AS PREPARED FOR DELIVERY
ON FEBRUARY 19, 2025

PhRMA 2025 Special 301 Hearing Statement

Thank you, my name is Ernest Kawka, and I am Deputy Vice President for International at the Pharmaceutical Research and Manufacturers of America – PhRMA.

On behalf of biopharmaceutical innovators in the United States and the nearly 5 million jobs they support across the country, PhRMA appreciates the opportunity to testify before the Special 301 Committee.

U.S. biopharmaceutical innovators lead the world in medicines research and development and have invested over $800 billion in R&D activities over the past decade. Intellectual property protections – including patents and regulatory data protection:

- drive and sustain biopharmaceutical innovation,
- enable access to today's new medicines; and
- promote investment in tomorrow's treatments and cures.

Where markets are open and intellectual property is protected, U.S. innovators have the predictability and certainty necessary to research, develop and deliver new medicines for patients who need them.

But urgent challenges abroad are threatening medical advances and undermining American jobs and exports. The Special 301 process gives the Administration a powerful tool to break down trade barriers and level the playing field.

Today's hearing comes at a time when reasserting American leadership on intellectual property has never been more critical. Unfortunately, over the last four years, the previous Administration deprioritized, and in certain instances proactively opposed, bipartisan trade and intellectual property protections needed by U.S. workers in this important sector.

The 2025 Special 301 Report should reflect the America First Trade Policy which requires USTR and other agencies to lead reviews of U.S. trade agreements and unfair practices abroad to ensure reciprocal treatment.

PhRMA's submission highlights how trading partners are failing to implement their trade commitments with the United States. For example:

- **Mexico** and **Canada** have yet to implement key intellectual property provisions required by USMCA, and Canada's pricing policies continue to undervalue innovative medicines. Addressing these issues now is critical given next year's USMCA review.

- **China** has yet to fully implement intellectual property commitments in Phase One of the Economic and Trade Agreement and continues not to provide regulatory data protection.

- **Korea** has failed to adopt market access policies that are transparent and appropriately value U.S. innovative medicines as required by the U.S. Korea Free Trade Agreement.

Accordingly, we ask that Mexico, Canada, China and Korea be named Priority Watch List Countries, and recommend that China continue under Section 306 monitoring.

PhRMA's submission also focuses on unfair trade practices, including egregious and discriminatory market access and intellectual property policies.

- In **Japan**, unpredictable changes to drug pricing rules and annual price cuts to patented medicines undervalue American innovation, threaten billions of dollars in lost sales and diminish American competitiveness, jobs and exports.

- **India** and **Argentina** severely restrict the types of inventions that are patent eligible – denying protections on innovations that are widely recognized in the United States. This lack of reciprocity improperly penalizes American manufacturers seeking to access the Argentine and Indian markets.

- In **Brazil**, it takes almost a decade to receive a biopharmaceutical patent. This represents one of the longest patent backlogs in the world, underscoring the need for durable reforms, including adopting a Patent Term Adjustment mechanism.

- Last year, **Colombia** issued its first ever compulsory license for an innovative medicine – a move that advances a political agenda with threats of more compulsory licenses forthcoming. Colombian officials have made clear that Colombia will "lead or support the position of abolishing patents."

As such, we ask that Japan, India, Argentina, Brazil and Colombia be named Priority Watch List Countries, and recommend an Out-of-Cycle Review of Colombia given the immediate threats posed by the Colombian's stated policies.

PhRMA members are also facing growing intellectual property threats in advanced economies, including the **European Union**. Specifically, the EU is considering legislative changes that would significantly weaken existing intellectual property incentives in the region, including proposals to:

- reduce the RDP term in the EU by two years and require market access conditions outside the control of the innovator to restore the lost term; and

- establish a pan-EU compulsory licensing mechanism targeting patent applications, patents, trade secrets, and know-how.

We therefore recommend that the EU be named a Watch List Country, and because of the EU's ongoing assessment of its pharmaceutical legislation, we ask USTR to conduct an Out-of-Cycle Review of the EU.

Finally, we urge USTR to use all available tools and leverage to address the serious challenges just mentioned, as well as those outlined in our written submission. We particularly urge you to address intellectual property barriers in countries that are current or prospective U.S. trade agreement partners, which present immediate opportunities for engagement.

Thank you for the opportunity to testify today. I look forward to answering any questions and to working with you to address the serious concerns described in our submission for the 2025 Special 301 Report.