June 3, 2026

Chairman Jim Jordan
U.S. House Committee on the Judiciary
2138 Rayburn House Office Building
Washington, DC 20515

Ranking Member Jamie Raskin
U.S. House Committee on the Judiciary
2138 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Jordan and Ranking Member Raskin:

Ahead of the Committee's June 4 hearing, "Medicines and IP: Balancing Innovation and Access," I am writing to urge caution against relying upon misleading narratives to inform public policy in ways that could undermine American innovation, impede the pace of medical innovation against our most costly and complex diseases, and harm U.S. global competitiveness. For several decades, I have focused on research to inform the development of public policies to ensure a favorable environment for innovation in the United States. I am founder and president of Pritchett Policy Associates, LLC, and am affiliated with the Center for Strategic and International Studies, a bipartisan, nonprofit policy research organization and think tank dedicated to advancing practical ideas to address the world's greatest challenges.

The United States currently leads the world in the introduction of and access to innovative medicines. Medicines are in fact responsible for one-third of the gains in life expectancy over a 15-year period. That progress is due to recognition by the Framers of our Constitution of the importance of robust intellectual protections. In addition, Congress, recognizing the need to provide approval pathways that foster competition through the market entry of generic and biosimilar medicines while also maintaining incentives for innovation, has enacted two statutory frameworks that simultaneously reward innovation and establish streamlined approval pathways for generic or biosimilar products. Both patents and the exclusivities provided under the statutory schemes, the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, and the Biologics Price Competition and Innovation Act (BPCIA), have been successful in both fostering innovation and creating robust generic and growing biosimilar markets:

- Nearly 90% of prescriptions in the United States are filled with generics that have an average copay of under $7.
- According to the Association for Accessible Medicines generic and biosimilar medicines resulted in "$467 billion in savings in 2024 for patients and the U.S. healthcare system—and $3.4 trillion in savings the last ten years. Savings from biosimilar medicines alone increased to $20.2 billion in 2024 and $56.2 billion since the first biosimilar entry, a decade ago in 2015."[i]
- Intellectual property law includes provisions to allow for the challenge of patents resulting in an average effective patent life, as opposed to nominal patent life, of 13.35 years—significantly shorter than the 20-year patent term. The timeline for entry of generics stands in stark contrast to inaccurate claims from groups like I-MAK and Public Citizen that companies regularly "extend" the life of existing patents by filing new ones.

Organizations like I-MAK often highlight the number of patents on a given drug as evidence of competitive barriers, a study by the U.S. Patent and Trademark Office determined that this approach "can be misleading... because the number of patents does not provide a clear picture of the landscape without a review of the scope of the claims in each patent." I-MAK's misleading narrative underpins a growing number of legislative proposals aimed at weakening pharmaceutical patent protections, including measures like the ETHIC Act.

It is also important to recognize that companies cannot obtain patents for trivial or insignificant changes to a product. Patents are only granted for inventions that satisfy longstanding legal standards for novelty, usefulness, and non-obviousness. As a result, modifications to medicines that receive patents are not simply meaningless tweaks intended to expand patent portfolios -- as critics often assert -- but genuine advances, such as new formulations, delivery mechanisms, manufacturing processes, or new therapeutic uses that improve patient outcomes or treatment adherence.

The United States remains the global leader in biopharmaceutical innovation because it maintains a strong intellectual property policy framework that rewards lengthy, costly, and uncertain research and development that results in a U.S. Food and Drug Administration approval rate of about 10 percent. Despite the substantial scientific and regulatory uncertainties, American companies and research institutions develop nearly twice as many new medicines as Europe, while supporting millions of American jobs and driving more than $1.6 trillion in annual economic output.

However, America's continued leadership is not guaranteed. China is aggressively strengthening its biotechnology sector through state-backed investment and industrial policy. I would urge that as you consider how to foster continued innovation and how to sustain and grow U.S. economic strength, resilience, and global competitiveness that you consider the recommendations from a CSIS report that urges reinforcement of strong IP rights as a cornerstone of U.S. economic and national security. These and other recommendations for strengthening U.S. innovation and U.S. competitiveness are highlighted in my CSIS commentary.

In contrast, adopting proposals like the ETHIC Act -- which would make certain patents on medicines effectively unenforceable – risks undermining the foundation of America's leadership in pharmaceutical innovation. Weakening patent protections would discourage long-term private investment and empower competitors like China.

Such an outcome would be detrimental not only to America's global standing and national security, but also to patients. The drug development process involves substantial scientific uncertainty and enormous financial risk. Without a strong patent system to ensure that companies can earn a return on successful research and development investments, companies will have far less incentive to develop the new cancer treatments, Alzheimer's therapies, and rare disease drugs that patients need. Further, as China continues to gain on the United States in terms of the introduction of new medicines, given other public policies that have been implemented increasing the costs and uncertainty for the biopharmaceutical industry at the same time that China and other competitors are increasing government investments and incentives for innovation, we risk a future where U.S. patients are dependent on China for access to new medical advances.

There are better ways for lawmakers to help lower out-of-pocket costs for patients. For example, Congress would be wise to focus greater attention on the opaque system of insurers, pharmacy benefit managers (PBMs), and other intermediaries that directly dictate what Americans pay at the pharmacy

counter. These middlemen exercise enormous control over formularies, rebates, and patient access, and they frequently face strong incentives to inflate patient costs behind the scenes. Promoting transparency and accountability among these middlemen would do far more to reduce patient costs than weakening the patent system that underpins biomedical innovation.

In short, weakening patent protections would undermine future innovation while doing little to meaningfully lower out-of-pocket costs for patients. At a time when the United States needs to strengthen its position as the world leader in biopharmaceutical innovation, Congress should avoid policies that could discourage investment, weaken competitiveness, and slow the pace of medical progress.

Thank you for your consideration and for your attention to this important issue. Note that the comments herein reflect my views not necessarily those of CSIS.

Sincerely,

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