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Developing A Better Vaccine

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On Sept. 1, Rockville, Md.-based biotech company Novavax announced it had done successful animal testing on an H1N1 vaccine using new cell-based, rather than egg-based, technology. The new development has the potential to expand vaccine supplies while reducing the development time for a vaccine from six months to just one.

While this new vaccine has yet to undergo rigorous FDA testing, it is a remarkable achievement--due in large part to the often unsung efforts of former President George W. Bush.

Back in 2005, Bush gave a speech at the National Institutes of Health calling for a national effort to attack the problem of a potential influenza outbreak--the fear then was avian, not swine, flu. He proposed funding a variety of tools to deal with pandemics. These are the tools that--as we prepare for this fall's expected swine flu resurgence--are helping the U.S. combat what could be an ugly season.

Bush called for spending \$7.1 billion in preparedness funding. Congress ended up spending about half that amount--\$3.3 billion. But recent developments have shown this to have been money well spent. With that money, the government secured some key tools that will give the U.S. more versatility in dealing with potential bio-threats, whether natural or man-made.

This method, the "all-hazards approach," calls for the development of technologies and methods effective enough to handle the expected series of threats but nimble and multipurpose enough to deal with unexpected ones. This is why the tools developed for dealing with avian flu, for example, have also been effective in coping with H1N1.

Short-term tools include anti-viral stockpiling, more high-level exercises to prepare senior government officials for a variety of biological challenges--both natural and man-made--and rapid testing to identify samples and get fast answers back to the local officials who have to make decisions on the ground.

This past spring, the value of some of these tools was revealed. The federal stockpile of antivirals had increased from 2 million to 50 million courses (a course is the prescribed dosage to deal with a virus). At the beginning of the H1N1 outbreak in April, the career officials at the Department of Health and Human Services--without any of the new political leadership confirmed by the Senate--demonstrated how effective the series of exercises over the past few years had been. Rich Besser, Centers for Disease Control and Prevention's acting director at the time, received positive reviews from nearly all quarters for his calming and informative briefings during the crisis.



The federal official who made the biggest error of the whole campaign was Vice President Joe Biden, who almost caused a panic when he advised Americans to stay away from public transportation and closed environments. It is no accident that the misstep came from someone who had not been involved in the preparation of senior executive branch officials that had been taking place over the previous few years.

In addition to the short-term efforts, the Bush administration also undertook a "crash program" to "accelerate cell culture technology." For the last five decades, vaccines have come from eggs, and each vaccine dose grew out of a virus that was injected into an individual, or even multiple, eggs. While this approach was groundbreaking at the time and has saved countless lives, cell-based vaccines have several key advantages over the eggs.

Creating 300 million doses--enough to vaccinate the entire U.S. population--would require 900 million eggs. This is not only wasteful, it could also be dangerous, as an avian flu outbreak could deplete our egg-producing flocks, thereby threatening the U.S. egg supply. Eggs are also perishable, whereas cell lines can be frozen and maintained for a long time. Cell-based vaccines are also easier to create from a technical point of view, as growing virus strains in eggs makes the process longer and more complicated. Finally, people allergic to eggs can use the cell-based, but not the egg-based, vaccines.

In 2006, the U.S. Department of Health and Human Services, recognizing these advantages, spent over \$1 billion in contracts with five different companies to develop cell-based vaccine capabilities in the U.S. The Novavax development shows that the previous administration's efforts are bearing fruit. This is a perfect example of the "all-hazards approach"; it is also a vindication of the use of both short- and long-term investments to prepare for future events.

This progress in developing cell-based vaccine capability is worth celebrating--and we as a nation are now far better prepared to deal with this problem than we were just a few short years ago. Still, more than just improved technologies are necessary should a widespread flu outbreak occur in the next few months. The H1N1 strain is serious and potentially deadly, as we saw from the recent death of a 20-year-old Cornell University student who had no underlying health preconditions.

If a pandemic does strike, the Obama administration will need to ensure that we are also successful with the non-technological aspects of our national flu response. This includes messaging that has the right content, reach, and tone; careful coordination and cooperation, both within the federal government and with state and local partners; and rapid and smooth deployment of the appropriate countermeasures should they be needed. The next few months may determine if we are up to the challenge.

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