Before the
FOOD AND DRUG ADMINISTRATION
Rockville, MD 20852

In the Matter of	)	
	)	
Citizen Petitions; Actions That	)	Docket No. 99N-2497
Can be Requested by Petition; Denials,	)	

I.

[1] This comment represents the views of the Bureau of Competition and of Policy Planning of the Federal Trade Commission, and not necessarily the views of the Commission itself or any individual Commissioner.

[2] 64 Fed. Reg. 66822 (Nov. 30, 1999).

enforcing Section 7 of the Clayton Act[3] and Section 5 of the Federal Trade Commission Act[4] and from antitrust enforcement activities affecting both the branded and generic drug industries.[5] The staff of the FTC's Bureau of Economics has recently released a report studying competition issues in the pharmaceutical industry, which also informs this view.[6]

In this comment, we recognize that, as is the case for virtually any regulatory process, there is a potential for anticompetitive abuse of the FDA's citizen petition process.[7] Thus, rules designed to reduce this potential can be valuable; however, the restrictions may not unduly restrict the exercise of the First Amendment right to petition the government for redress of grievances. In considering the Proposed Rule, the FDA may wish to consider two additional informational requirements on citizen petitioners. First, to better identify potentially anticompetitive petitions, the FDA may wish to require the petitioner to reveal whether it has received, or will receive, consideration for filing the citizen petition and the identity of the party

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[3] 15 U.S.C. § 18 (1988). Mergers subject to Section 7 are prohibited if their effect "may be substantially to lessen competition, or to tend to create a monopoly." *See, e.g.*, Roche Holding Ltd., C-3809 (Feb. 25, 1998) (consent order) <http://www.ftc.gov/os/1998/9802/97100ag.agr.htm>; Ciba-Geigy, Ltd., 123 F.T.C. 842 (1997) (consent order); and Hoechst AG, 120 F.T.C. 100a (1995) (merger with Marion Merrell Dow, Inc.). *See, also,* U.S. Department of Justice and Federal Trade Commission, *Horizontal Merger Guidelines*, issued April 2, 1992, revised April 8, 1997.

[4] 15 U.S.C. § 45 et seq.

[5] *See, e.g., Federal Trade Commission v. Mylan Laboratories, Inc. et al.*, 1999-2 Trade Cas. (CCH) ¶72,573 (D.D.C. 1999), *appeal filed.*

[6] Staff of the Federal Trade Commission, "The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change" (Mar. 1999) (Levy Report) <http://www.ftc.gov/reports/pharmaceutical/drugexsum.htm>.

[7] Robert H. Bork, The Antitrust Paradox 347 (1978) ("The modern profusion of [. . .] governmental authorities offers almost limitless possibilities for abuse.").

It is well recognized, however, that regulatory processes can provide an opportunity for anticompetitive abuses.[9] To delay competition may be a lucrative strategy for an incumbent, especially in an industry where entry is regulated, such as those regulated by the FDA (*e.g.*, medical devices, pharmaceuticals, etc.). For example, empirical research has shown that relaxation of entry impediments has given rise to significant entry and price competition in drug markets.[10] This increased breadth and depth of generic drug market presence has been confirmed in FTC staff investigations of the pharmaceutical industry. Generally, the staff has found that the more generic versions of the same drug product that are on the market, the closer the price is to its competitive level, regardless of which generic companies are marketing the drug product. To avoid such price and other competition may be a significant goal of an incumbent.

Moreover, new entrants into pharmaceutical markets typically face major hurdles due to rivals' intellectual property claims and new and abbreviated drug approval proceedings. The stakes are often very high in light of the lucrative nature of many pharmaceutical product markets. Improper petitioning may be appealing in part because it can be used against any size firm, regardless of relative resources of the parties. The cost of filing an improper citizen petition may be trivial compared to the value of securing a delay of a year or more in a rival's

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[9] *See e.g.*, Federal Trade Commission, In the Matter of Amerco and U-Haul International, Inc., 109 F.T.C. 135 (1987) (consent order prohibiting U-Haul from initiating or participating in any judicial or administrative proceeding in which the main purpose is to harass or injure any competitor or potential competitor).

[10] Levy Report, *supra* n. 6, at 13. (Competition in pharmaceutical markets has increased since the enactment of the Hatch-Waxman Act which, among other things, streamlined the approval process for generic drugs. American consumers now have greater access to generic drugs at lower prices than their branded counterparts.)

[11] Bork, *supra* n. 7, at 348.

[12] *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus. Inc.*, 508 U.S. 49 (1993); *see also* Bork, *supra* n. 7, at 354.

[13] *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965). In its simplest terms, the *Noerr-Pennington* doctrine shields private parties from antitrust liability when they engage in concerted and genuine efforts to influence governmental action, even though the conduct is undertaken with an anticompetitive intent and purpose. The doctrine is significant because it seeks to accommodate two rights that are important in guaranteeing personal liberty: the right to petition government, and the right to an economic system driven by free and unfettered competition. For a further discussion of the Noerr-Pennington doctrine, *see* James D. Hurwitz, "Abuse of Governmental Processes, the First Amendment, and the Boundaries of Noerr," 74 Geo. L. J. 601 (1985).

[14] *Professional Real Estate Investors*, 508 U.S. 61 (quoting *Columbia v. Omni Outdoor*

[16] *Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. at 380

or paying a third party is less than the expected lost revenue from competing against the new entrant, it could be profitable for the existing market participant to engage in this behavior. More important, this type of behavior is not limited to the generic drug industry, but applies with equal force to other market segments that the FDA regulates.

The FDA also may wish to consider an additional requirement that the party filing the citizen petition provide a list, to the best of the petitioner's knowledge, of the other citizen petitions that have been filed on the same underlying matter (*i.e.*, the same underlying drug product). By requiring petitioners to list all previous citizen petitions on the same subject matter, the FDA could potentially ease its burdens by allowing it to consolidate the petition with other pending petitions or to respond to the petition more quickly. Such a requirement also could help ensure that the petitioner has all the relevant facts and information before submitting a citizen petition and perhaps even obviate the need for filing a citizen petition with the agency altogether once the petitioner has all the relevant information on the issue.

The FDA has proposed to amend the certification that petitioners must make to attest to the accuracy of the petition and to its underlying nature.[17] The FDA may wish to further amend the certification so that the petitioner certifies that it has not knowingly and willfully made any materially false, fictitious, or fraudulent statement or representation in the petition such that the

[17] Under the Proposed Rule, a petitioner would certify that "to the petitioner's best knowledge and belief, the citizen petition includes all information and views on which the petition relies, that it is well grounded in fact and is warranted by existing laws or regulations, that it is not submitted for any improper purpose, such as to harass or to cause unnecessary delay, and that it includes representative data and information known to the petitioner which are unfavorable to the petition."

petitioner would be subject to criminal penalties for doing so.[18] The possibility of criminal penalties for perjury may also increase the reliability of the information contained in the petition to allow the FDA to review and respond to the petition in an expeditious manner.

IV. The FDA May Wish to Refer Suspected Improper Petitions to the FTC for Review.

The FDA may wish to consider instituting a system through which petitions that the FDA suspects are being used for improper competitive purposes are referred to the FTC to determine if the antitrust laws may have been violated. For example, a case in which a series of petitions is filed by the same party that raise no new issues, or in which a competitor files petitions that are duplicative or meritless, could be referred to the FTC.

V. Conclusion

The FDA, in addition to amending its rules to narrow the scope of citizen petitions and to provide greater flexibility in processing these petitions, may wish to include two additional information requirements in its citizen petitions -- identification of any consideration received

[18] *See* 18 U.S.C. § 1001.

and other petitions filed involving the same underlying matter. The FDA also may want to refer petitions to the FTC that the FDA suspects are being used for improper competitive purposes.

Respectfully submitted,

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