



June 16, 2026

The Honorable Bill Cassidy
Chair
Committee on Health, Education, Labor
and Pensions
United States Senate
Washington, DC 20510

The Honorable Bernie Sanders
Ranking Member
Committee on Health, Education, Labor
and Pensions
United States Senate
Washington, DC 20510

Dear Chairman Cassidy and Ranking Member Sanders:

The U.S. Chamber of Commerce strongly opposes S. 2658, the Medication Affordability and Patent Integrity Act, and urges Congress to reject it.

This bill is a solution in search of a problem. There is no evidence that inconsistent disclosures between the U.S. Food and Drug Administration (FDA) and U.S. Patent and Trademark Office (USPTO) are a systemic issue, and existing law already provides a powerful deterrent. Failure to disclose material information with intent to deceive the USPTO renders an entire patent unenforceable. Rather than address a demonstrated need, the bill would instead flood an already overburdened USPTO with volumes of FDA submission data that may not be useful to USPTO, slowing patent examination and ultimately delaying new treatments from reaching patients.

The bill also poses a serious threat to American competitiveness. Companies share extensive confidential data with the FDA, including trade secrets, with the reasonable expectation that it will be protected. Requiring companies to provide USPTO with information submitted to FDA that is deemed material to patentability risks moving highly sensitive regulatory information into a patent-review process that, even with the bill's confidentiality provision, is not designed to handle confidential FDA data in the same way, creating a serious risk of public exposure and handing a direct advantage to foreign competitors, including China. On top of that, the bill would create a new patent infringement defense based on procedural noncompliance rather than the merits of the patent itself, inviting costly litigation that undermines the integrity of the patent system without benefiting patients or innovators.

By layering a new certification-based issue on top of the existing inequitable conduct framework, S. 2658 would increase litigation complexity and costs for all parties. In effect, it would create a second, procedural dispute within patent litigation

that is untethered from the merits of patentability or infringement. This would increase litigation costs and complexity for both parties.

S. 2658 represents a radical departure from the United States' longstanding commitment to a technology-neutral patent system. It would lower the threshold for challenging patent validity and create a new infringement defense applicable only to a single industry. That approach is especially misguided in the biopharmaceutical sector, where strong patent protection is essential to support the extraordinary risk, cost, and time required to develop new medicines—and where global competitors, particularly China, are moving aggressively in the opposite direction by strengthening their own patent systems.

The Chamber urges Congress to reject S. 2658 and instead focus on preserving the strong intellectual property framework that has made the United States the global leader in biopharmaceutical innovation.

Sincerely,

A handwritten signature in blue ink, appearing to read "Neil Bradley", with a stylized flourish at the end.

Neil Bradley
Executive Vice President, Chief Policy Officer, and
Head of Strategic Advocacy
U.S. Chamber of Commerce