

# Roche Flu Medication Fraud Stole Billions

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## STORY AT-A-GLANCE

- › A whistleblower lawsuit has been filed against drugmaker Roche over influenza medicine Tamiflu
- › The suit alleges the company made false claims and misrepresented studies, causing the U.S. government to stockpile \$1.5 billion of the drug for use during potential pandemics
- › The whistleblower lawsuit alleges that Roche knew Tamiflu was ineffective at fighting influenza pandemics but went ahead and “masterfully marketed this drug to fill Roche’s coffers at taxpayer expense”
- › The lawsuit was filed under the False Claims Act by Dr. Thomas Jefferson, who has been questioning Tamiflu’s effectiveness since 2009
- › Because the False Claims Act mandates payment of triple damages along with civil penalties, Roche could face a judgment in excess of \$4.5 billion

**A whistleblower lawsuit has been filed against drugmaker Roche, alleging the company made false claims and misrepresented studies, causing the U.S. government to stockpile \$1.5 billion of its influenza medicine Tamiflu (oseltamivir).<sup>1</sup>**

**The lawsuit was filed by Dr. Thomas Jefferson, a researcher associated with the Cochrane Collaboration research network, under the False Claims Act, in which individuals may file suit on behalf of the government. Jefferson has been questioning Tamiflu’s effectiveness since 2009.**

The lawsuit, which was unsealed in September 2019, alleges Roche duped the U.S. government into stockpiling Tamiflu while misrepresenting its effectiveness. According to the Houston-based Lanier Law Firm, which filed the suit:

*“The lawsuit claims the drugmaker’s scheme involved publishing misleading articles falsely stating that Tamiflu reduces complications, severity, hospitalizations, mortality and transmission of influenza.*

*The company then used those articles to aggressively market the drug to the government for pandemic use. Relying on the supposed truthfulness of Roche’s claims, federal and state governments spent about \$1.5 billion to stockpile Tamiflu to combat influenza pandemics.”<sup>2</sup>*

## **‘Multisystem Failure’ Involved in Tamiflu’s Success**

Antiviral drugs like Tamiflu are still recommended by government agencies like the U.S. CDC,<sup>3</sup> despite long-standing studies questioning their effectiveness and safety.

At one point, the World Health Organization even classified Tamiflu as an “essential” medicine even though scientists like Peter Doshi, Ph.D., had already begun to question whether it worked any better than Tylenol.<sup>4</sup> By 2015 several researchers were questioning the risk-benefit ratio of the drug,<sup>5</sup> and it was ultimately downgraded by the WHO in 2017.<sup>6</sup>

In July 2017, WHO moved Tamiflu from a “core” essential medicine to a “complementary” drug, which is used for those that are less cost effective.<sup>7</sup> (To clarify, a correction to the article was published in November 2017, saying the drug was still on the essential list, but “downgraded.”<sup>8</sup>)

In a BMJ editorial, Mark Ebell, professor of epidemiology at the University of Georgia, called the move “far too late” and described a multisystem failure that allowed Tamiflu to become a blockbuster medication.<sup>9</sup> According to Ebell:<sup>10</sup>

*“Oseltamivir (Tamiflu) was approved by the US Food and Drug Administration in 1999 for the treatment of uncomplicated influenza within 48 hours of the onset of symptoms. The manufacturer’s press release stated that the drug was studied in two randomised trials enrolling a total of 849 patients with influenza and reported a 1.3 day mean reduction in the duration of symptoms.*

*The drug was described as safe, with less than 1% of patients discontinuing it because of adverse effects. It was approved by the European Medicines Agency in 2002. On the basis of these limited (and ultimately revealed as incomplete) data, governments acted.*

*Concerned about a possible outbreak of avian influenza, as well as the H1N1 pandemic in 2009, the UK government stockpiled oseltamivir at a cost of over £600m (€680m; \$770m) from 2006 to 2014. Similarly, the US government has spent over \$1.5bn stockpiling the drug, based on recommendations from the Centers for Disease Control and Prevention (CDC).”*

Examples of system-wide failures that let Tamiflu slip through regulatory cracks included a failure to publish all available evidence and make that data available at the individual patient level, along with a failure of recognizing the limitations inherent to observational data.

It wasn’t until repeated requests from The BMJ were honored that data from unpublished trials were released to researchers, revealing the true extent of Tamiflu’s effectiveness – or lack thereof.<sup>11</sup>

## **Tamiflu Reduced Duration of Flu by Just 16.8 Hours**

In the BMJ review of Tamiflu it’s found that Tamiflu shortened the duration of flu symptoms by less than a day, specifically, by just 16.8 hours, and did not affect the number of hospitalizations.<sup>12</sup> In exchange for this very modest benefit, Tamiflu caused nausea and vomiting and increased the risk of headaches and renal and psychiatric syndromes.

“The trade-off between benefits and harms should be borne in mind when making decisions to use oseltamivir for treatment, prophylaxis or stockpiling,” the researchers added.<sup>13</sup> What’s more, in a Cochrane Review of the data on both Tamiflu and Relenza (zanamivir), another antiviral drug, Jefferson and colleagues noted:<sup>14</sup>

*“Based on our assessments of the regulatory documents (in excess of 160,000 pages), we came to the conclusion that there were substantial problems with the design, conduct, reporting and availability of information from many of the trials ... We identified problems in the design of many of the studies that we included, which affects our confidence in their results.”*

Further, the review noted that the drugmakers’ proposed mechanism of action, which suggests the drugs work via a multisystem and central action, does not fit with the clinical evidence they reviewed. Any beneficial effects of the drug may have occurred due to lowering levels of pro-inflammatory cytokines or via depressing the central nervous system, not by actually inhibiting the replication of the influenza virus.<sup>15</sup>

## **Tamiflu Causes Psychiatric Symptoms**

Tamiflu and Relenza are part of a group of anti-influenza drugs called neuraminidase inhibitors, which work by blocking a viral enzyme that helps the influenza virus to invade cells in your respiratory tract.

The problem is that your nervous system also contains neuraminidase enzymes essential for proper brain functioning, and when blocked with these dangerous drugs, severe neurotoxicity may ensue, especially in the infants and children whose blood-brain barrier has not yet developed sufficiently.

Serious side effects include convulsions, delirium or delusions and suicidal behavior. In January 2020, an Oregon woman warned that her son experienced hallucinations while taking the drug, telling a news outlet, “He was saying that everything was going fast and that everything was in fast forward. He was hearing voices. He was seeing things. He was crying and grabbing his head and it was really scary.”<sup>16</sup>

The boy's pediatrician said the hallucinations were due to Tamiflu, and Dr. James Shames, Jackson County medical health director, likewise stated, "Psychiatric symptoms are more unusual. It wasn't even recognized until after the drug had been released and they started doing further studies. It does look like it occurs more commonly in children."<sup>17</sup>

In another report, a 6-year-old girl in Texas also had hallucinations while taking Tamiflu and even tried to jump out of a second story window.<sup>18</sup> A 16-year-old boy with no prior suicidal thoughts or depression also committed suicide less than 24 hours after taking the drug, which his parents believe is what caused the suicide to occur.<sup>19</sup>

Japan banned the use of Tamiflu in children and teens in 2007, after cases of teenagers trying to jump from apartment building windows while taking the drug. In 2018, the country lifted the ban, but still said the relationship between Tamiflu and the unusual actions is unclear and patients should be warned of such side effects.<sup>20</sup>

## **Corruption Surrounding Tamiflu**

Corruption has surrounded Tamiflu from the start. Former U.S. Defense Secretary Donald Rumsfeld was made the chairman of a company called Gilead in 1997. While drug company Roche manufactured Tamiflu, it was developed by Gilead decades ago, and they gave Roche the exclusive rights to market and sell the drug in 1996 (an agreement they attempted to terminate in 2005).<sup>21</sup>

Rumsfeld held major portions of stock in Gilead and was reported to have made more than \$5 million from selling shares of the company around the time of the bird flu hoax in 2005. Rumsfeld was on the board of Gilead between 1988 and 2001, and when he left to join the Bush administration he reportedly retained a large shareholding (worth \$25 million or more).

Roche also engaged in extensive lobbying to influence countries to stockpile Tamiflu, including in Denmark. In a 2018 review published in the Journal of Public Health,

researchers investigated how members of Denmark's pandemic planning committee experienced lobbying efforts by Roche, noting:<sup>22</sup>

*“Roche promoted Tamiflu using two arguments: that the procurement deal had to be signed quickly because the drug would be delivered on a first-come, first-served basis, and that Denmark was at heightened risk in the event of a major influenza outbreak because it had a smaller Tamiflu stockpile than other countries.*

*One informant pointed to how Roche ‘toured’ Denmark and neighbouring countries to ratchet up the volume of Tamiflu stockpiles. Interestingly, and in line with this allegation, in March 2005 Roche sent an official letter directly to the Swedish Minister of Health and Social Affairs (and copies to the Director Generals of the National Board of Health and Welfare and the Crisis Management Agency) that exactly repeated these two arguments ...*

*Furthermore, Roche practised tactics that included both lobbying through direct contact and lobbying through a seemingly independent third party, i.e. the DSI [Danish Health Institute].*

*In addition, some interviewees suspected third party lobbying via colleagues. The DSI was established by the public sector to conduct independent research, yet it still agreed to act on behalf of the company – quite a disturbing finding.”*

## **Lawsuit Alleges Roche Knew Tamiflu Was Ineffective**

The whistleblower lawsuit alleges that Roche knew Tamiflu was ineffective at fighting influenza pandemics but went ahead and “masterfully marketed this drug to fill Roche’s coffers at taxpayer expense,” Clayton Halunen of Halunen Law said. “This is precisely the type of corporate behavior the False Claims Act is designed to stop.”<sup>23</sup>

Because the False Claims Act mandates payment of triple damages along with civil penalties, Roche could face a judgment in excess of \$4.5 billion. Attorney Mark Lanier, of Lanier Law Firm, added:<sup>24</sup>

*“As alleged in the complaint – Tamiflu does not do what Roche promised. Roche hid this fact for many years by selectively citing its studies and suppressing the data about Tamiflu. The company utilized lobbyists, key opinion leaders and ghostwriters to promote Tamiflu with a deceptive promise to governments fearful of an influenza pandemic.”*

Even in the face of such damning evidence, Roche still attempted to have the courts dismiss the suit. They weren't successful, though, and a Maryland federal judge formally denied it in September 2020.<sup>25</sup>

While Roche is on trial for fraud, the fact remains that Tamiflu is likely to do little to help in the event you or a loved one comes down with flu, and it could end up causing harm. Prevention is a far better option, and along these lines vitamin D testing and optimization has been shown to cut your risk of respiratory infections, including colds and flu, in half if you are **vitamin D deficient**.<sup>26,27</sup>

In my view, optimizing your vitamin D levels is one of the absolute best respiratory illness prevention and optimal health strategies available. Influenza has also been treated with high-dose vitamin C,<sup>28</sup> and taking zinc lozenges at the first sign of respiratory illness can also be helpful.

Following other basic tenets of health, like eating right, getting sound sleep, exercising and addressing stress are also important, as is regularly washing your hands – sound advice for staying healthy not only during flu season but also year-round.

## Sources and References

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- <sup>20</sup> [The Mainichi May 17, 2018](#)
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