



Pfizer Inc
235 E. 42nd Street
New York, NY 10017-5755
USA

John Clark
Chief Security Officer, Pfizer
Vice President, Global Security

March 28, 2014

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight & Investigations
Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington DC, 20515

Dear Chairman Murphy,

Thank you for this opportunity to expand upon my recent testimony before the Subcommittee on Oversight and Investigations as part of its hearing on *Counterfeit Drugs: Fighting Illegal Supply Chains*. For Pfizer, as for the members of your Committee, counterfeit medicines are first and foremost a matter of patient health and safety.

My responses to the three additional questions for the record posed by The Honorable Renee Ellmers are as follows:

1. Mr. Clark, given your experience in law enforcement and now at Pfizer, what additional tools could Congress and/or the Administration provide to help combat this threat to patient safety?

Current regulations and procedures impede the ability of rights holders to assist Customs and Border Protection (CBP) in determining whether goods being imported into the U.S. are authentic or counterfeit. Congress could enhance the ability of rights holders, such as Pfizer, to prevent counterfeit medicines from reaching patients in the U.S. by passage of the Customs Authorization Act or other legislation that would permit CBP to provide rights holders with unredacted photographs or samples of goods and/or packaging to facilitate their authentication.

Historically, IPR holders had provided invaluable assistance to CBP by authenticating suspect merchandise before it entered the stream of commerce in the U.S. In 2008, however, CBP advised its personnel that disclosing certain "identifying information" – including serial numbers, batch/lot numbers and barcode clearly visible on the packaging – to rights holder was a violation of the Trade Secrets Act, a criminal misdemeanor. The failure to disclose such information to rights holders, such as Pfizer, impedes their ability to determine the authenticity of "suspect" articles.

Interim CBP Regulations, introduced in 2012 purportedly to address this problem, failed to do so, providing rights holders access to redacted images only after a delay of seven days to afford the importer an opportunity to demonstrate that the suspect articles were not counterfeit.

The Customs Reauthorization Act would amend the Tariff Act of 1930, providing rights holders with immediate access to unredacted images and samples of the suspect merchandise.

Additional information from CBP on the source of goods detained and seized would also facilitate our ability to initiate pro-active investigations to disrupt counterfeits at or near their source, more effectively protecting patients in the US and around the world.

2. Mr. Clark, I have a Pfizer vaccine manufacturing facility in my district and as a former health care provider I recognize the importance of vaccination in preventing serious diseases for people in the US and abroad. Have Pfizer vaccines been counterfeited and if so where is it happening?

In June 2010, based on evidence referred by Pfizer Global Security, authorities seized counterfeit doses of Pfizer's Prevnar from a pediatric clinic in El Salvador. The seizure of empty vials and stoppers indicated that doses of the counterfeit vaccine had been administered to patients at the clinic. Further investigation led to the identification and arrest of an individual who was distributing the counterfeits to several clinics in El Salvador.

Lab tests on a sample of the counterfeit vaccine confirmed not only that it was counterfeit, but also that it was missing a critical ingredient, impacting its efficacy.

Are counterfeit vaccines making their way to the US?

To date, we have not confirmed the presence of counterfeit versions of Pfizer's Prevnar in the US. I cannot speak to the presence of counterfeit versions of vaccines produced by other pharmaceutical companies.

3. Mr. Clark, Pfizer is located in Sanford NC, which is in my district, and according to your testimony Pfizer launched a robust Internet Program in 2006 to identify and disrupt rogue online pharmacies (OLPs) that dispensed counterfeit Pfizer medicines to unsuspecting patients. Can you please update me on recent program activities and what you have been able to identify through this program since 2011?

Patients in the US are most at risk for receiving counterfeit medicines when they order their medicines online, often without a valid prescription, from OLPs that have not been certified by the National Association of Boards of Pharmacies. To supplement monitoring activities of OLPs, begun in 2006, we have

- Collaborated with Microsoft in takedown of Rustock botnet, thought to be responsible for between 20 and 40% of all internet SPAM and sites dispensing counterfeit medicines (2011)*
- Replaced "cybersquatting" OLP, which used Pfizer name or product trademark in its URL, with Public Service Announcement advising patients (1) that the medicines sold were counterfeit and (2) how to buy safely online (2011)*
- Disrupted call center in Philippines that employed as many as 200 agents to call patients in the US, UK and Australia, encouraging them to refill orders for Viagra and other ED medicines (2012)*
- Extended monitoring efforts to ads appearing on Craigslist, made test purchases, referred sales of counterfeit Viagra to law enforcement, resulting in arrests across the US, including California, Florida, Maryland and Missouri, and Canada (2012 to present)*
- Launched OLP Disruption Program, in collaboration with Microsoft, to disrupt OLPs by disabling domains to disrupt web traffic and eliminating ability to process credit card*

transactions, resulting in takedown of two affiliate networks and disruption of more than 3200 OLPs (2013)

Sincerely,

A handwritten signature in blue ink, appearing to read "John P. Clark". The signature is stylized and cursive.

John P Clark

cc: John Halliwell, Ken Cole