a threat is to develop and license a universal vaccine—one that protects against all influenza viruses and that can be administered in advance of a pandemic strain emerging. Such a vaccine is years away and will require substantial, consistent funding from Congress.

The U.S. and other developed countries also need to do much more to provide pandemic preparedness assistance to the developing world. Today, influenza is essentially a disease of wealthy countries. Not that it only sickens people from such countries—obviously this is not the case. But for those who live in the developing world, there is absolutely no reasonable expectation of ever seeing influenza vaccine or antiviral drugs, no matter how severe the outbreak. So, influenza is a disease of the well-to-do because only the well-to-do can do anything about it. This might be a purely humanitarian concern if it were not for two considerations. First, developing countries are an essential partner in influenza surveillance. Remember H5N1 is widespread in Asia.¹¹⁸ And many countries most at risk for the emergence or re-emergence of novel influenza viruses—viruses with pandemic potential—have absolutely no incentive to spend precious resources on looking for an infectious disease that they can do nothing about. This must change if we expect their full participation in infectious disease surveillance. They must have access to the fruits of their labor—and in time to make a difference. Providing developing countries access to vaccine—and in quantities sufficient to protect them—is one way to incentivize their full participation in the global influenza surveillance enterprise.

The second reason developing countries are important to U.S. pandemic preparedness is that the world is many orders of magnitude more connected today than it was in 1918. We have a vested interest in preventing the developing world from being ravaged by a pandemic. When I say we have a vested interest, I mean this to include a national security interest. Today, manufacturing in the U.S. relies heavily on the developing

118. HHS PANDEMIC INFLUENZA PLAN, *supra* note 70, at B-7.

world for raw materials and constituent components. And so much of what we consume comes from abroad. Last year when H1N1 was still spreading, a British newspaper reported that a U.N. analysis concluded that H1N1 could cause large-scale anarchy in the developing world unless vaccine and antiviral drugs were made available to these countries.¹¹⁹ And H1N1 was known at that time to be a relatively mild virus. Imagine what such a U.N. analysis would say about a 1918-like event.

Logic seems to compel, then, that the U.S. and other developed countries consistently and meaningfully invest in influenza preparedness. We need to improve and secure egg-based infrastructure, license a cell-culture vaccine, discover better diagnostics, and develop a recombinant vaccine. And while it may take years to achieve, our (properly funded) goal must always be a universal influenza vaccine—the Holy Grail of influenza preparedness. As we make advances, we also must ensure that developing countries have meaningful access to these advances and share in our improved ability to protect ourselves. But, all of this takes money and a great deal of it. Now that the H1N1 pandemic is over, there will be enormous pressure to declare victory and move on. Indeed, there has already been at least one attempt to shift funding away from the HHS pandemic preparedness program.¹²⁰ While we have come a long way in the last few years, it is simply not intellectually honest to say that we are ready for a 1918-like event.¹²¹

The 1918 pandemic was a catastrophe and there is absolutely no reason to think it will not happen again—quite the contrary. And while the H1N1 was a mild pandemic, it should remind us how vulnerable we are to the caprices of Mother Nature. The only way to protect ourselves against a 1918-like catastrophe is to invest in the full-range of influenza countermeasures, including recombinant vaccines. In hard times this is a difficult sell. But, if we choose to ignore the danger and take solace in the experience of the H1N1, we will live to regret it.¹²²

119. Rajeev Syal, *Poor Nations Need £900m to Avert Swine Flu Disaster*, OBSERVER, Sept. 20, 2009, at A23.

120. See Matishak, *supra* note 6.

121. See Martin Enserink & Jon Cohen, *The Novel H1N1 Influenza*, 326 SCIENCE 1607, 1607 (2009).

122. It is difficult to overstate the devastation that can be wrought by pandemic influenza. Indeed, the 1918 pandemic has been compared with the Black Death. See ALFRED W. CROSBY, *supra* note 15, at 257 (In discussing factors that influenced morbidity and mortality during the 1918 pandemic, Professor Crosby observed that “[i]f either complacency, incompetency, sickness, or bad luck crippled the ability of the leaders to react efficiently to the pandemic, then Spanish influenza could be as deadly as the Black Death.” *Id.*).

