

Attachments—Additional Questions for the Record

**Subcommittee on Health
Hearing on
“Improving Safety and Transparency in America’s Food and Drugs”
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Johnson & Johnson**

The Honorable Larry Buchson (R-IN)

In your testimony you discussed Johnson & Johnson's work in Bangladesh seizing counterfeit contact lenses.

1. Where are the most vulnerable points of entry in the legitimate supply chain for counterfeit contact lenses to enter?
2. Are these specific points of sale that are riskier or less regulated than others?

Response from Johnson & Johnson:

At Johnson & Johnson, our Vision Care company serves more than 50 million patients across 103 countries with the gift of clear sight through our ACUVUE® Brand contact lenses. While contact lenses are an everyday item for many patients, they are still complex medical devices. As you may be aware, in the United States, the FDA classifies contact lenses as Class II and Class III medical devices that require a prescription for dispensing. The authenticity of a contact lens brand is critical for patient safety, because each brand is designed based upon unique combinations of material and design properties to suit individual patient’s eye physiology, anatomy, and lifestyle needs. At Johnson & Johnson Vision, we’re dedicated to manufacturing high-quality products that meet or even exceed government standards, so patients not only feel safe, but have a consistent experience with their lenses every day.

To best serve our patients, we work to ensure that our global supply chain, which crosses six continents, is safe and secure. Our Global Brand Protection team monitors active complaints as well as proactively implements preventative measures. We also collaborate with regulatory, law enforcement agencies, industry, distributors, and patients to combat the threat of counterfeit devices and products. Currently, Johnson & Johnson Vision is not aware of counterfeit issues directly affecting its products in the United States.

However, despite these and other efforts, in today’s global marketplace, we are likely to continue to see counterfeit contact lenses become more prevalent and sophisticated. According to the

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World Health Organization, the illicit trade of health care products is difficult to quantify but is growing. In fact, health care products are the 6th most targeted counterfeit category—and included in that, are contact lenses. Online marketplaces have made for ideal storefronts for selling counterfeit products, because in the e-commerce space, most of the time the seller is invisible. We're working to combat this threat by using programs that scan our products to make sure they're authentic and safe, and advanced analytics and algorithms to determine whether product images and listing information online are suspicious and might need further investigation. We're also constantly monitoring and taking down illicit internet sites and listings.

We look forward to continuing to work with our partners in industry, law enforcement, and Congress to address the threats posed by counterfeit goods sold online to patients and consumers.