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,	)	
Withdrawals, and Referrals for Other	)	
Administrative Action	)	

COMMENT OF THE STAFF OF THE BUREAU OF COMPETITION AND OF POLICY PLANNING OF THE FEDERAL TRADE COMMISSION

March 2, 2000*

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*Inquiries regarding this Comment should be directed to
Michael Wroblewski (202) 326-2155

I. The FTC's Interest in this Proceeding

The staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission (FTC) welcomes this opportunity to present its views on important competition issues raised in the above-captioned proceeding.[1] In this proceeding, the Food and Drug Administration (FDA) has issued a Proposed Rule aimed at improving the citizen petition mechanism as one way for persons to contact the agency concerning matters within FDA's jurisdiction.[2] Not only is the proceeding seeking to improve the efficiency of the citizen petition mechanism, it also is seeking to reduce the potential that citizen petitions can be used for improper purposes, such as delaying competition. Currently, citizen petitions are often used to request that the FDA engage in certain activities or make certain rulings concerning a drug product or medical device. The FDA proposes to narrow the scope of FDA actions that citizen petitions can be used to initiate and to provide flexibility on how FDA can respond to these petitions. In addition to these proposals, which are likely to increase the effectiveness of the citizen petition process, this comment provides suggestions to discourage abuse of the FDA's regulatory processes.

The FTC is an independent administrative agency charged with promoting the efficient functioning of the marketplace by taking law enforcement action against commercial practices injurious to consumers and by increasing consumer choice by promoting vigorous competition. Staff approaches the competition issues presented in this proceeding from experience in

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[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/1998/9802/9710103.agr.htm>; Ciba-Geigy, Ltd., 123 F.T.C. 842 (1997) (consent order); and Hoechst AG, 120 F.T.C. 1010 (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.").

furnishing the consideration. Second, to better identify cumulative or duplicative petitions aimed at delaying competition from rivals, the FDA may wish to require that the petitioner 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). In addition, the FDA may wish to bolster the proposed certification that citizen petitioners must make so that, at least potentially, criminal penalties can be assessed against a petitioner that knowingly supplies false information in its petition.

Lastly, the FDA may wish to consider instituting a system through which it refers petitions that are suspected of being used to delay competition to the FTC to determine if competitive issues are implicated.

II. Background

The FDA has noted in its Proposed Rule that there are several informal and formal ways for consumers to contact it on a particular issue (*e.g.*, via letter, meeting, or citizen petition) and that the proposals in this proceeding are not intended to curtail the First Amendment right to petition the agency.[8] Citizen petitions often raise legitimate issues concerning matters within the agency's jurisdiction. In fact, issues raised in citizen petitions have played useful roles in ensuring the safety of various drug products.

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[8] 64 Fed. Reg. at 66823. The FDA has proposed to limit the types of actions that may be requested in a citizen petition to those requesting that the agency: (1) issue, amend, or revoke a regulation; (2) amend or revoke an order that the agency has issued or published; or (3) take an action as specifically authorized by another FDA regulation. In addition, the FDA has proposed to increase its flexibility in responding to citizen petitions by allowing the agency to consolidate like petitions, provide a response of an appropriate length depending upon the subject matter, and permit parties to withdraw a citizen petition. Thus, petitioners will be able to continue to raise safety and effectiveness issues about new drugs that have been approved by FDA order.

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.)

entry into a lucrative market.[11] If regulatory intervention (or a series of interventions) is used to impede competition, antitrust concerns may be raised.[12]

Participation in the regulatory process, however, is often protected from antitrust scrutiny by the Noerr-Pennington doctrine.[13] There are exceptions to this doctrine: the Supreme Court has made clear that where one uses "the governmental process – as opposed to the outcome of that process – as an anticompetitive weapon," the protection of the Noerr doctrine may not apply.[14] Indeed, if litigation or regulatory intervention is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits," a party's behavior may not be immune from antitrust challenge.[15] As an example, the Supreme Court identified as unprotected conduct "the filing of frivolous objections to the license application of a competitor," with no real expectation of achieving denial of the license, "in order to impose expense and

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[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 Advertising, Inc.*, 499 U.S. 365, 380 (1991)).

[15] *Id.*

delay."[16] FTC staff investigate allegations of this type of anticompetitive conduct in the pharmaceutical industry. We will continue to look for circumstances where competitors improperly use the regulatory or judicial process to prevent consumers from receiving the benefits of a competitive market. Nonetheless, tailoring these rules may further, and more effectively, limit the filing of improper citizen petitions in the first place.

III. Citizen Petitions Should Include Additional Information to Ease FDA's Administrative Burdens.

In addition to the Proposed Rule, which is likely to reduce the opportunities for filing anticompetitive petitions, the FDA may wish to require petitioners to include two more informational items in their petitions. First, the FDA may wish to consider requiring notification of whether the petitioner has received, or will receive, consideration for filing the citizen petition, and identification of the party furnishing the consideration. If the petitioner receives consideration after the petition is filed, the petitioner would be obligated to notify the FDA of that fact as well.

Our observation of the pharmaceutical industry shows that existing product holders have an incentive to block generic entrants and may do so by raising concerns about a potential generic entrant's drug application before the FDA. A competitor may raise these concerns itself or have them raised by independent parties (either individuals or groups) by providing consideration to file a citizen petition raising the issues, so as to disguise the anticompetitive intent behind the petitioning. The effect of such a petition could be to delay FDA approval of a rival drug application, even if the petition is not ultimately upheld. Because the costs of filing the petition

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[16] *Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. at 380 *(*quoting *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972)).

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,

Richard G. Parker, Director
David A. Balto, Assistant Director for
Policy and Evaluation
Bureau of Competition

Susan S. DeSanti, Director
Michael S. Wroblewski, Advocacy Coordinator
Policy Planning

FEDERAL TRADE COMMISSION
600 Pennsylvania Ave., NW
Washington, DC 20580

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