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## Flu Drugs May Do More Harm Than Good, Researchers Find

By Oliver Staley - Apr 9, 2014

Tamiflu and Relenza, antiviral drugs stockpiled by governments to tame influenza outbreaks, haven't been proven to prevent pandemics and may cause more harm in some patients than good, researchers said after reviewing 170,000 pages of clinical-trial data.

The findings, published today in the journal BMJ, came from the Cochrane Collaboration, a nonprofit U.K. research organization, using information obtained from [Roche Holding AG \(ROG\)](#), maker of Tamiflu, and [GlaxoSmithKline Plc \(GSK\)](#), which sells Relenza.

The U.S. has spent \$1.3 billion, and the U.K. 424 million pounds (\$710 million), stockpiling the drugs following a 2009 outbreak of the H1N1 swine flu. The Cochrane researchers, who examined the reports of 20 Tamiflu trials and 26 Relenza studies, found Tamiflu reduced flu symptoms for adults by 17 hours without curbing the number of hospitalizations. Tamiflu also caused vomiting, delirium and loss of kidney function in some patients. There was no evidence that using the treatments could stop a massive outbreak, the researchers said.

"There's no credible way these drugs could prevent a pandemic," [Carl Heneghan](#), one of the authors of today's study and a professor of evidence-based medicine at the University of Oxford, said at a media briefing in [London](#). Money spent on stockpiling "has been thrown down the drain."

Policy makers need better information to make decisions about buying medicines, and they can't depend on manufacturers for unbiased data, said Fiona Godlee, editor-in-chief of the BMJ, at the briefing.

### Irreducible Conflict

"Drug companies have an irreducible conflict of interest," Godlee said. "It's not in their interest to create a clear picture of a drug."

Roche hasn't broken any laws, and much of the responsibility falls on the [European Medicines Agency](#), which regulates such products in [Europe](#), and the politicians who authorized the stockpiling, Godlee said.

“It was a system-wide failure,” she said. “This should lead to serious soul searching among policy makers. The current system is clearly broken.”

Roche, based in [Basel, Switzerland](#), recorded [revenue](#) of 3.2 billion Swiss francs (\$3.6 billion) in sales from Tamiflu in 2009 when sales increased in response to the swine flu outbreak.

Tamiflu has been approved by regulators in more than 100 countries and used to treat 130 million patients, said Barry Clinch, Roche’s global development leader for Tamiflu, in a phone interview. The product label packaged with the drug spells out all the possible side effects, Clinch said.

## Roche Study

“We stand behind our data and we stand behind our label,” he said. “We haven’t changed it on the basis of any previous Cochrane review and we won’t change it on the basis of this one.”

Clinch pointed to a [study](#) conducted by the University of Nottingham that showed products like Tamiflu may reduce the risk of death by 19 percent. Roche funded the study, he said.

The European Medicines Agency said it used 43 studies in its approval of Tamiflu, 18 of which were included in the Cochrane review. The agency stands by its initial assessment.

“The review, we believe, supports our benefits-risk assessment and does not raise any new concerns that would not be already addressed in the product information,” said Enrica Alteri, head of EMA’s Human Medicines Evaluation Division.

The EMA doesn’t have the means to provide advice to governments on whether a drug should be stockpiled, Alteri said.

In a statement, London-based Glaxo said the data shows its Relenza drug is effective “and when used appropriately, in the right patient, it can reduce duration of flu symptoms.”

## 170,000 Pages

[Cochrane](#) received almost 400,000 pounds from the U.K. government to produce the study, Heneghan said. The group first began examining the efficacy of Tamiflu in 2009 and asked Roche to supply information. It wasn’t until last year that researchers received 170,000 pages of clinical trial data.

Their analysis revealed flaws in how some of the trials were conducted, said Tom Jefferson, another of the authors. In one study, the color of the placebo capsule was different from the medicine, suggesting the trial administrators knew which was which and no longer making the trial double blind, he said. In another study to determine if Tamiflu was effective against

pneumonia, doctors asked patients if they had the disease, rather than using X-rays, he said.

“The outcomes on pneumonia is not something we can take very seriously,” Jefferson said.

Only one trial was conducted on whether Tamiflu could prevent a pandemic, and its design meant the results were inconclusive, he said.

## Reducing Symptoms

Given the side effects, the drugs might cause more harm than good, Jefferson said.

“Why did they stockpile? What was the rationale?” he said. “The evidence doesn’t support it.”

Other researchers said Tamiflu and Relenza may still be effective, particularly if taken before signs of illness appear. Reducing symptoms by half a day in a disease that only lasts six days makes a difference in getting people back to school and work, said Wendy Barclay, a professor of influenza virology at [Imperial College London](#).

Much of the Cochrane’s criticisms were aimed at the design of the clinical trials, Barclay said in a statement.

“Influenza virus infections can lead to death,” Barclay said. “It would be awful if, in trying to make a point about the way clinical trials are conducted and reported, the review ended up discouraging doctors from using the only effective anti-influenza drugs we currently have. This might be particularly important in a pandemic before a vaccine is available.”

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