CHAMBER OF COMMERCE
OF THE
UNITED STATES OF AMERICA

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The Honorable Dick Durbin
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20510

The Honorable Chuck Grassley
Ranking Member
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Chairman Durbin and Ranking Member Grassley:

The U.S. Chamber of Commerce is concerned with several antitrust bills scheduled to be marked up in the committee on July 29. The Chamber has long held that antitrust laws should remain a law of general application. As a matter of principle, the Chamber opposes crafting special antitrust rules applicable only to certain industries.

Existing antitrust laws are already quite capable of evaluating the conduct the legislation seeks to address. Efforts to "groove" antitrust law specific to an industry is something for legislation to direct as a matter of regulation, not antitrust enforcement.

Further, antitrust enforcement and decisions made by a court are intensely fact specific to the case before the court. While general inferences can be made from one case to another, attempts through legislation to move antitrust away from the rule of reason toward a quasi-*per se* approach and government directed market outcomes should be avoided.

Affordable Prescriptions for Patients Act of 2021 (S. 1428)

While S. 1428 be well-intentioned, we are concerned about significant unintended consequences. While we share and support the need to address potential barriers to lowering drug costs, re-evaluate potential perverse incentives that may impact the way manufacturers set list prices, and correct distortions in the distribution chain, we are concerned that the legislation's rebuttable presumption provision would effectively codify a quasi-*per se* theory of liability for certain types of pharmaceutical-related patent settlements. By doing so, the legislation would have the unintended consequence of creating a barrier to entry for generic pharmaceutical companies, resulting in less competition and higher drug prices for consumers.

Patent dispute settlements are a valuable tool to ensure that affordable generic and biosimilar medicines are quickly introduced to the market. They typically take place in the context of challenges to patents where the period of exclusivity (or patent term) has not yet

expired. The Hatch-Waxman Act expressly encourages these pre-expiration challenges, which usually end in an agreement on how soon before a patent expires a generic competitor will enter the market. This provides legal certainty to both generic and name-brand drug manufacturers.

The settlement out of court is an alternative to litigation, which burdens the court system with unnecessary costs and may often delay generic market entry beyond what could otherwise be achieved through settlement. By limiting the types of settlements that can be used in the types of patent litigation covered by the bill, S. 1428 would increase uncertainty in a market that is already experiencing significant price challenges. Uncertainty in this space only serves to increase cost and ultimately limit the ability of both generic and name-brand pharmaceutical manufacturers to resolve their disputes and bring their products to patients in a timely and cost-effective manner.

The legislation would put a thumb on the scale in these types of cases by presuming that all these types of settlements are anti-competitive. Instead, the legislation should focus on fostering earlier access for generics by enshrining a "rule of reason" standard along the lines of what the U.S. Supreme Court articulated in *FTC v. Actavis*, 570 U.S. 136 (2013). Congress should enunciate a standard that looks at whether the overall facts and circumstances of the settlement agreement amount to having an inappropriate anti-competitive effect. This would allow generic pharmaceutical manufacturers to enter the market earlier, resulting in more competition and lower costs for the consumer, and limit protracted litigation.

Finally, we oppose the legislation's retroactive application.

Preserve Access to Affordable Generics and Biosimilars Act (S. 1435)

S. 1435 would undercut investment in biopharmaceutical innovation and discourage improvements to approved medicines as it will subject such efforts by drug manufacturers to heightened antitrust scrutiny. Genuine efforts to improve products are clearly pro-competitive, but this legislation will chill such efforts. Newly created antitrust scrutiny comes as the legislation prescribes in regulatory-like terms how a drug manufacturer can transition to an upgraded version of its medicine. As expressed above, the Chamber strongly believes that the role of antitrust is distinct and should remain distinct from the role of regulation.

Further, S. 1435 would create a government-imposed burden through the timetables it imposes to effectively require the drug manufacturer to assist generic drug entry into the marketplace. Generic entry into the market should not be impeded, but neither should the law require an existing competitor to assist new entrants. S. 1435 creates such a burden as it outlines when changes to pre-approved drugs can be made and when earlier versions of a manufacturer's product can be withdrawn from the market. Despite the legislation's attempt to allow drug manufacturers to rebut the presumptions made in the law, S. 1435 represents the heavy hand of government in antitrust law.

We urge the Committee to reject reporting these bills in their current forms.

Sincerely,

Neil Bradley

cc: Members of the Committee on the Judiciary