

Thank you for your introduction, Mr. Chairman. On behalf of the nearly 120,000 employees of Johnson & Johnson, thank you for the opportunity to speak here today.

Let me briefly tell you about Johnson & Johnson.

Our consumer companies are responsible for many familiar personal products used in baby care, skin care, oral care, wound care and women's health, including familiar brands such as JOHNSON'S* Baby and BAND-AID*. We also market an extensive line of over-the-counter medicines that include such well-known names as TYLENOL® and MOTRIN®.

Our device companies supply professional products to physicians, surgeons, consumers, and laboratories for many uses, including patient care, wound closure, diagnosis, blood testing and surgery. Surgical implants, needles, sutures, endoscopic instruments, orthopedic products, infection control products, cardiovascular monitoring and vascular access products are among our wide array of products used by medical professionals.

Our pharmaceutical companies develop and have brought to market prescription products including products for psychiatry, infection control, cancer, immunotherapy, family planning, and cardiovascular disease. We discover and manufacture both traditional and small molecule medicines, as well as biotechnology-derived products.

Counterfeit healthcare products present an extraordinary risk to patients and consumers.

According to the FDA, the United States pharmaceutical supply chain is one of the safest in the world. Nonetheless, counterfeiting of healthcare products is a growing concern for society. The World Health Organization estimates that 8-10% of pharmaceutical products outside the United States are counterfeit. In some countries, counterfeit products may represent 50% of medicines in the marketplace.

Until recently lifestyle and biological products have been primary targets of counterfeiters. Counterfeit heart, arthritis, asthma, AIDS, diabetes, and cancer medications have been found. Even relatively low cost consumer products such as shampoo and toothpaste have been counterfeited.

Medical devices are not immune to counterfeiting. A Gray Sheet article dated June 2, 2008, stated - "Counterfeiting of medical devices, including sophisticated implantable devices, is a growing threat to patient safety and manufacturers' reputations". Medical device operating companies of Johnson & Johnson have experienced counterfeit medical devices.

The Internet is becoming the marketplace of choice for the counterfeiter. Counterfeit pharmaceutical products can be purchased from a wide variety of unregulated Internet pharmacies. These Internet pharmacies are in many cases shams, selling potentially ineffective or unsafe products. The counterfeiter can easily sell their products via a website and distribute them into the US via the US postal or private express mail services to their unsuspecting customers. Counterfeit and diverted medical devices can be purchased via on-line auction sites.

These scams are so widespread that according to the Pharmaceutical Security Institute, "seizures of bogus prescription medicines jumped 24 percent to 1,513 incidents in 2007, and illicit versions of 403 different prescription drugs were confiscated in 99 countries." The FDA Office of Criminal Investigations and border inspection officials make many seizures of illicit products each year, but the federal resources cannot catch every package containing an illegal product.

Another avenue for counterfeiters to introduce fakes or substandard product into the supply chain is diversion. Diversion refers to merchandise that is distributed into markets other than originally intended in violation of a contract, law or regulation. Diverted product, commonly referred to as "grey market" product, is frequently past dated or expired, had been previously marked for

destruction, had not been properly stored, or is counterfeit product. When product is diverted, authentic and grey market products travel together through the supply chain creating confusion. For example, a hospital could receive legitimate and diverted product in the same shipment. The diverted product is stocked on the same shelf beside the legitimate product. A surgeon could unknowingly select the diverted product and implant a substandard product into the patient. The patient could experience a wide range of medical complications.

Counterfeiters show total disregard for the safety of consumers, patients, doctors and nurses who unwittingly encounter the counterfeit product. Counterfeiters don't care about product quality, safety, or efficacy. People who use a counterfeit healthcare product run the risk of a wide variety of medical problems ranging from experiencing no therapeutic benefit... to new illnesses... and even death.

Counterfeiters have no regard for intellectual property rights. They take advantage of countries with gaps in intellectual property laws or where enforcement of IP laws is nonexistent or lax. Some countries do not enforce IP laws for products made for export only. These countries provide the counterfeiter a safe haven for their operations. The active ingredient can be manufactured in one country, exported to a second where the product is packaged, exported to a third country where it is labeled and finished packaged, and exported for final sale.

Both healthcare manufacturers and governmental regulators have begun taking action to combat counterfeiting and to protect our consumers and patients. Many healthcare manufacturers have invested in measures to tighten the security of supply chains and products. These measures are multifaceted with IP and trademark protection being just two key areas of focused effort.

While much work remains, here are some examples where manufacturers are focusing their efforts:

- ❑ Renegotiating trade agreements with authorized distributors of record (ADR's) to ensure ADR's only buy directly from the manufacturer or a manufacturer's approved source.
- ❑ Conducting market monitoring activities and auditing trading practices to identify sources of illicit trade.
- ❑ Collaborating with customs and police to investigate suspected cases of counterfeit or tampering activities, and aggressively prosecuting the offenders.
- ❑ Working with governmental agencies to ensure trademark and IP laws are enforced and prosecuting infringements.
- ❑ Applying overt and covert features to products and product packaging to aid in product identification.
- ❑ Deploying communication programs to healthcare professionals and downstream supply chain partners encouraging them to buy from approved sources and alerting them to the dangers of counterfeit or tampered products.
- ❑ Investigating and piloting track & trace and pedigree systems to communicate the product's chain of custody. These systems are intended to improve visibility into the supply chain and gain greater clarity into where products have been and where they are moving to in the supply chain.

Pedigree documents the chain of custody of a specific product. Regulators have been working on regulations at state and federal levels, and in other countries requiring pedigree on pharmaceuticals. Over 30 U.S. states have enacted pharmaceutical pedigree legislation. Countries as diverse as Turkey, Japan, Brazil, Serbia and Slovenia have, or are considering, legislation requiring tracking and tracing of pharmaceutical products. As a result, we have a patchwork quilt of pedigree laws and regulations that could defeat the purpose of improving supply chain security.

We believe that the Senate Judiciary Committee should be interested in eliminating the complexity of multiple pedigree laws, which may result in fraudulent - and even counterfeit - pedigrees, and in its place implement a simple and potentially effective solution: the electronic

pedigree (ePedigree). Making distributors produce ePedigrees for law enforcement when products are questioned would increase the effectiveness of law enforcement in combating counterfeiting. Immediate information about the authenticity of a product puts powerful information in the hands of law enforcement for enforcement action. Within the US, a federal standard is required for electronic pedigree. This is an area where the federal government can and should take the lead.

We cannot over emphasize that the integrity of the pharmaceutical and medical device supply chain is essential to the well being of all of our citizens. Patients and consumers rely on our medicines, medical devices and personal products everyday to improve the quality of their lives and, in many cases, to save their lives. Healthcare manufacturers depend upon the integrity of our supply chain to ensure that patients and consumers receive genuine products from approved sources.

As the healthcare supply chain becomes increasingly global, coordination across manufacturers, distributors, pharmacies, hospitals, and a wide variety of governmental agencies will be imperative to ensure the integrity of the healthcare supply chain.

There is a critical and concerted effort to maintaining supply chain integrity across the industry. Yet, as counterfeiters increase their activity and sophistication in creating fake products, industry must also increase resources to address this criminal activity. This requires a diversion of industry resources that otherwise would be applied to drive medical innovations that will address some of today's most pressing health care challenges.

Here are some examples where we believe Congress could encourage governmental agencies to work together to protect patients and consumers from counterfeit products.

Congress should....

- ❑ Pass legislation that would enable the FDA to establish industry-wide implementation dates for federal pedigree standards. The FDA should be encouraged to work with state and international regulators to develop effective, practical pedigree and track & trace standards for the United States and globally.
- ❑ Support a review of the FDA's Office of Criminal Investigation's procedures and organizational capacity for handling enforcement actions. OCI is an important FDA resource to help manufacturers combat counterfeit products.
- ❑ Encourage the FDA's regulatory and OCI divisions to develop a common approach for working with the healthcare industry on investigation and enforcement actions.
- ❑ Enact legislation that ensures manufacturers can protect their products no matter where they are in the supply chain so that consumers are protected from unwittingly receiving adulterated products. Including requiring that all returned product be sent back to the manufacturer.
- ❑ Provide sufficient resources to the Patent and Trademark Office to work with their international counterparts to ensure proper IP protection and the enforcement of existing IP laws.
- ❑ Sponsor a nation-wide awareness campaign aimed at consumers to warn them about the dangers of opportunistic purchases of medications from non-licensed health care providers.

As I stated earlier in my comments, we are fortunate to be living in the United States and to be served by one of the most secure healthcare supply chains. Johnson & Johnson believes it is our responsibility to help ensure that all people receive genuine, unadulterated products from trusted authorized trading partners. All people deserve the right to be protected from the dangerous effects of counterfeit products.

Johnson & Johnson is pleased to work with Congress, the FDA and any other governmental agencies whether Federal, State or International to develop effective laws and regulations to protect patients and consumers from counterfeit products. We are ready to make our company experts available to these legislative and regulatory efforts.

Thank you for allowing Johnson & Johnson to share our perspective on this critical issue with you today. If we can be of any further assistance, we are available to help this committee. I am happy to answer your questions.