



Flu Prevention Saves Lives, Money

Sometimes Government is the Solution

Opinion

By Steve Brozak, Henry Bassman, and Emad Samad



Stephanie Dugger gets a flu shot from nurse Bhagwati Bhakta at Mollen Immunization Clinics in Scottsdale, Arizona on January 10, 2013. (Cheryl Evans/The Arizona Republic/AP Photo)

Link: [See story at ABCNews.com](http://www.abcnews.com)

January 18, 2013 - The U.S. is now in the grip of a nationwide influenza surge that threatens the lives of thousands of people. City and state governments are declaring health emergencies and television personalities are getting vaccinated on live TV. Still, people so greatly misperceive the severity of flu that it became the punch line for a joke during Sunday night's Golden Globe Awards show.

But flu is not a laughing matter. More than 3,700 people have been hospitalized and at least 20 children have already died from flu-related causes since Oct. 1, 2012, when the flu season officially began.

Thousands of people die in the U.S. of seasonal flu each year. Many more are hospitalized and require long recuperation times before they can return to fully active lives. Most of the tragic victims of flu are among the very old, young and sick. The cost of caring for them is staggering.

Influenza prevention and treatment is an area where there is an urgent need to spend money in order to save money and lives. As many as 49,000 people have died of seasonal flu-related causes in one year in the U.S., and many more elsewhere.

Novel influenza strains that pop up unexpectedly can cause many more fatalities. In 2003, an extremely deadly strain of H5N1 avian influenza began infecting people in Asia. The number of cases increased in 2004 and 2005, causing great concern among U.S. government agencies that the disease could spread to the U.S.

In response to the avian flu threat, Congress created the Biodefense Advanced Research and Development Authority (BARDA) in 2006 as part of the Pandemic and All Hazards Preparedness Act. Among BARDA's responsibilities is stockpiling vaccines and antiviral

medicines in the case of a severe flu attack, advancing innovation to protect the U.S. against the flu, and insuring that the U.S. has a manufacturing infrastructure to make the country self-sufficient in combating a flu epidemic.

In 2006, BARDA began to make long-term investments in biodefense- and pandemic-related vaccine production facilities and drugs. Those investments are now starting to bear fruit. Just three months ago, Novartis opened a new vaccine manufacturing plant in North Carolina that was begun in 2006 with \$500 million in funding from BARDA.

This new plant will increase the production speed of seasonal flu vaccines and enable faster response to flu emergencies. It uses the latest vaccine technology, which cultivates the virus used for flu vaccine in 1,250 gallon vats rather than thousands of fertilized eggs in an outdated manufacturing process. In the event of a worldwide pandemic, our nation is guaranteed to have production capacity on our own shores through investments like this one with Novartis.

Vaccine manufacturing went out of vogue decades ago as a high-risk, low-reward endeavor. Without government involvement, large pharmaceutical companies like Novartis wouldn't be able to justify to their stockholders the commitment of capital to build a new vaccine facility in the U.S., especially when other companies are moving vaccine production offshore to countries like China, where they can save several dollars per vaccine and compete in the Chinese marketplace.

The Novartis plant is not the first example of BARDA's efforts paying off. During the 2009-10 flu season, when the H1N1 swine flu struck suddenly and without warning in the U.S., a new vaccine was created, packaged and distributed in a record time of six months, making it available during the second surge of that flu threat. Fortunately, the second surge was milder than the first and the vaccine was not as crucially needed as it could have been. But the experience demonstrated that in an emergency, flu vaccine can now be developed and produced in time to meet an unforeseen threat.

The work to improve response to influenza continues in several government agencies. The National Institute of Allergy and Infectious Diseases (NIAID), which is a part of the National Institutes of Health, under the Department of Health and Human Services, has been leading an effort to develop new and better flu vaccines for more than eight years.

In 2005, when GlaxoSmithKline wanted to produce a vaccine not yet approved for manufacture in the U.S., NIAID staff worked with the company to gain accelerated approval for Fluarix, the branded vaccine that is used widely in the U.S. today. In 2014, an additional component will be added to Fluarix vaccine, giving people immunity to four, rather than three flu subtypes.

The ultimate goal for vaccine research and development is a universal one-shot-for-life vaccine that protects most people against a wide range of flu variants. Previous funding from BARDA and NIAID may have brought that goal within reach. Five vaccine candidates that confer broad immunity against flu have advanced to the first phase of human trials. These candidates were developed by a group within NIAID that is working with the pharmaceutical manufacturer, MedImmune, under a Cooperative Research and Development Agreement.

Efforts such as these will help hold down health care costs. Seasonal flu imposes an \$87.1 billion annual economic burden on the U.S., as estimated in a study by researchers at the CDC. Though the results of government-business cooperative efforts may not be reported on the nightly news, we, as a nation, already reap the rewards of such investments that improve the quality of health care while reducing the economic impact of yearly flu.

But seasonal flu, as tragic and expensive as it can be, is only part of the challenge facing public health agencies. The steps that agencies like BARDA and other divisions within HHS take also protect us from the threat of a novel flu strain that could strike suddenly with devastating impact. The worst-case scenario is a 1918-like flu. In that year there were 500,000 flu-related deaths in the U.S. and as many as 50 million people died worldwide. The potential for a repeat of a flu epidemic of such deadly proportions is the nightmare of many health care professionals. But antiviral development isn't their only concern.

Even among the healthiest people, a common side-effect of an influenza infection is a secondary or opportunistic bacterial infection that develops when the body's resistance is lowered from fighting the flu. These infections can be equally or more life-threatening than the original virus.

Since the late 1940s, antibiotics have been used to battle bacterial infections, but because of the overuse of antibiotics and natural evolutionary processes, the bugs are developing immunity to the antibiotics at an alarmingly rapid rate.

BARDA has funded development of new antibiotics to meet the challenge of increased resistance to drugs currently in use. Last year, Congress incorporated the Generate Antibiotic Incentives Now (GAIN) Act into reauthorization legislation for the FDA. The purpose of this legislation is to extend the exclusivity time for new antibiotics and thereby encourage their development. When these new antibiotics become available, they will provide additional opportunities to reduce flu-related deaths.

The progress made in combating flu is evident in the headlines. Government agencies, scientists and companies are working together to achieve progress in an area that could present a great threat to our nation and its people. The fact that vaccine shortages this season are localized as people rush to get their vaccines and not widespread because of manufacturing issues means they are doing their job to protect us. It also demonstrates that what was once a greatly feared disease appears a lot less frightening to the general public, but only because government planning years ago made it possible.

This work is the opinion of the columnists and in no way reflects the opinion of ABC News.

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