Johnson & Johnson

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Chairwoman Eshoo, Ranking Member Burgess, and members of the subcommittee, good morning and thank you for the opportunity to discuss how we can strengthen patient safety by granting the Food and Drug Administration (FDA) the same authority for dealing with certain counterfeit medical devices as it has for drugs that have been refused admission into the United States. My name is Rich Kaeser and I am Vice President of Global Brand Protection at Johnson & Johnson, responsible for combatting illicit trade, including counterfeiting, illegal diversion and tampering, across all Johnson & Johnson business segments – pharmaceuticals, medical devices and consumer health.

I am here today because illicit trade has increased dramatically in recent years, impacting nearly every industry. According to one estimate, global trade in counterfeit goods will hit $1.9 trillion by 2023.[1] The problem is obviously a serious concern in the health care and personal care industries where patients and consumers can be injured or even die due to unsafe, counterfeit, and illicit products. In fact, of the $1.9 trillion in illicit trade, counterfeit drugs are the biggest market at $200 billion per year.[2] Given that figure, it's no surprise that INTERPOL estimates that 1 million people, mostly in developing economies, die each year from taking counterfeit medicines.[3]

Commitment to the Safety of Products for Patients and Consumers

At Johnson & Johnson, our response to illicit trade is guided by Our Credo. The opening line reads, "We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services." That means all who use our products must have unequivocal confidence in the quality, safety and authenticity of Johnson & Johnson products.

Thus, we have a strong enterprise-wide anti-counterfeiting and brand protection strategy in place to proactively and aggressively manage risks related to illicit trade and, more importantly, protect patients and consumers from potential harm.[4] We take a holistic view of potential risks across our

[1] Frontier Economics (2017), *The Economic Impacts of Counterfeiting and Piracy*.
[2] Havocscope (2016), Global Black-Market Information.
[3] OECD (2016), Illicit Trade: Converging Criminal Networks, OECD Reviews of Risk Management Policies.
[4] Johnson & Johnson Health for Humanity Report (2018).

end to end value chain and deploy a wide variety of controls to enhance the integrity of our products and supply chain, while also employing tactics to disrupt the illicit supply chain. Controls include, for example, a range of product and packaging security measures that enable us to distinguish genuine product from fake and minimize the risk of product tampering. We also conduct extensive market monitoring, both online and offline, to identify the presence of illicit products and remove them from the supply chain.

Protection Requires Multi-Stakeholder Collaboration

Our Global Brand Protection (GBP) team, which I lead, is responsible for these efforts across the company. While my team is 100% dedicated to this mission, effective brand protection also requires significant teamwork across our entire business. Internally, GBP works closely with Johnson & Johnson Global Security to maintain supply chain security and undertake investigations and enforcement actions; with Quality & Compliance to capture and respond to suspect incident reports; and with the Law Department to handle issues related to trademarks and intellectual property. GBP also works with other functional and commercial business partners to advise on illicit trade risks and embed brand protection best practices and processes in ongoing operations.

Externally, GBP collaborates with industry partners, suppliers, academic institutions, law enforcement and government agencies, including the U.S. Department of Homeland Security, U. S. Customs and Border Protection, and the National Intellectual Property Rights Center.

Lawmakers play a critical role in promoting international collaboration and strengthening our nation's laws to increase penalties for illicit traders and reduce incentives for engaging in illegal trade, and we appreciate the leadership of Representative Guthrie (R-KY) and Representative Engel (D-NY) on this issue. As such, Johnson & Johnson is very pleased to support H.R. 5663, the "Safeguarding Therapeutics Act," which extends FDA authority to destroy counterfeit drugs, devices, and combination products valued at $2500 or less. We believe this authority is important to protect consumers, patients, and the integrity of the supply chain by preventing counterfeit products from reaching end users.

Critical Examples and Efforts to Address Illicit Trade

I would like to share a recent example of counterfeiting that impacted our medical devices business involving a product known as SURGICEL® Absorbable Hemostats, a blood-clot-inducing material used to control bleeding during and after surgeries. We learned that counterfeit products labelled and sold as SURGICEL® were entering the supply chain in the United States and other markets through unauthorized gray market distributors - smaller distributors that buy from the secondary market.

The case began when a neurosurgeon in the United States flagged a SURGICEL® product that did not look or feel right to him, based on his experience using the product. He contacted J&J and we immediately acted to understand if there was an issue with the product. Subsequent testing by an independent laboratory showed that the product was, in fact, counterfeit. It did not have the same safety and efficacy as an authentic product and, due to its lack of sterility and performance, it posed a serious risk to patients.

The incident was escalated to senior leadership and the Johnson & Johnson Global Brand Protection Team. The counterfeit products were removed, and no patients were harmed. A timely investigation identified and shut down an international counterfeiting scheme and we are now pursuing global civil and criminal remedies against the illicit manufacturer and traders. We engaged our customers to notify them about the counterfeit issue and to explain that buying our products only from authorized distributors is vital to protect both patients and providers. Importantly, we also involved the FDA and are cooperating with their criminal investigation teams as they consider taking enforcement action against the parties involved.

While cases like this put illicit traders on notice and have a deterrent effect, unfortunately in today's global marketplace, we are likely to continue to see illicit medical devices, drugs and personal care products entering legitimate supply chains. This is a problem that impacts not only the U.S., but the broader global market as well. Illicit traders target a variety of products, including contact lenses. Late last year we worked with enforcement authorities in Dhaka, Bangladesh who raided a wholesaler and seized over 600 packets of counterfeit Acuvue® Clear contact lenses before they could reach the public. Healthcare products will continue to be one of the most commonly targeted industries for counterfeiters.

Solutions to Address the Challenges We Face

These situations demonstrate why businesses must partner with one another and with government, so collectively we can be a greater force to deter the growing threat of counterfeit. As the world's largest and most broadly-based healthcare company with more than 130,000 employees worldwide, we recognize the vital roles played by various members of the healthcare and supply chain system. It is important for Johnson & Johnson to be a strong partner in the healthcare industry's response to this problem. Our ultimate aim is to keep patients and consumers safe, but we cannot do it alone.

We look forward to continuing to work with lawmakers and regulators to advocate for solutions to illicit trade. We support solutions that seek to:

- Strengthen government authority to protect the public when counterfeits are detected, for example ensuring FDA can destroy medical products they have determined to be counterfeit
- Better understand the impact of counterfeit health and personal care products here in the U.S. and increase awareness among patients and consumers
- Address the supply of illicit products via online marketplaces, social media platforms and the dark web
- Organize key stakeholders, including industry, academia, law enforcement and our government to develop solutions to deter counterfeiting and take enforcement action; and
- Prohibit the importation of unauthorized products—and potential counterfeits— into the U.S.

Conclusion

Illicit trade and counterfeit products present growing risks to patients and consumers. We have the opportunity to make our world safer by ensuring that FDA has the authority needed to destroy counterfeit drugs, devices and combination products. Together, we can work to protect patients and consumers from the threat of counterfeit health and personal care products.

Thank you for your time and attention today to this critically important issue.