STATEMENT OF
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before the

Subcommittee on Oversight and Investigations
House Energy and Commerce Committee
February 27, 2014

"Counterfeit Drugs: Fighting Illegal Supply Chains"

My name is Jean-Luc Moreau and I am the Global Head of Product Security for Novartis International AG. I am a French National and former Senior Officer and veteran with 25 years' experience in the French military. My overarching responsibility at Novartis is to protect the company, its products, and, most importantly, the individuals who rely on Novartis' medicines from counterfeit, substandard, adulterated, or expired medications. To this end, I coordinate the Group Brand Integrity Program which embraces all of Novartis' functions and divisions. I also manage a Group Product Security Steering Committee and a team which specializes in detecting and investigating counterfeiting and other product security incidents in the 140 countries in which Novartis currently does business. My many years of personal experience in this arena affirm the following well-documented facts:

- Drug counterfeiting is a pervasive and rapidly expanding global problem engineered by increasingly sophisticated and resourceful criminal enterprises.

- The products peddled by these illicit operations are fakes, produced, labeled, and packaged to mislead patients, health care givers, and others in the legitimate distribution chain into believing that the drugs are genuine.
- Pharmaceutical counterfeiting causes very real and serious harm to public health and safety: patients who need medicines to treat diseases, relieve pain, or save their lives don't get them; public confidence in drug manufacturers, pharmaceutical therapies, and health care delivery systems is eroded; patients who take products adulterated with dangerous impurities may be injured or die; and drug resistance is accelerated.
- The proliferation of drug counterfeiting operations is facilitated by a multiplicity of factors including, inter alia: countless unregulated Internet pharmacies which make fake products easily available anywhere on the globe; the absence of strong and qualified regulatory agencies in many countries; minimal risks of prosecution and relatively low penalties (even in the United States); and the lack of effective import/export controls.

Novartis Has a Compelling interest
In Preventing Drug Counterfeiting

Novartis is a multinational research-based health care business with its corporate global headquarters in Basel, Switzerland and U.S. headquarters in East Hanover, New Jersey. Novartis has approximately 135,000 employees worldwide, 27,000 of whom are located in the United States. In 2013 alone, Novartis invested $9.9 billion in the research and development of new

pharmaceutical therapies. Across all of its divisions, Novartis' product line includes drugs, vaccines, devices, and surgical appliances to treat conditions such as cancer, multiple sclerosis, diabetes, hypertension, Alzheimer's disease, high cholesterol, epilepsy, organ rejection in transplants, and eye and vision care. All in all, Novartis manufactures and markets an extensive line of products across its diverse health care portfolio including innovative pharmaceuticals, eye care products, generics, consumer health products, vaccines, and diagnostic tools that are made available in 140 countries. Unfortunately, many of these products have been the target of pharmaceutical crime such as counterfeiting and diversion including Glivec (cancer), Exelon (Alzheimer's), Diovan (high blood pressure), Neoral (immunosuppressant for organ transplants), Zometa (bone cancer), Femara (breast cancer), Optalidon (pain), and Coartem (malaria).

Novartis attaches an extremely high priority to ensuring that patients using Novartis products, and the physicians who prescribe them, have complete confidence that its drugs are safe and effective. If patient and prescriber trust in Novartis products is compromised, patients will not take medicines that can ease their pain, treat their diseases, or save their lives. In addition, the reputation of the company will suffer and its ability to spend billions of dollars on researching and developing new therapies will be jeopardized. For these reasons, Novartis has dedicated considerable manpower and financial resources to combating drug counterfeiting on a global scale. Novartis works closely with law enforcement and health authorities in numerous countries to investigate and suppress the counterfeiting of its products and to ensure that drugs purchased from Internet pharmacies are authentic, safe and effective.

Pharmaceutical Counterfeiting Is Pervasive and Pernicious

Counterfeiting is an enormous global business which will grow rapidly if left unchecked. It has been estimated that in 2010, activities related to counterfeit drugs generated revenue of $75 billion and that an annual rate of growth of 20 percent in such revenue is not unrealistic.

Experts on drug counterfeiting believe that 1 percent of the drugs in the developed world, including the U.S. and Europe, are fake. In developing countries, between 10 and 50 percent are thought to be counterfeit. In some underdeveloped countries, fake products could comprise as much as 70 percent of the drug supply. According to the Pharmaceutical Security Institute, there were 1,664 new counterfeiting incidents reported in 2012, a 2.2 percent increase over the prior year. During this period, there were 483 counterfeiting incidents involving 207 different pharmaceutical products which impacted the legitimate supply chain in 47 separate countries.

The pernicious impact of counterfeit pharmaceuticals must not be measured exclusively by statistics because the toll on human life is staggering. For example, the World Trade Organization has estimated that counterfeit anti-malaria drugs kill 100,000 Africans annually. More generally, 700,000 deaths a year have been attributed to counterfeit drugs. Although it is impossible to estimate the number of individuals whose health was jeopardized because they took a counterfeit drug, the number could easily be in the millions.

A counterfeit drug may be defective for many reasons. The drug may contain no active pharmaceutical ingredient (“API”), too little or too much API, or the wrong API. It may be

adulterated and contain dangerous impurities. The products may be expired and relabeled to reflect a new expiry date and/or they may have incorrect or misleading labeling. Counterfeiters have developed the capability to produce fake products and package them in ways which make them virtually indistinguishable from the genuine drug. See Attachments 1, 2, and 3. Counterfeiters are also adept at evading technological solutions to pharmaceutical crime. For example, Russian counterfeiters went so far as to add holograms to the packaging for their fake products. The hologram carried the statement: "Protected against counterfeits". See Attachment 4.

Counterfeit drugs are frequently made in substandard facilities most of which are downright filthy. Novartis manufactures its pharmaceuticals in state-of-the-art facilities which comply with FDA good manufacturing practices. See Attachments 5 and 6. By contrast, counterfeiters produce their illicit products in decrepit conditions. See Attachments 7, 8, 9, and 10. Counterfeiting operations ship and/or store their fake products under unsanitary and inappropriate conditions. See Attachments 11, 12, 13, and 14. Drugs not stored and shipped under proper conditions can lose their potency or become totally useless, if not harmful.

Modern Drug Counterfeiting Operations
Are Often Highly Sophisticated

Pharmaceutical counterfeiting in today's world is often highly organized, transnational, and industrialized. Drug counterfeiters are aggressive, diversified, and utilize highly detailed and flexible business strategies. They have the capability to target low volume/high margin products in the oncology, cardiovascular, and neurosciences fields as well as high volume/low margin products such as over-the-counter drugs, generic medicines, and vaccines. The

operations can reach patients directly through the Internet or street dealers in Africa and elsewhere. They have the capacity to infiltrate legitimate supply chains as they have in the Middle East, Latin America, Southeast Asia, and Sub-Saharan Africa. Counterfeiters operate illicit and unregulated industrial production facilities, many of which have the capacity to flood markets with fake products.

Counterfeiting syndicates operate business models parallel to the legitimate supply chain with geographically diverse manufacturing facilities, logistics hubs, and sales personnel all under the direct control of the counterfeiters. The depth, breadth, and sophistication of modern drug counterfeiting operations are clearly illustrated by the following three examples.

Rx North

In May 2006, Customs officers at London Heathrow Airport in the United Kingdom seized a shipment from Dubai, en-route to the Bahamas which contained several thousand packs of eight confirmed counterfeit pharmaceutical products from seven companies, including more than 3000 packets of a counterfeit Novartis medicine for hypertension. See Attachment 15. The counterfeit products had been manufactured in China, transported by road to Hong Kong, flown to Dubai where they were stored in a duty free warehouse before being shipped to the Bahamas via the UK. Based on information provided by the pharmaceutical industry, local authorities in the Bahamas executed a search warrant at the destination address where additional counterfeit drugs were seized, including more of the counterfeit Novartis hypertension drug as well as a fake Novartis treatment for Alzheimer's.

The counterfeiting facility in the Bahamas was a fulfilment center established by Rx North, an Internet drug website. The facility processed orders placed on the Internet by American and Canadian patients and shipped pre-addressed orders for Rx North to mail forwarders based in the UK and the Netherlands Antilles. The products were then shipped from the UK or Netherlands Antilles direct to individual customers in the United States and Canada. These routes were used in order to reduce suspicion and avoid Customs inspections.

In August 2006, the Food and Drug Administration issued a warning to consumers not to buy or use prescription drugs from certain websites, including Rx North. In September 2006, RxNorth.com informed prospective customers that responsibility for order fulfilment would be transferred to Canadadrugs.com. Canadadrugs.com had previously been implicated in incidents of counterfeit pharmaceutical products and later became the center of another international counterfeit drug scandal, mainly affecting U.S. patients.

Following investigations in all of the countries impacted by Rx North, a Dubai-based trading company general manager and three co-defendants were convicted in the United Arab Emirates and imprisoned for terms ranging from one to eight years. Two men in the UK were also prosecuted and convicted for their roles in the RxNorth operation. Andrew Strempler, a Canadian citizen, pleaded guilty in the Southern District of Florida for his role in a scheme to defraud consumers purchasing pharmaceuticals online through his ownership of Rx North. In January 2013, he was sentenced to 4 years in prison and also ordered to pay a forfeiture of

$300,000 and a fine of $25,000. He was also ordered to pay restitution to the companies whose products he counterfeited.

Middle East Network

A counterfeiting enterprise in the Middle East operated a network which encompassed China, Syria, Iraq, Jordan, Occupied Palestinian Territories, and Egypt. See Attachment 16. In 2003, Jordanian nationals registered a company specializing in "garments, electronics and international economic consultancy" in Shenzen, Guangdong Province in China. The organization then opened two distribution hubs--one at the point where the Iraqi border meets Syria and Jordan and the other in the United Arab Emirates. The Syrian/Jordanian hub focused on distributing counterfeit life-saving drugs to supply Iraqi demand while the UAE hub specialized in distributing fake lifestyle drugs in Gulf countries. The counterfeit Novartis products distributed by this network across the Middle East included treatments for hypertension, leukemia, breast cancer, and Alzheimer's.

In 2007, Jordanian authorities conducted a series of successful raids against the organization in Amman. Soon after, the leader of the group, who had escaped a raid on his facilities in Amman, moved to Egypt and set up a third hub in Cairo. In 2008, Chinese authorities arrested and prosecuted three Jordanians linked to this syndicate, while other members of the same group were being arrested and prosecuted in the Occupied Palestinian Territories. The Jordanian who escaped from Amman to open the Egyptian hub was arrested in Cairo and the business closed down by authorities in April 2009. In May of the same year, a clandestine

counterfeit drug manufacturing site was discovered by authorities in Damascus, Syria. The facility was equipped with modern industrial Chinese-made machinery and professional printers. Over 60 suspects were arrested and several tons of bulk blister packs, vials, folding boxes, newly printed leaflets, and barrels of unknown chemical substances were seized.

In this case, nearly 100 members of the criminal counterfeiting group were arrested between 2007 and 2009. Businesses owned in China and in the Middle East provided the network with legitimacy and the means to transfer money as well export and import products. The counterfeit manufacturing facility in Damascus allowed the network to continue its illicit trade unhindered, despite Chinese authorities disrupting their operations in Shenzen. The international spread of this organization – which profited from the porous borders of the Iraqi warzone and generated opportunity in a politically tense region--made enforcement actions lengthy and difficult. Nevertheless, Novartis played a key role in investigation by providing information and encouraging law enforcement and security agencies in the affected countries to take action.

Counterfeit Antimalarial Treatment

Novartis manufactures a breakthrough drug, Coartem, for the treatment of multi-drug resistant malaria. It was the first ACT (artemisinin combined therapy) added to the World Health Organization's Essential Medicines list (40 percent of the world's population is at risk of contracting malaria with children and pregnant women being the most vulnerable.). Coartem is a highly-effective 3 day malaria treatment with cure rates of over 96% and holds the potential

for helping to eradicate the disease. In 2001, Novartis signed a memorandum of understanding with the WHO to make Coartem available at cost (i.e., without profit) in malaria-endemic countries. Novartis has provided over 500 million Coartem treatments since that time. Novartis manufactures two presentations of this treatment – the only difference between them is the packaging. One is for private sale and is manufactured in China. The other is sold at cost to international aid agencies and donation funds, including the U.S. President's Malaria Initiative and the Global Fund to Fight Aids, Tuberculosis and Malaria. This public version is manufactured in the U.S. and distributed for free all-over the malaria burden zone, particularly in Sub-Saharan Africa.

In 2009, multiple diversion incidents were reported in Guinea, Malawi, Nigeria, Cameroon, Ivory Coast, and the Democratic Republic of Congo. Put simply, the treatments donated to Eastern African countries were being stolen and sent to Western and Central African countries where they were made readily available for sale to patients at street markets – not for free but at the price of $6.00 to $8.00 per treatment. In March 2010, Ministry of Health officials in charge of the National Malaria Program of Uganda were sent to prison for corruption and diversion -- they were syphoning the donated treatments --essentially stealing millions of dollars of international aid from the malaria stricken population. Novartis found that up to 24% of its deliveries to Eastern African countries were being diverted elsewhere. Novartis continues to work very closely with PMI, The Global Fund and the WHO to support investigations into these thefts.

This large-scale systemic, organized, transcontinental enterprise made the diverted malaria drugs a valuable commodity rendering them an attractive prospect for counterfeiters. In July 2012, a container shipped from Guangzhou in Guangdong Province, China to Luanda in Angola was seized by Customs officers. The shipment contained Hi-Fi speakers containing a total of 1.4 million fake treatments. See Attachments 17, 18. Subsequent investigations in Western Africa confirmed that the counterfeit version of Coartem – a placebo containing nothing but flour, corn starch, dextrose and an industrial colorant - had flooded markets across the region. See Attachment 19. In terms of volumes seized, scale, and direct substantiated risk for patients, this case is the biggest single seizure of fake pharmaceuticals ever recorded by the Pharmaceutical Security Institute.

An established African diaspora in Guangzhou, China, has set up a complex structure of export and import companies with associated sister companies in recipient countries in Africa. The China-based group arranges the manufacture of the fake drugs (not only the Novartis product) with local facilities and as well as the shipping for the fake medicines under covering loads to Africa. Close tribal networks in Africa ensure the passage of counterfeit product upon arrival and distribution to illicit street retailers.

The industrial-scale counterfeiting of the antimalarial, Coartem, originally intended to reach sick patients at no cost to them, is killing thousands of innocent patients and severely damaging hopes of eradicating malaria. In some countries, the counterfeit treatment is more readily available than the genuine. The non-profit treatment has been mutated into a lucrative money-making scheme by criminal networks that operate with impunity because the

local operating environments are corrupted and permissive and the target population is many and widespread.

Conclusion

It is beyond quibble that drug counterfeiters present a grievous threat to public health and safety on a global basis. Their ingenuity and sophisticated, large-scale operations generate sizeable profits which come at the expense of those who rely on medicines to treat disease, ease pain, and prevent death. In an effort to help thwart counterfeiters and other pharmaceutical crime, Novartis, along with many other companies and interested parties, worked with Congress to ensure that effective track and trace provisions were included in the Food and Drug Administration Safety and Innovation Act ("FDASIA"). Track and trace requirements along with other anti-counterfeiting efforts by the industry hold the promise of helping to prevent fake drugs from entering legitimate drug supply chains. Unfortunately, such mechanisms are likely to be ineffective in stopping counterfeiters who supply their product through illicit channels such as Internet websites, street vendors or pharmacists, hospitals and doctors who are willing to participate in the counterfeiting schemes. Novartis believes that the United States must seize the momentum created by FDASIA and take further steps to combat counterfeiting. Much stiffer penalties for pharmaceutical crimes should be put in place in the U.S. and other countries—and each government must make the commitment to aggressive enforcement of anti-counterfeiting laws. Efforts are also urgently needed to increase international awareness of the threats posed by drug counterfeiting in the hope that other countries will develop regulatory schemata and enforcement tools to effectively confront the

well-resourced criminal counterfeiting networks. As for Novartis, it will continue to dedicate substantial corporate resources to detecting and deterring drug counterfeiting.