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Thank you for the opportunity to participate in this FDA Public meeting to discuss economically motivated adulteration. I am Martin VanTrieste and I am the VP of Quality for Amgen, working on an effort to start an industry consortium to address economically motivated adulteration and finally representing PhMRA as a member of PhMRA's Quality Technical Group.

Recent highly publicized events have highlighted a weakness in the pharmaceutical supply chain. Significant harm to patients, including death, has been associated with these events. These incidents have led to a loud and swift reaction from the public, pharmaceutical companies, health authorities and policy makers. These events have shown us how unethical players and criminals have entered into the supply chain, introducing counterfeited, adulterated and contaminated materials, often with tragic consequences.

We must realize that it's not if economically motivated adulteration will happen again, but when and where it will happen. These issues and their resolution are of extreme importance to PhRMA. PhRMA member companies are regulated by the FDA. Through the New Drug Approval (NDA) and current Good Manufacturing Practice (cGMP) requirements, pharmaceutical companies control each input into a pharmaceutical product and each step in the product's manufacture. But this is not a Good Manufacturing Practice issue. Good Manufacturing Practices keep the honest people honest but does little to prevent unethical players or criminals from exploiting the supply chain.

PhRMA agrees with the FDA, that we our responsible for our suppliers and supply chains. With that in mind PhRMA member companies have also taken initiative to help further assure a secure supply chain, in the interest of product quality throughout the supply chain and patient safety, ultimately. A consortium (rx-360) is being formed to develop novel approaches to ingredient supplier auditing, adopting best practices of supply chain management, encouraging the development of new technologies to prevent and detect adulteration, and surveying the global marketplace for potential vulnerabilities. In addition, several PhRMA members have been involved in the development of a proposal for a voluntary certification program for highly compliant importers called the Qualified Trusted Importer Program (QTIP).

PhRMA is supportive of the FDA efforts to address economically motivated adulteration, and the Agency's efforts to help ensure the supply chain remains secure. We believe a strong, well-funded FDA is critical to the health and safety of the American public, both for the purposes of helping to assure the safety, effectiveness and availability of medicines and to help ensure continued access to innovative new therapies for American patients. As such PhRMA is supportive of efforts to provide additional resources to the FDA so that the Agency can enhance its inspection efforts abroad and ensure a safe, secure supply chain.

PhRMA encourages the FDA to use a risk-based approach to target inspections of domestic and foreign facilities and we believe the Agency should have the discretion to consider the use of accredited third parties, provided the third party accreditation process is sufficiently robust. This will help ensure efficient use of FDA resources targeted to areas of greatest risk.

We also believe the FDA should increase the number of cGMP inspections it conducts overseas, particularly of active pharmaceutical ingredient manufacturers. These inspections should also focus on good distribution practices and the authenticity of data submitted to the FDA.

Based on results from risk assessments or suspicious reports from the field, the FDA should deploy specially trained investigators that can detect fraud, the use of "show" factories and the potential for economic adulteration, since these skills are vastly different from the skills needed for a cGMP inspection.

FDA should require all entities supplying materials used in finished products to be registered with the Agency if the finished products are sold in the US and should require regular updates to this registration information. This will help promote greater transparency in the pharmaceutical supply chain.

FDA should also consider whether to monitor or provide special scrutiny to products or ingredients in short supply since these situations may provide additional incentives and opportunities for unethical players to engage in economically motivated adulteration of products. For example, we know that the shortage of pigs in China provided an opportunity for unethical players and criminals to introduce economically motivated adulterated heparin into the supply chain. Learning from this lesson, does it apply to today, where we face a potential pandemic flu with a shortage of effective anti-viral agents that governments around the world are trying to stockpile? For example, the FDA and FTC have warned consumers about potentially fraudulent H1N1 treatments. We must stop and think like a criminal would in order to anticipate how someone could try to counterfeit or economically adulterate these anti-viral agents. Once we have this knowledge, we can start to look for early warning signals and develops methods of detection.

In addition, we believe there should be increased FDA oversight of the supply chain to help ensure it remains secure. To that end, we also support increased state licensure requirements for wholesale distributors and greater oversight of repackaging operations.

Penalties for economic adulteration and / or counterfeiting -- such as 20 years for any violation, and life in prison for any related deaths – should be incorporated into any new legislation, so FDA can more effectively respond to suspected adulterations and contaminations. And, of course, FDA should exercise all of its enforcement powers as appropriate and to the fullest extent possible when unethical and / or criminal activity is detected.

The recent publicized events involved economic adulteration of ingredients but one can not forget about the risk of counterfeiting and economic adulteration of finished drug products. The U.S. has a closed pharmaceutical distribution system, which requires all products distributed within the US to be approved by the FDA. The nature of closed

systems provides a level of security not found in open systems. At a time when we are struggling to combat counterfeit drugs and tighten security at our borders, we should be searching for ways to close existing loopholes in the supply chain, not creating new ones by opening up the borders to foreign imports of non-FDA approved drugs or drugs produced in facilities not inspected by the FDA.

Again, I want to thank the FDA for this opportunity to present.