PhRMA

Testimony Presented to the
Trade Policy Staff Committee

Hearing on Initiation of Proposed
United States-Korea Free Trade Agreement Negotiations
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Presented by

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Madam Chairman, Members of the Committee, Ladies and Gentlemen:

On behalf of PhRMA, I want to express our appreciation for the opportunity to testify in support of this historic FTA initiative. PhRMA represents America's leading biopharmaceutical companies. Our business is pioneering new ways to save lives, cure disease, and promote a healthier aging process. We are businesses, but our broader mission is enabling patients around the world to live longer, healthier, and more productive lives. In 2005, America's pharmaceutical and life sciences companies invested over $39.4 billion in advanced scientific research and development of new medicines to treat human diseases and conditions. The fruits of our efforts are new and more effective innovative medical treatments that can bring life, cures, and hope to patients and their families around the world.

PhRMA welcomes the launch of U.S.-Korea FTA negotiations. Korea is an important and growing market for U.S. research-based pharmaceutical/biomedical companies. Korean patients, like patients everywhere, want access to new advances in medical treatment, and America is a global leader in biotechnology and pharmaceutical research.

Over the past decade, PhRMA has worked closely with USTR, the Commerce Department, and the U.S. Embassy in Seoul to promote patient-centered reforms and open Korea's market to America's innovative medicines.

In particular, PhRMA has worked to eliminate discriminatory barriers that kept imported medicines off the National Reimbursement List (NRL); promote better recognition of the value of innovative medicines; separate the prescribing and dispensing of medicines in accord with internationally-accepted good medical practice; eliminate widespread illicit discounts that contributed to excessive NHI reimbursements and distorted medical prescribing practices; and improve the transparency of National Health Insurance (NHI) decision-making processes.

We view the U.S.-Korea FTA initiative as an unparalleled opportunity to enhance the access of Korean patients to leading U.S. biomedical products; further improve the transparency and accountability of the NHI system; and secure better and lasting recognition of the value of innovative American biomedical discoveries.

In supporting the FTA, we recognize the NHI is a major health policy accomplishment which reflects the commitment and determination of the Korean people to provide universal health care for all Koreans. The NHI reflects important choices and decisions by the Korean people about health care for the Korean nation. PhRMA respects these choices.

However, the operating environment in Korea presents numerous challenges for PhRMA's member companies that could be improved through the FTA

Some of the key areas of concern include:

- Recognition of Innovation. The NHI's policies and procedures for listing and reimbursing medicines need to be improved to strengthen recognition of the value of innovative medicines. Currently, the Korean pharmaceutical reimbursement system, for which the NHI is in effect a monopsonist single purchaser, lacks transparency and clear, fair, criteria in determining the value of innovative medicines, and systematically undervalues such medicines. Moreover, it is clear that local, generic products are reimbursed at very high rates (typically about 70% of the price of originator products), which simply directs scarce NHI resources away from newer, innovative drugs, and puts in place conditions that discourage local innovation. Korea's current reimbursement policies in fact represent a disguised industrial policy that not only hinders foreign companies wishing to expand business and investment in Korea, but actively dis-incentivizes local R&D by providing such high returns to those who merely imitate. This appears directly inconsistent with Korea's ambition to become a global biotech hub in the 21st century.

  Korea, and most importantly Korean patients, can only gain from a more transparent, science-based system that allows patients, foreign manufacturers and researchers, doctors, and other stakeholders to provide meaningful input into reimbursement policymaking and decisions, and subjects such decisions to independent review and real accountability. Korean and foreign innovators looking to develop drugs in Korea would likewise benefit from a system that rewarded and thus provided incentives for innovation, rather than imitation.

- Reimbursement Guidelines. A more objective process for establishing the guidelines and conditions under which drugs can be reimbursed would improve access to innovative medical discoveries that are developed abroad would only benefit Korean patients. It is common in Korea that even when new drugs are approved, the conditions under which doctors can prescribe them are sharply

limited. Such decisions should be driven by sound science, internationally-recognized good medical practice, and the best interests of Korean patients, not local protectionism.

- Transparency/Meaningful Consultation. In general, the Korean Government's decision-making processes relating to innovative medicines and drug policy lack transparency and do not ensure meaningful consultation with foreign companies regarding major policy or rule changes. Such decisions can lead to major changes in access to breakthrough U.S. medicines, with important consequences for Korean patients. The lack of independent appeal mechanisms contributes to arbitrary decision-making and a troubling lack of accountability.

- Ethical Business Practices. Better adherence to ethical practices would strengthen the health care system, boost doctor-patient relations, and bring Korea into accord with internationally-accepted good medical practices.

- Intellectual Property Rights. In general, Korea has a strong intellectual property system. It has provided product patent protection for pharmaceuticals since the 1980s. The government has taken a strong stance against counterfeiting. However, Korea provides only a limited *de facto* form of data exclusivity for purposes of TRIPS Article 39:3 and does not have a system to ensure patent linkage. These provisions should be clarified and strengthened in the FTA.

These reforms can be achieved without undermining the NHI's core drug benefit or the ways in which medicines are delivered to the Korean people. Indeed, these changes would benefit Korean patients; enhance public confidence in the integrity of doctors, hospitals, and medical professionals; strengthen the NHI system; and bring Korea into line with internationally-accepted good medical practices. Moreover, improved recognition of the value of innovative biomedical discoveries would ensure more timely and full access to leading U.S. pharmaceuticals, and support Korea's efforts to develop a world class biopharmaceutical sector that can be a global leader in advanced drug discovery.

Conclusion

PhRMA applauds the launch of U.S.-Korea FTA negotiations. We welcome Korea's goal of becoming an Asian leader in the advanced life sciences, particularly as biotechnology begins to play an increasingly important role in innovative drug discovery. We view the FTA as a potential breakthrough for Korean patients. We look forward to working closely and cooperatively with U.S.

and Korean negotiators to build an FTA that can advance patient-centered reforms; support improved recognition of the value of innovative drug discovery; and build an enduring U.S.-Korea partnership in innovative biopharmaceutical research.