

**Prepared Statement by Senator Chuck Grassley of Iowa
Chairman, Senate Judiciary Committee
Antitrust Subcommittee Hearing on
“The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring
Drug Price Competition,”
Tuesday, June 21, 2016**

Unfortunately I have other appointments scheduled for this afternoon, so I won't be able to stay long. Mr. Chairman, I appreciate you allowing me to speak first.

When I hold my Q&A meetings with Iowans, I constantly hear from constituents about how expensive drugs are and how that's impacting their bottom line. So I've worked with my Senate colleagues not only on policy solutions to incentivize innovators to find new cures for diseases, but also on ways to facilitate competition in the drug marketplace. I've conducted oversight of the drug market to make sure drug companies aren't acting in an anti-competitive or predatory manner.

And, I've worked with Ranking Member Klobuchar on legislation to put a stop to anti-competitive pay-for-delay deals between brand and generic drug companies.

So I was concerned when we heard of other tactics that appeared to frustrate the intent of the Hatch-Waxman Act – a law enacted to streamline and expedite the approval process for generic drugs. We heard that certain brand drug companies were misusing their Risk Evaluation and Mitigation Strategies, known as REMS, to withhold access to drug samples for bioequivalence testing and generic drug development in violation of FDA regulations and the Hatch Waxman Act.

We also heard that certain brand companies were misusing REMS to deny access to the REMS single shared system requirements under FDA regulations.

These concerns were discussed at a March Judiciary Antitrust Subcommittee oversight hearing where Federal Trade Commission (FTC) Chairwoman Ramirez spoke about drug company strategies that could have the effect of delaying or preventing generic competition.

In response to written questions that I submitted at that hearing, Chairwoman Ramirez reiterated her position: “The FTC continues to be very concerned about potential abuses by branded pharmaceutical companies of REMS or other closed distribution systems to impede generic competition. . . . [T]his conduct undermines the careful balance Congress struck in the Hatch-Waxman Act to encourage competition from lower-cost generic drugs, and may violate federal antitrust laws.”

So I joined my colleagues Senator Leahy, Lee and Klobuchar in looking at how we might address these concerns. These strategies basically amount to brand drug companies using an FDA regulatory process set up as a safety measure, to instead block generic competition. This keeps prescription drug costs high for patients, insurers and government programs.

Now I'm the first one in line when it comes to making sure our drugs are safe and potentially dangerous drugs are restricted and carefully monitored and distributed. But we also need to make sure that games aren't being played and laws aren't being undermined when we're trying to increase the availability and affordability of prescription drugs.

So we narrowly tailored our bill to address the specific anti-competitive abuse and manipulation of the FDA safety regulations we had heard about from the FTC. The CREATES Act targets the delay tactics of brand companies 1) refusing to share samples and 2) refusing to agree on shared safety protocols.

The bill doesn't impact the ability of our antitrust regulators to go after violations in this area under the antitrust laws. But it does provide for a faster, less complex, avenue by which to seek limited relief – primarily injunctive relief – to get lower cost, safe generic drugs on the market as soon as possible.

I'm always open to hearing how legislation can be improved, but I believe we strike the right balance in ensuring that health, safety and competition goals are appropriately balanced.

And a large number of groups agree. The CREATES Act is supported by a number of groups, including the Iowa AARP, the Iowa Medical Society, the Iowa Pharmacy Association and Wellmark. I'd like to ask the Chairman to put in the record letters from Iowans that I've received in support of this bill.

I want to make sure that consumers can enjoy the benefits of drug competition – more choice and lower prices for their lifesaving drugs. The CREATES Act will help do just that.

Again, thank you Chairman Lee and Ranking Member Klobuchar for allowing me the courtesy of making my statement first at this important hearing.