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Chairman Scott, ranking member Gillibrand, members of the committee, thank you for the opportunity to testify today. My name is Peter Baker and I am a former FDA Drug Investigator – who specialized in drug manufacturing inspections overseas. I want to thank you for this bipartisan focus on enhancing the securing of our generic pharmaceutical supply chain.

Trust is one of the most, if not the most important ingredient for a healthy public health system in any country. When a patient, especially those most vulnerable (such as the young and old) fill a prescription, which has a 91% chance of be generic here in the United States, there can be no doubt about the safety and efficacy of the medicine, or if the generic will perform as well as the brand-name. There are too many uncontrollable variables to allow this one to play any role.

The role of ensuring a safe and effective drug supply is the responsibility of many players, but most of the burden falls on the FDA. The FDA has a long history of protecting and promoting public health, and performs extremely challenging and hard work around the world on a daily basis to achieve that goal through site inspections, often in remote corners of the world that do not have internationally recognized regulatory bodies. I will refer to these areas of the world without a recognized regulatory system as unregulated markets. As a result, our FDA investigators may be the only external insight into the quality of critical medicines bound for the United States (including thousands of different critical sterile injectable drugs). The ability of these investigators to identify poor manufacturing practices and prevent these medicines from reaching a patient is literally a life or death situation. However, these investigators face incredible challenges when trying to fulfil their job of determining if a site is producing, or capable of producing, a product that meets the standards outlined in our laws, regulations and guidance.

To start, FDA Investigators often have to deal with demanding travel conditions and can fall ill due to other unsafe conditions, such as drinking untreated water, a contaminated meal, communicable and non-communicable diseases, or fall prey to other risks often present in still-developing nations.

For example, a good number of sites operate in countries where English is not the primary language. The site provides a translator, typically an employee from the sales department, to facilitate interviews with site staff (there is no independent

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translator required). In my experience the information is often not complete and is biased to provide the information the investigator "wants to hear". It is difficult if not impossible to gain insight into how our drugs are being manufactured when employees performing the critical work cannot be interviewed in an unbiased way. Documents cannot be reviewed if not in English, and confusion over the truthfulness of critical questions related to quality causes significant disruption to completing the mission.

The majority of our overseas pharmaceutical inspections are pre-announced, often up to 2 months in advance of our arrival. In my experience, upon arrival for the inspection – a strong smell of fresh paint is in the air, the landscaping is immaculate, all garbage bins are empty, any potential problematic operations are shut down, some employees are sent home, and critical operations are choreographed as if performing on a stage. Those of us who performed foreign inspections refer to this as the "dog and pony show" – which is frustrating because this is serious business.

How do I know this to be true? Having spent 7 years in three different FDA foreign offices starting in 2012 – based out of our embassies strategically located around the world, we were tasked with developing inspection techniques capable of identifying if products exported to the United States from unregulated markets were really meeting our standards: things seemed too good to be true. No rejected batches, no issues at all? Really? In the United States we rely on the company itself to certify the quality of imported products, unlike our colleagues in the European Union who require independent third party testing of each batch of imported drugs – so we needed a way of gaining deeper insight. Our foreign office leadership and ORA worked with us to introduce new ways of inspecting, as the current inspection program at that time was largely based on trust and good faith commitments, which is completely different than how sites in the US are inspected and regulated. We knew the quality of products being manufactured in Ohio, but had really no idea what was happening outside of our borders, especially in unregulated markets. We worked on developing forensic computer inspection techniques, dug through piles of garbage, and showed up at times unannounced – booking our travel on Expedia vs. the embassy travel portal to alleviate any concerns someone would tip off the sites to our plans.

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What we found was terrifying. This testimony only addresses the tip of a massive iceberg.

- Fake laboratories pumping out hundreds of results a day that certified products as 100% pure, when in fact the product was never tested.
- For those products that did get tested, any failing result was simply ignored and replaced by a fabricated passing value.
- We identified filthy unregistered "shadow" facilities that would funnel their drugs through modern and clean registered sites, which we refer to as the "show" facility.
- We found fabricated manufacturing and quality records – painting a picture of a site in total compliance, when in fact substandard or fake medicines were being shipped to the United States by the tens of thousands a day.

Following these experiences, I have no doubt that adverse events, including death, happen on a daily basis here in the United States as a result of substandard generic products from unregulated markets. The true culprit of these preventable adverse reactions lies in shortcuts and fraud.

The big tragedy in this story is that the uncovering of this large-scale fraud was too late. In the age of rapid offshoring, starting around ~2005, the agency approved thousands of generic products from sites based in unregulated markets using a process of pre-announced choreographed inspections using biased translation, and an inspection and enforcement model based on trust and good faith. These bad actors grew to be monsters. The inspection force was under resourced, so an approval of 20 or more different drugs would be made as long as the investigator looked at one and found it to be acceptable. We were fooled by low costs and false promises.

Continuing today, any consequences faced by these bad actors are negligible. When the FDA does choose to take action, they issue a "warning letter" to the site instructing them to clean up their act, and the site quickly shifts production to their other sites, evading any financial disruptions. We call this the "cat and mouse game". Prosecutions and injunctions are exceedingly rare. Sometimes the agency issues an "import alert" banning products entry into the United States – except any product that may cause a hint of a shortage concern – these are exempted from the

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ban, and these patients must face the consequences of consuming what we know to be substandard medicines. Do they even know they are consuming a product proven by an FDA investigator to be unsafe? The answer is likely no.

Personally, if I had a choice, I would never consume a drug produced in an unregulated market, and any experienced FDA investigator will give you the same answer. The problem is I and all Americans do not have a choice, as decisions are made by middle-persons such as Pharmacy Benefit Managers who purchase generic products based on the lowest costs – I have seen the consequences of producing the cheapest substandard products to win the contract.

When my 91 year old grandmother was alive, we would go pharmacy hopping around our rural Oregon hometown in the hopes of finding a batch that was made by a reliable producer. Sometimes we succeeded, and sometimes not. I remember one time having to settle for a product manufactured by Ranbaxy, who had just settled with the DOJ for $500 million for faking countless data points used to demonstrate their products were safe. In my mind I imagined they were allowed to sell the product in the US because they had monopolized the market with rock bottom prices and false promises to the FDA. I tried to stay positive because causing her to panic wasn't going to help, but inside I felt sick – and I was not the one receiving cancer treatment.

So what about today? One might think a decade after this large-scale fraud was identified and documented in hundreds of FDA inspection reports, we would have figured this out. But I'm afraid I have bad news. Once a site is caught (often because of an unannounced visit), FDA may conduct a re-inspection in 1-2 years (which may or may not be unannounced), and the choreographed pageantry of the inspection will commence, likely resulting in a green light once again – and the game resets. Many of these bad actors have received multiple bad inspection results over the years – going in and out of good "compliance" status with FDA. Each year they improve their ability to play the game and hide illegal practices, meanwhile the FDA struggles to keep up.

There are world-class manufacturing sites all around the world, including in unregulated markets, but they struggle to survive, and are unlikely to win contracts with our middle-people in the United States, as it costs money (but not much more

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money) to train people and generate reliable data – basically to make a medicine that is safe and effective.

Shocking inspection reports continue to roll in on a monthly basis – and the bad players in industry, we all know who they are, continue to avoid any significant consequences – meanwhile those most vulnerable in our society who may need medication to aid with healing have no idea of the games being played, and certainly no idea that the game, as designed today, can never be won.

I urge this committee to consider these four points:

1. harsher penalties for companies who engage in illegal practices via the existing authority within the FDA and DOJ
2. changes to labeling so that patients can see where their medications were made and put pressure on any middle-person who provides them with a pill made in an unregulated market.
3. independent third party testing of every batch of every product arriving from an unregulated market
4. improving the FDA Investigator toolbox, such as independent translation and logistical and training support to show up to more sites unannounced. Showing up to a site in some of the most remote places on earth is not easy and it is not feasible or practical to conduct all foreign inspections unannounced. A risk-based approach is the most realistic solution. The FDA has made great progress to increase the number of unannounced inspections they are conducting, but they need additional resources to be directed to expand on unannounced inspections, as already outlined in Commissioner Makary's public communications.

Thank you for your time and attention to this important matter. I welcome your questions.