June 24, 2019

Senator John Cornyn
517 Hart Senate Office Bldg.
Washington, DC 20510

Dear Senator Cornyn,

As strong supporters of free markets, property rights and innovation, we write to share our concerns about S.1416, the "Affordable Prescriptions for Patients Act of 2019," as introduced by you and Sen. Blumenthal (D-CT).

In recent years, skeptics of free markets and property rights like Bernie Sanders have continually lobbed baseless, inaccurate criticisms at the patent system, and specifically at the biopharmaceutical industry. We were quite surprised to see you sponsoring legislation that assumes these uninformed critiques, defines incremental innovation as anticompetitive, and subjects it to newly expanded regulatory scrutiny and penalties. It is hard to overstate the harm this legislation could pose, not only to biopharmaceutical innovation, but eventually to all innovative industries and our economy at large.

Companies in every industry protect their innovations through patents, and they continue to innovate and improve their products after patents have been granted and throughout the product life cycle. Patents are issued for inventions, not products, and many products involve numerous, sometimes hundreds of patented innovations. An expert agency, the U.S. Patent and Trademark Office, determines whether a given innovation qualifies for a patent. In every industry new, innovative products are more expensive, but the prices soon scale down as products go off-patent and are replaced by newer, more-innovative products. In fact, a patent grant often attracts competitors to enter a market with similar but non-infringing products, creating price competition even while the patent is in effect. This system, enshrined in the U.S. Constitution, tremendously benefits consumers, and in the process it has made the United States the global leader in exporting the products of innovation. None of this is unique to the biopharma industry.

Yet your legislation assumes that this beneficial system is somehow nefarious when used by the biopharma industry, characterizing it as "product hopping" and "patent thicketing." It subjects biopharma patents to second-guessing by a non-expert agency, the Federal Trade Commission (FTC), and punishes biopharma innovation through expanded antitrust scrutiny.

This legislation would also dramatically expand the authority of the FTC and turn it into an additional regulator of biopharma innovation. Such an expansion in regulatory power is not only contrary to limited government and free markets, but it is also unnecessary. Where genuine anti-competitive behavior might occur, the federal government already has the tools to deal with it.

Your legislation would also dramatically expand antitrust as a remedy, because its provisions weigh heavily in favor of an antitrust violation. Almost no follow-on product could pass the legislation's three-part test, which places the burden on companies to rebut presumptions of anti-competitive activity.

Under your bill, *almost any incremental innovation made after filing of an original new drug application or biologics license application would be presumed to be anti-competitive and subject to penalties.*

By classifying incremental innovation as anti-competitive, your legislation erodes incentives and threatens innovation. These provisions should be of grave concern to proponents of limited government.

But perhaps most ominous is the threat posed to continued medical innovation. Beyond discouraging incremental improvements in biopharma products, your legislation actually assumes incremental improvement to be suspect. The most notable losers are the patients who would have benefitted from such improvements.

There are certainly ways to improve how we pay for drugs, which include forcing insurers to live up to the commitments they made under the Affordable Care Act and increasing scrutiny of pharmaceutical benefit manager middlemen. We would be delighted to share our thoughts with you on how to make drugs more affordable without threatening innovation.

Recent Supreme Court decisions have already weakened our patent system. As USPTO Director Andrei Iancu has said, "[O]ur current law surrounding patentable subject matter has created an unpredictable patent landscape that is hurting innovation and, consequently, investment and job creation . . . . We are at an inflection point with respect to the patent system itself. As a nation, we cannot continue down the same path if we want to maintain our global economic leadership."

We hope you will reconsider your advocacy of this harmful legislation, and we will be happy to work with you toward solutions to high drug prices that do not threaten biopharma innovation.

Sincerely,

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Institute for Policy Innovation

Thomas A. Schatz, President
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Daniel Schneider, Executive Director
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* Organizations are listed for identification purposes only