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Antitrust Concerns and the FDA Approval Process

Testimony before the Subcommittee on Regulatory Reform, Commercial and Antitrust Law

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Chairman Marino, Ranking Member Cicilline, and distinguished Members of the Subcommittee:

I am pleased to testify today regarding Antitrust Concerns and the U.S. Food and Drug Administration (FDA) Approval Process. I applaud you for convening this hearing.

My name is Alden Abbott. I am the Deputy Director and the John, Barbara, and Victoria Rumpel Senior Legal Fellow in the Edwin Meese III Center for Legal and Judicial Studies at The Heritage Foundation.[1] The views I express in this testimony are my own, and should not be construed as representing any official position of the Heritage Foundation. Today I will very briefly note the interplay between regulation and the competitive process, before commenting specifically on the potential abuse of FDA Citizen Petitions. I will then summarize my views on the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2017, introduced in the House and in the Senate on April 27, 2017.[2]

[1]The title and affiliation are for identification purposes. Members of The Heritage Foundation staff testify as individuals discussing their own independent research. The views expressed here are my own, and do not reflect an institutional position for The Heritage Foundation or its board of trustees, and do not reflect support or opposition for any specific legislation.

[2] The CREATES Act was introduced in the House by Subcommittee Chairman Tom Marino and Ranking Member David Cicilline as H.R. 2212 and in the Senate by Senator Patrick Leahy of Vermont. The House and Senate versions are identical. *See* H.R.2212 - CREATES Act of 2017, https://www.congress.gov/bill/115th-congress/house-bill/2212; S.974 - CREATES Act of 2017, https://www.congress.gov/bill/115th-congress/senate-bill/974.

Regulation and the Competitive Process

There is an extensive academic literature on how regulated entities may manipulate the regulatory process to undermine competition.[3] Such regulatory manipulation is harmful to the American economy. It often deters entry into a market and thus precludes competition on the merits, thereby raising prices above competitive levels, reducing product quality, spawning economic inefficiency, and deterring innovation, which is a key driver of economic growth.

As a general matter, in order to maximize economic welfare, federal regulators should seek to devise rules that are as procompetitive (and as little subject to anticompetitive manipulation by private parties) as possible, consistent with statutorily-set goals. This can be a difficult task, given the complexity of the issues and the congressional mandates which federal agencies confront. There are, however, certain general procompetitive principles which federal regulators can turn to in formulating rules, such as those found in the Organization for Economic Cooperation and Development's (OECD) "Competition Assessment Toolkit,"[4] or the International Competition Network's ICN "Recommended Practices on Competition Assessment."[5] In addition, the Trump Administration might wish to consider providing federal regulatory agencies assistance from U.S. Department of Justice and U.S. Federal Trade Commission economists who specialize in the economics of competition. Such an effort would comport with the Administration's focus on regulatory reform.[6]

Moving from the general to the specific, one particular sort of regulatory manipulation that undermines competition is the taking of actions by an incumbent firm to forestall entry into the market by a potential competitor. Concerns have been raised that some incumbent brand name pharmaceutical companies have used FDA "Citizen Petitions" to delay entry from producers of generic versions of their branded drugs, after the expiration of brand name company patents. A Citizen Petition authorizes an individual to request that the FDA "issue, amend, or revoke a regulation, or order to take, or refrain from taking, any other form of administrative action."[7] Current regulations require that the FDA review and respond to every Citizen Petition it receives, including supplements or amendments to petitions.[8]

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[3] *See generally*, *e.g.*, Amihai Glazer, *Regulatory Policy*, in THE ELGAR COMANION TO PUBLIC CHOICE, SECOND EDITION (William F. Shughart II, Laura Razzolini, and Michael Reksulak, eds., 2013), https://www.elgaronline.com/view/9781849802857.00029.xml. A detailed analysis of this literature is beyond the scope of my testimony.

[4] OECD, Competition Asssessment Toolkit (2017), http://www.oecd.org/daf/competition/assessment-toolkit.htm.

[5] *See* Alden F. Abbott, "The ICN's Recommended Practices on Competition Assessment: Reflections on Measuring Competitive Harm," *Competition Policy International* (ICN Column) (Sept. 22, 2014), https://www.competitionpolicyinternational.com/the-icns-recommended-practices-on-competition-assessment-reflections-on-measuring-competitive-harm/.

[6] The Trump Administration has announced a focus on excessive federal regulatory impediments that merit being eliminated, in the context of agency-specific regulatory review task forces established by Executive Order in February of this year. *See* Executive Order No. 13777, "Enforcing the Regulatory Reform Agenda" (Feb. 24, 2017), https://www.whitehouse.gov/the-press-office/2017/02/24/presidential-executive-order-enforcing-regulatory-reformagenda.

[7] 21 C.F.R. § 10.30(b)(3).

[8] 21 C.F.R. § 10.30(e)(1).

Claims have been made that Citizen Petitions have been filed to undermine competitive generic entry into certain pharmaceutical markets. In 2015, the FDA stated that it was "concerned that . . . [the existing FDA statutory scheme] is not discouraging the submission of [Citizen] [P]etitions that are intended primarily to delay the approval of competing drug products and do not raise valid scientific issues."[9] Most recently, in February 2017, the Federal Trade Commission filed a complaint in federal district court alleging that a branded pharmaceutical company, Shire Viropharma Inc., engaged in a repetitive series of meritless filings (including 24 FDA Citizen Petitions) to delay generic competition and maintain the monopoly status of its prescription drug, Vancocin HCl Capsules.[10]

Clearly baseless FDA filings made by brand name pharmaceutical firms, that lack any plausible efficiency justification and are used solely to forestall competition, undermine the competitive process and harm the economy. The FDA and Congress certainly should consider what further legislative or regulatory steps may be appropriate to curb such abusive filings, including (but not necessarily limited to) reform of the Citizen Petition process.

The Federal Trade Commission's suit against Shire Viropharma appears to advance sound policy. I would, however, add a slight note of caution. Although antitrust actions to curb clearly pretextual petitioning have the potential to reduce harmful regulatory delays, such cases need to be selected with great care by public officials. Although the Supreme Court has found that "sham" petitioning is not protected, it has held that an effort to influence the exercise of government power, even for the purpose of gaining an anticompetitive advantage, may not create liability under the antitrust laws.[11] Furthermore, there is the risk that at some future time, overzealous antitrust enforcers may mistakenly characterize genuine petitioning as sham activity. In short, a bit of antitrust "regulatory humility" is in order, to avoid chilling genuine petitioning activity.

The CREATES Act of 2017

The CREATES Act of 2017 is a modified – and, in my view, improved – version of the CREATES Act of 2016, on which I testified favorably before the Senate Judiciary Antitrust Subcommittee in June 2016.[12] Both the 2016 and the 2017 versions of the CREATES Act target two

[9] U.S. FOOD & DRUG ADMIN., SEVENTH ANNUAL REPORT ON DELAYS IN APPROVALS OF APPLICATIONS RELATED TO CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION FOR FISCAL YEAR 2014 1 (Aug. 3, 2015), https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBudgets/UCM464282.pdf.

[10] *See* Fed. Trade Comms'n, Press Release, FTC Charges That Shire ViroPharma Inc. Abused Government Processes Through Serial, Sham Petitioning to Delay Generics and Maintain its Monopoly over Vancocin HCl Capsules (Feb. 7, 2017), https://www.ftc.gov/news-events/press-releases/2017/02/ftc-charges-shire-viropharma-inc-abused-government-processes.

[11] *See* Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961); United Mine Workers v. Pennington, 381 U.S. 657 (1965); David E. Bernstein, *Freedom of Petition*, in THE HERITAGE GUIDE TO THE CONSTITUTION 415-418 (2nd ed. 2014). As Professor Bernsteing explains, the "*Noerr-Pennington* doctrine" line of cases that shields "non-sham" government petitioning from antitrust review is influenced by the Freedom of Petitioning Clause of the First Amendment, which provies that "Congress shall make no law . . . abridging . . . the right of the people . . . to petition the government for a redress of grievances." U.S. Const., Amend. 1.

[12] Testimony of Alden F. Abbott, Deputy Director and John, Barbara, and Victoria Rumpel Senior Legal Fellow, Edwin Meese III Center for Legal and Judicial Studies, The Heritage Foundation, before the Subcomm. on Antitrust, Competition Policy, and Consumer Rights, Comm. on the Judiciary, U.S. Senate (June 21, 2016),

types of abusive delay tactics that may be used by brand name drug companies to block the entry of generic drugs into the marketplace. The first type involves unreasonable refusals by a brand name company to allow a potential generic competitor to obtain samples of the branded product. This prevents the generic firm from performing the testing necessary to show that its product is equivalent to the brand name product, a prerequisite for FDA approval. The second type involves the brand name company's refusal to allow generic competitors to participate in safety-based regulatory protocols, without which a generic producer cannot gain FDA approval for the production of certain "high risk" drugs.

In 2016, I testified before the Senate Antitrust Subcommittee as follows:

> I believe that the current [2016] version of the CREATES Act would, if enacted by Congress, enhance competition and consumer welfare. Specifically, the Act would promote welfare-enhancing competition in the market for brand name pharmaceuticals and biologics, and their lower-priced generic and biosimilar substitutes, without inappropriately undermining the intellectual property rights of individuals who bring forth new innovative medical treatments that greatly improve the quality of American health care. The Act also would not impose undue burdens on the manufacturers of brand name drugs and biologics. The Act would further its objectives in two ways. First, it would help prevent prospective generic and biosimilar entrants from unreasonably being denied access to the drug samples that are needed for regulatory testing to enter the market, without challenging the validity of the established firms' intellectual property protections. Second, it would afford prospective generic and biosimilar competitors access to safety-based regulatory protocols required to compete in the market.[13]

The 2017 version of the CREATES Act, similar to the 2016 version, allows a generic drug manufacturer facing the first delay tactic (unjustified denial of access to drug samples) to bring an action in federal court for injunctive relief, in order to obtain the drug samples it needs. The bill also authorizes a judge to award damages to deter future delaying conduct. With regard to the second delay tactic (denial of access to regulatory protocols), the 2017 Creates Act allows the FDA more discretion than the 2016 version to approve alternative safety protocols, rather than require parties to develop shared safety protocols. Mandated access to a safety protocol developed by a brand name company (backed by the threat of costly litigation) is no longer required under the 2017 Act. The 2017 Act thus eliminates the concern expressed by some brand name companies that the 2016 Act would unjustifiably allow generic firms to "free ride" on regulatory protocols they had not developed. Under the 2017 Act, any safety protocol approved by the FDA must meet the rigorous statutory standards already in place.

Finally, the 2017 CREATES Act fills a statutory gap. As I explained in my 2016 Senate Antitrust Subcommittee testimony, the antitrust laws are ill-suited to combat anticompetitive regulatory manipulation.[14] In particular, as I emphasized, antitrust litigation tends to be slow, which cuts against the policy interest of promoting rapid competitive generic entry following the expiration of a patent. In addition, the need to show antitrust-related harm presents obstacles to a successful antitrust lawsuit against a brand name company for allegedly restricting access to its products by generic firms. Private plaintiffs face problems in showing causation and harm to their business

https://www.judiciary.senate.gov/imo/media/doc/06-21-16%20Abbott%20Testimony.pdf (Abbott 2016 Testimony).

[13] Abbott 2016 Testimony at 1.

[14] Abbott 2016 Testimony at 4-5.

interests, and government enforcers could have difficulty in demonstrating likely harm to consumers. Furthermore, requiring a brand name company to provide samples would run afoul of the general antitrust presumption against requiring a firm to assist a competitor.[15] The narrow and targeted statutory remedy set forth in the 2017 CREATES Act avoids these problems.

In sum, the 2017 Act represents an improvement on the 2016 version. While not a panacea, it would, on balance, reduce the incidence and burden of abusive regulatory delays that undermine pharmaceutical industry competition.

Conclusion

In conclusion, anticompetitive manipulation of the regulatory process is a serious problem. Moreover, baseless petitioning of a regulatory agency to undermine competition may justify antitrust intervention. Nevertheless, the mere violation of agency regulations – and, in particular, FDA regulations – does not (and should not) give rise to antitrust liability. In light of this, there is a role for targeted legislation to disincentivize brand name firms from denying generic drug producers access to samples they need to enter the market, after patents have expired. In my opinion the CREATES Act of 2017 fulfills this role in an appropriate fashion.

Thank you once again for inviting me to testify at this hearing. I look forward to your questions.

[15] *See* Verizon Communications, Inc., v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398 (2004) (telecommunications company's violation of its regulatory duty (under federal communications law) to make its facilities available to a rival did not constitute an antitrust violation).

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