

Flu vaccine: drugmakers could be ready soon

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Fears over infectious outbreaks, from SARS to bird flu to the latest swine-borne virus, have boosted investment in vaccines and fostered fresh approaches.

No one knows yet whether the flu outbreak in Mexico and in states like New York and California will turn into a major pandemic or a forgettable blip in the annals of infectious diseases. It's not even clear exactly what to call the virus, since it seems to have acquired genes from both pigs and birds on its evolutionary journey to making people sick. "As far as we know, this never happened before," says Laurie A. Garrett, senior fellow at the Council on Foreign Relations and author of *The Coming Plague: Newly Emerging Diseases in a World Out of Balance*. Maybe we should call it the swinebird flu.

The good news is that the world—especially the vaccine industry—is far better prepared to deal with a threat such as the new influenza virus than it was just a few years ago. Key decisions to rush through a vaccine have yet to be made. But governments around the world could move quickly to tap the industry's capability if the outbreak continues to worsen. One scenario floated by the Centers for Disease Control in Atlanta: The U.S. government could direct a drug company to drop some of its current development projects, create a swine flu vaccine, and start ramping up manufacturing.

An action like that would be costly and politically fraught. But the surprising thing is that such a step is even possible. That certainly was not the case during the flu season of 2004-2005. Back then, the pharmaceutical industry couldn't make enough vaccine for regular flu. There were only two companies in the business—Aventis Pasteur (now a unit of Sanofi-Aventis (SNY)) and Chiron (since acquired by Novartis (NVS)). One of Chiron's facilities had to be shut down during that outbreak because of safety concerns.

Egg-cultivated vaccines take time

What has occurred in the interim is a vaccine revival fueled by both improved profitability and an increase in government dollars. Three pharmaceutical giants now manufacture flu vaccine: Sanofi-Aventis, Novartis, and GlaxoSmithKline (GSK), along with small players such as MedImmune, a unit of AstraZeneca (AZN). These companies are already gearing up to make the vaccine for next winter's flu season. There's enough capacity among the players to ramp up production of swine flu vaccine—assuming funding is available—and still prepare for the regular flu season.

The bad news? The latest threat can't be squelched quickly or completely with a vaccine produced by traditional methods. The manufacturing process takes months because the virus first must be carefully grown in eggs, then harvested to be turned into a vaccine.

Yet there's possibly a way around this problem. Over the past few years, several companies have sprung up to develop methods for making vaccines more quickly, such as growing viruses in cells rather than eggs. These processes hold considerable promise, but none has been licensed yet by the Food & Drug Administration. One of the difficult decisions the Obama Administration will face if the epidemic threatens to spin out of control is whether to fast-track approval of one of these next-generation vaccines in order to make it available more quickly. "If this turns out to be a crisis, the government might go to one of the newer technologies that has quicker production," explains John Clerici, chair of the life sciences and public health practice at law firm McKenna Long & Aldridge. The bigger the crisis, the greater the tolerance for regulatory risks.

New vaccines are turning big profits

Just a few years ago the pharmaceutical industry was fleeing the entire vaccine arena in droves because it just didn't pay. Making vaccines is a complex operation that requires special expertise and lots of investments in manufacturing. But vaccines were seen as cheap commodities. Global sales for such products in 2004 were a mere \$8 billion, less than those of some individual blockbuster drugs.

Since then, however, the economics have changed. Companies have learned that vaccines can be a premium product, not a low-margin commodity. Wyeth paved the way with its vaccine against pneumococcal bacteria, charging a high price—now \$84 per dose—instead of the few dollars most vaccines commanded. Sales exceeded \$2 billion by 2007. In fact, Wyeth's strong vaccine business was one reason the company was snapped up by Pfizer (PFE) earlier this year.

Since then other companies have launched high-priced vaccines. Merck's (MRK) Gardasil for human papillomavirus (HPV), which causes cervical cancer, goes for a cool \$130 per dose. The company reported sales of \$262 million for the vaccine in the first quarter of 2009. GlaxoSmithKline sells a similar HPV vaccine in 95 countries while awaiting approval in the U.S., and the company's vaccine pipeline is now often seen as more promising than its drug pipeline. "Vaccines are a critical part of our business model. They are viewed as a high-growth area for the company," explains Glaxo spokesperson Sarah Alspach. The company purchased Canada's flu vaccine maker ID Biomedical in September 2005 for \$1.5 billion, and has beefed up its own research team in Belgium. Under development are vaccines for such diseases as herpes, malaria, dengue, and several cancers.

Snapping up vaccine startups

The vaccine industry also got a multibillion-dollar boost from Uncle Sam. In 2005, worried that the country was unprepared for flu and other threats, Congress authorized \$7.1 billion to get ready for a pandemic. Some of it went to stockpile the flu drugs Tamiflu (Roche) and Relenza (Glaxo), but about \$1 billion went to companies to develop cell culture methods for producing influenza vaccines. "The government has put a serious marker down—\$7.1 billion is a lot of money," says Clerici, who helped write the original legislation. "There's no question a very nice foundation has been laid, and a lot of planning and thought has gone into it."

The dollars from both the private markets and the government, in turn, have led Big Pharma to grab promising vaccine startups wherever it can. Last year, for instance, Sanofi-Aventis put down \$482 million to acquire Britain's Acambis, which was developing vaccines for smallpox, West Nile, herpes, and other illnesses. And in 2006, Pfizer acquired Britain's PowderMed, which developed a method to shoot DNA vaccine molecules bound to microscopic gold particles directly into the skin.

The progress in vaccines hasn't gotten much attention since the threat of SARS and avian flu last loomed large. But quietly the industry has grown far more adept at tackling a crisis than it was just five years ago. And investors have taken notice. On Apr. 27, Glaxo's stock jumped 6% in Europe and 7.5% in the U.S., with analysts attributing the rise to interest in vaccines. On the same day, Rockville (Md.)-based Novavax (NVAX)—which is developing a fast method for making vaccines—soared 79.6%.

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