Fight for swine flu vaccine could get ugly

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(AP) -- An ugly scramble is brewing over the swine flu vaccine - and when it becomes available, Britain, the United States and other nations could find that the contracts they signed with pharmaceutical companies are easily broken.

Experts warn that during a global epidemic, which the world is in now, governments may be under tremendous pressure to protect their own citizens first before allowing companies to ship doses of vaccine out of the country.

That does not bode well for many nations, including the United States, which makes only 20 percent of the regular flu vaccines it uses, or Britain, where all of its flu vaccines are produced abroad.

"This isn't rocket science," said Michael Osterholm, director of the Center for Infectious Diseases Research and Policy at the University of Minnesota. "If there is severe disease, countries will want to hang onto the vaccine for their own citizens."

Experts say politicians would not be able to withstand the pressure.

"The consequences of shipping vaccine to another country when your own people don't have it would be devastating," added David Fedson, a retired vaccine industry executive.

About 70 percent of the world's existing flu vaccines are made in Europe, and only a handful of countries are self-sufficient in vaccines.

The U.S. has limited flu vaccine facilities, and because factories can't be built overnight, there is no quick fix to boost vaccine supplies.

Earlier this week, the U.S. Department of Health and Human Services announced it was spending $884 million to buy extra supplies of two key ingredients for a swine flu vaccine. The U.S. has contracts to get swine flu vaccines from Sanofi Pasteur, MedImmune, GlaxoSmithKline and Novartis. Sanofi Pasteur and MedImmune both have vaccine plants in the U.S., while GlaxoSmithKline and Novartis have plants in Europe.

Even if the U.S. held onto all the swine flu vaccine produced domestically, it would still not be enough for all Americans.

About 80 million Americans are vaccinated against the seasonal flu every year. In 2004, when problems with the U.S.' flu vaccine supply at a British factory hit, there were less than 54 million shots available. Flu vaccines were saved for those in high-risk groups like the elderly and pregnant women, and officials asked other people to simply forgo their usual flu shot.

If there are limited swine flu shots during a pandemic that turns more serious, experts are not sure people will be as willing to skip getting a vaccine.

Last week, the World Health Organization reported nearly 95,000 cases of swine flu, including 429 deaths worldwide. If swine flu turns deadlier in the winter, the main flu season in the Northern Hemisphere, countries will likely be clamoring for any available vaccines.

"Pandemic vaccine will be a valuable and scarce resource, like oil or food during a famine," said David Fidler, a professor of law at Indiana University who has consulted for WHO. "We've seen how countries behave in those situations, and it's not encouraging."

Britain claims it will start vaccinating people in August, Italy says it will begin by the end of the year, and many other countries have similar strategies. Those mass vaccination plans could be derailed by problems making the vaccine and by other countries' refusal to ship it abroad.

If the virus remains mild, this could all be moot. Experts estimate swine flu to be about as dangerous as seasonal flu, and there usually isn't a high demand for those vaccines. Still, regular flu kills up to 500,000 people a year.

In past pandemics, or global epidemics, vaccines were never exported before the country that produced them got enough for its own population first.

Unlike the last two pandemics in 1957 and 1968, however, many more countries this time around have struck deals with companies which they say guarantee them first access to vaccine. Yet in a global health emergency, those contracts may ultimately be meaningless.

Countries with flu vaccine plants might decide to seize all vaccines and ban their export, thus breaking the pharmaceutical contracts promising other countries vaccine supplies. These private contracts are not binding international law between two countries, according to Fidler.

He said most vaccine contracts include a clause allowing them to be broken under extraordinary circumstances, such as a health emergency. That would leave the countries who had brokered such deals not only without vaccine, but without legal recourse.

"There's nothing in international law that helps you resolve this, it's just a political nightmare happening in the midst of an epidemiological nightmare," Fidler said.

Britain has ordered 60 million doses, enough to cover its entire population. But those doses are being manufactured by GlaxoSmithKline PLC and Baxter International Inc., whose production plants are in Germany, Austria and the Czech Republic. Neither Britain's department of health or the vaccine manufacturers would comment on delivery plans.

On Thursday, Britain's chief medical officer estimated that as many as 75,000 Britons could eventually be killed by the swine flu pandemic, if 1 in 3 people are infected.

Osterholm said about 80 percent of the United States' pandemic vaccine supply will be coming from abroad and he is very concerned about when it might arrive. Timing could be everything to avoid a vaccine spat.

"It's easy to move vaccine around if the disease is relatively mild. But if it is more severe, countries may not be willing to let it go," he said.

So far, swine flu remains a relatively mild disease, and most people don't need medical treatment to get better. But experts fear the virus could mutate into a more dangerous form. And during the flu season, when the virus spreads more easily, more people will probably fall sick and die.

Public health officials are aware that so-called "vaccine wars" might break out if the swine flu outbreak worsens, but are loathe to even discuss the topic.

The European Centre for Disease Prevention and Control, an agency of the European Union, said it had no mandate to advise countries in such circumstances. WHO said it was not aware of any nations planning to block the shipment of vaccines and said it would work to ensure all countries get enough doses to protect their health workers.

Questions also remain about when a swine flu vaccine will even be available, as WHO reported this week that a fully licensed vaccine might not be ready until the end of the year.

With little or no safety data about a swine flu vaccine, governments that are planning to roll out mass campaigns are taking a gamble, since any rare side effects won't show up until millions of people start getting the shots.

Experts say government promises about when vaccines will arrive should be taken with a huge grain of salt.

"Many pieces of the puzzle are missing," Osterholm said. "Anyone who pretends to have a well-defined schedule of vaccine delivery is obviously very poorly informed."

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