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Mr. Chairman, Madame Director General, and distinguished delegates, I am very pleased to have the opportunity to speak to this important issue. As the Commissioner of the Food and Drug Administration in the United States, a public health practitioner and a medical doctor, I have seen first hand the preventive damage to health caused by drugs and other medical products that people depend on, but they are, not what they purport to be.

Counterfeit, falsified and/or substandard medicines severely impact the health of individuals and populations in all countries. They put people at risk of harm from medical products that may contain too much, too little, or the wrong active ingredient, and/or contain toxic ingredients. They increase the likelihood of drug resistance and they undermine the security and trust of our health systems. Moreover, these fraudulent products many prevent patients from getting the real medical products they need to alleviate suffering and save lives.

The problem of counterfeit, falsified, and substandard medicines and medical products are a global threat. The issue was first addressed at the international level in 1985 at the Conference of Experts on the Rational Use of Drugs in Nairobi. The topic has also been discussed over time at the International Conferences of Drug Regulatory Authorities and through various WHO efforts over the decades that have developed guidance and information for regulatory authorities to aid in combating counterfeits.

Unfortunately, this global threat continues as technology and distribution and communication channels become more sophisticated, making it more difficult to detect and deter counterfeiting and protect the public health. In addition, little progress has been made in the development of information surveillance systems that can frame the global problem, identify stresses and risks for public health, and provide data for decision-making by policy makers to effectively address the challenges of counterfeit medical products and supply chain security.

Counterfeiting is growing in complexity, scale and geographic scope. Lack of reliable data prevents public health policy makers from comprehensively addressing the issues surrounding counterfeit, falsified or substandard medical products in a systematic, sustainable way. The threats surrounding counterfeit, falsified or substandard medicine require active engagement by a diverse range of all stakeholders at the international, regional and national levels.

The cornerstone to addressing the challenges of counterfeit, falsified or substandard medicines in this venue is public health. WHO has a leadership role to play in raising the awareness at the highest political levels about the complexities and negative impacts that these medical products pose, and in the building of global surveillance and monitoring system(s) that will assist in identifying areas of public health risk including such challenges and threats as diversion, intentional adulteration, and the increasing complexity

and reduced transparency of the global supply chain. This is especially important to Member States with limited regulatory capacity and infrastructure.

The U.S. Government would like to recognize the leadership of WHO and the International Medical Products Anti-Counterfeiting Task Force (IMPACT) for its work to address the public-health aspects of the counterfeiting of medical products. We also appreciate the Secretariat's actions to more carefully articulate the role of WHO within IMPACT, and the role of Member States to help in increasing the transparency around and knowledge about WHO and IMPACT's processes and outcomes.

The U.S. Government takes all reports of suspect counterfeit falsified or substandard medical products seriously, and puts the necessary resources into expeditiously investigating and following up on these reports, and into putting in place any actions (such as recalls) and public-awareness campaigns appropriate to protect U.S. citizens. This includes outreach and coordination with international regulators and law enforcement.

We are also aware that the focus globally must be on preventing the manufacturing and distribution of counterfeit, falsified or substandard medical prodcuts in the first place. Thus, we are committed to continuing to collaborate with WHO and Member States in strengthening their capacity to produce high-quality medicines, detect counterfeit, falsified or substandard medical products, track responsible parties, respond to toxicity cases, and raise public awareness.

While we recognize that there are a number of other issues related to counterfeit, falsified or substandard medical products being discussed, WHO is the forum to address the public health issues related to counterfeits, falsified or substandard medical products. The other issues should be addressed in other forums. We cannot deny the public health impact that counterfeit, falsified or substandard medical products pose and we should capitalize on the tremendous public health expertise that lies within WHO and Member States to combat the public health impact.

In closing, a strong, public health-focused, and action-oriented resolution can help to guide the Secretariat and Member States in addressing the challenges and complexities of counterfeit medical

products and supply chain integrity in sustainable, meaningful ways. We call on this Assembly to work together toward such a positive outcome.