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PhRMA 2026 Special 301 Hearing Statement

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

- PhRMA appreciates the opportunity to testify before the Special 301 Committee on behalf of the country's leading innovative biopharmaceutical companies.

- Our industry supports more than 5 million U.S. jobs and recently announced $500 billion in new U.S. manufacturing and infrastructure investments over the next decade.

- U.S. biopharmaceutical leadership depends on strong IP, pricing and reimbursement systems that reward innovation, and a level playing field abroad.

- The Special 301 Report is a critical tool to identify and resolve emerging and longstanding issues with trading partners.

- We welcome USTR leveraging the Report in the recently announced trade frameworks and investigations and support USTR building on these outcomes to secure durable policy reforms in future negotiations.

- PhRMA's 2026 submission highlights how key trading partners deny U.S. companies fair and reciprocal treatment by failing to provide adequate IP protections and appropriately value innovative medicines.

- For example, countries are increasingly measuring regulatory data protection terms from first global launch, limiting product eligibility for protection, conditioning protection on localization requirements, and reducing terms.

    - The **EU** recently finalized proposals that would shorten RDP terms and make restoration of the lost term contingent on prioritizing the EU for global medicine launches.

    - Despite currently not providing any RDP, **China** and **India** are developing policies that limit full RDP to products that are not approved elsewhere or tying RDP to patent status.

- Together, these measures are not reciprocal to U.S. practice and reinforce the need for a Special 301 review that compares trading partner policies with U.S. standards.

- The ability of U.S. innovators to secure, maintain, and enforce their patent rights abroad is also under pressure.

- The **EU** recently expanded exceptions to biopharmaceutical patent infringement–known as the Bolar Exemption–to enable activities that every other economy considers commercial and patent infringing.

- Just this month, **Brazil's** congress advanced harmful compulsory licensing bills affecting a wide range of medicines.

- The Special 301 statute also requires USTR to consider harmful market access practices, such as unfair pricing and reimbursement policies, that undermine the value of U.S. IP, and, in turn, U.S. competitiveness.

- Previous Administrations have provided insufficient attention to this requirement of the statute.

- We urge this Committee to utilize the Special 301 Report to prioritize such market access concerns, consistent with the President's directive to his Administration to ensure that foreign governments are not engaged in acts, policies or practices that suppress the price of pharmaceutical products below fair market value.

- PhRMA strongly urges USTR to prioritize these issues in the 2026 Report, particularly in **Europe**, **Japan**, and **Canada**.

    - **Germany and France**, for example, set low prices using biased health technology assessments, reference older inferior products as price benchmarks, and mandate price cuts and rebates to meet government budget targets.

    - **Japan** devalues new innovative medicines through draconian rules that set low prices of patented medicines at launch and then aggressively cut prices further throughout the patent period.

    - **Canada** uses low and outdated monetary thresholds per life year gained for clinically proven treatments to make reimbursement contingent on price cuts of 70-90%.

- The U.S.-UK pharmaceutical pricing agreement established important first steps by the **United Kingdom** to pay its fair share for innovative medicines. This outcome demonstrates that U.S. government trade tools are effective leverage to address unfair pricing and reimbursement policies abroad.

- Finally, the 2026 Report should highlight how **China**, **Canada**, **Mexico** and other trading partners have failed to implement their trade commitments with the United States.

- In conclusion, PhRMA encourages USTR to use all available tools, including its Special 301 authorities, to address the challenges outlined today and in our written

submission, which recommends the listing of 17 markets in the 2026 Special 301 Report.

- Thank you for the opportunity to testify. I look forward to answering your questions.