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PhRMA

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Secretary
Federal Trade Commission
Room H-159
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: Generic Drug Study – FTC File No. V000014
Request for Comment, 65 F.R. 61,334 (Oct. 17, 2000)

Dear Sir or Madam:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") welcomes the opportunity to comment on the Federal Trade Commission's ("FTC's") proposed study of the effects of certain provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), Pub. L. 98-417.

PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies. PhRMA's member companies will invest nearly 26 billion dollars this year alone in discovering new medicines that greatly improve the public health and the lives of patients and their families. This substantial commitment to discovering new medicines depends on strong intellectual property protection. As a consequence, PhRMA and its members have a deep interest in preserving the carefully crafted balance of the Hatch-Waxman Act between the needs of innovator companies for strong intellectual property protection and the desire to speed generic versions of new medicines to market.

The FTC has issued a Notice and solicited comments on its intention to collect information from innovator and generic pharmaceutical manufacturers regarding the effects of certain provisions in the Hatch-Waxman Act. The Notice explains that the FTC seeks "documents and information [to] determine whether agreements or other strategies are being used to delay generic drug competition and thus may merit law enforcement action, and to evaluate the effectiveness of the generic drug provisions of the Hatch-Waxman Act." FTC, Agency Information Collection Activities, Proposed Collection, Request for Comments, 65 F.R. 61,334 at 61,336 (Oct. 17, 2000) ("FTC Notice").

The proposed study raises fundamental concerns and does not comply with the requirements of the Paperwork Reduction Act.

I. The Proposed Study is Not Necessary

PhRMA believes that the proposed study is not necessary. Among the FTC's central missions, of course, is protecting consumers by enforcing the antitrust laws. The FTC

quite properly should be concerned to understand regulatory systems and private agreements that might affect competition between an innovator and a generic or other competitor. However, as the FTC itself noted in its press release ("FTC to Study Generic Drug Competition," October 11, 2000), it is already aware of a substantial number of agreements between innovator and generic companies relating to the Hatch-Waxman Act and has conducted extensive investigations concerning several such agreements. As a result of these investigations, the FTC has become quite sophisticated in analyzing such agreements and understanding their implications. This has been highlighted, among other ways, through the recent consent agreements entered into between the FTC and innovator and generic companies, as detailed in the FTC press release.

These efforts by the FTC have already sent a strong message to the industry of the FTC's concerns. Private litigation stimulated by the FTC's investigations has further reinforced the FTC's message. Moreover, the FDA has proposed to change its regulations to resolve precisely the FTC's concern that agreements under the existing rules between innovators and generic companies may illegally delay effective generic competition by establishing a 180-day "use it or lose it" trigger for Hatch-Waxman Act exclusivity. See FDA, 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 F.R. 42,873, 42,874-75.[1] (Aug. 6, 2000) ("FDA Proposed Rule").[2]

The incentives built into the Hatch-Waxman Act and its current implementing regulations are well known to the FTC and fully illustrated by the agreements already known to the FTC. And the FTC Staff has acknowledged that the FDA's proposed rules "may remedy the delayed generic competition that has resulted from certain types of agreements between generic and innovator companies." Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission, In re 180-Day Generic Drug Exclusivity for ANDA, p. 2, FDA Docket No. 85N-0214 (Nov. 4, 1999) ("FTC Staff Comments"). Thus, to the extent the FTC wishes to make recommendations concerning amendments to the Hatch-Waxman Act or its implementing regulations, it is unlikely that the proposed study would add new insight. Further, any agreements of concern to the FTC are likely to become publicly known fairly readily. Innovator companies and generic manufacturers usually publicize the entry of such agreements because they often exert a substantial impact on the participants' businesses. Thus, there is little risk that the FTC will not become aware of any new agreements of concern.

In short, the proposed study seems unlikely to uncover new agreements of concern, will add little to the FTC's already sophisticated understanding of the motivation for,

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[1] Although PhRMA believes that the particular solutions selected by the FDA in the Proposed Rule and the Interim Rule do not comply with the carefully balanced requirements of the Hatch-Waxman Act, it understands that the FDA is revising its regulations to accommodate court-ordered changes.

[2] Since initiating the rulemaking, the FDA has also issued an Interim Rule to reduce uncertainty caused by additional court decisions. See FDA, Court Decisions, ANDA Approvals, and 180-Day Exclusivity, 65 F.R. 43,233 (July. 13, 2000).

and dynamics of, brand-generic agreements arising out of the Hatch-Waxman Act, and would needlessly expend resources studying a type of agreement, the incentives for which already have been drastically reduced. The FTC's investigatory resources should be deployed elsewhere.

II. Licenses and Patent-Dispute Settlements Between Innovators and Generic Manufacturers Can Benefit Consumers and Need Not Be Anticompetitive

The breadth and thrust of the proposed study also raise concerns that the FTC may incorrectly suspect that all licenses and agreements to resolve patent disputes between innovator and generic companies are inherently anti-competitive and violate the antitrust laws. As the FTC's public statements about its recent investigations reflect, nothing could be farther from the truth. As a general matter, patent licenses and dispute settlements are a time-honored mechanism for inventors to remove a cloud of uncertainty about the scope of or their contribution to an invention and proceed to develop and market it. In the long run, providing a less costly means than full litigation to remove these clouds of uncertainty helps to preserve the value of patents and the consequent attractiveness of inventing in the first place. Licenses and patent dispute settlements thus can play a central role in fostering innovation, to the benefit of both competition and consumers. This is particularly true in the pharmaceutical industry, in which innovators risk enormous sums to discover and develop innovative products but do not enjoy the full fruits of patent exclusivity because of the need for lengthy regulatory review before being allowed to market their innovations.

The antitrust laws, of course, prohibit competitors from illegally reducing or eliminating competition, to the detriment of consumers, and the FTC should be concerned to identify any such anticompetitive agreements that would illegally eliminate or reduce competition between an innovator and a generic or other competitor. In seeking to protect competition, however, the FTC should be careful to target only those agreements likely to cause an illegal anticompetitive effect. PhRMA is concerned that the proposed study would subject innovator and generic pharmaceutical companies to a broad-based search of data and documents before there is any reason to suspect that their licenses or agreements settling patent disputes actually have any illegal anticompetitive effect. Simply put, that some companies choose to resolve patent disputes by license or settlement rather than full litigation does not justify a fishing expedition.

III. The Proposed Study is Overly Broad and Ambiguous

In addition to its larger concerns discussed above, PhRMA also is concerned about the particular specifications of the proposed study. The FTC proposes to collect all agreements between an innovator and any other person that relate to an "ANDA involving any Drug Product," including not only those relating to the filing of an ANDA, but also patent dispute settlements, licensing agreements, and acquisition or divestiture agreements affecting products that are the subject of an ANDA. FTC Notice, 65 F.R. at 61,335 (Request 1). In addition, the study would collect a broad range of other documents and data, some already available to the FDA (such as patents and ANDA filings) and some very sensitive and

confidential (such as an amorphous category of documents relating to the reasons for making the agreement). Id. (Requests 1 through 4). These requests are both overly broad and ambiguous.

The FTC's only stated concern is that agreements between innovator and generic companies relating to an ANDA may "slow or thwart the entry of competing generic drug products." 65 F.R. at 61,334. As currently drafted, however, Request 1 would sweep in a host of agreements that almost certainly will have no effect on when a generic product will be introduced. For instance, the proposed request appears to cover licensing and other agreements between innovators and generic manufacturers that relate to already marketed generic drug products and thus do not affect when a new generic product may begin to be marketed. Similarly, it appears to cover such agreements entered into before the innovator became aware that the generic manufacturer had filed or intended to file an ANDA and thus could not have been intended to delay the introduction of a competing generic product. The proposed request also appears to cover merger, acquisition, and licensing agreements between two innovator companies if one of them manufactures a drug product that is the subject of an ANDA, again without any likely effect on when a third (generic) company might begin marketing a generic product.

PhRMA also believes that the FTC does not need the additional documents and data relating to agreements called for in the remainder of Request 1 and in Requests 2 through 4. Commenting on proposed revisions to the Hatch-Waxman Act implementing regulations, the FTC Staff has noted that receiving a copy of any agreement between innovators and generic manufacturers is sufficient to make the FTC "aware of any possible anticompetitive issues involved." FTC Staff Comments, at 2-3. If the FTC were to identify an agreement raising such issues, then it has ample power to investigate and, if needed, to collect this additional information from the particular companies involved. See 15 U.S.C. §§ 49 and 57b-1. The merely theoretical possibility that this additional information might prove useful in a later law enforcement action – if an agreement is produced and if that agreement involves "anticompetitive issues" – does not justify collecting it in a dragnet of all innovator companies against whom ANDAs have been filed.

The second half of Request 1, specifying additional documents relating to the agreements identified, is also extremely ambiguous. It calls for "all studies, surveys, analyses and reports . . . that evaluate or analyze the reasons" for entering an agreement. This language appears to track that long used for Item 4(c) of the Notification and Report Form implementing the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Item 4(c), however, is limited to documents evaluating or analyzing a transaction with respect to largely objective concepts such as "markets," "market shares," "prospects for sales growth or expansion." In contrast, Request 1 relates to the inherently subjective concept of "reasons." Whose "reasons" count – any employee's? Only an officer or director's? Some official decision-making body or other official organ of the company? Similarly, are handwritten notes mentioning a reason sufficient to constitute an "analysis" or "evaluation"? If not, then at what point does a written discussion become an "analysis" or "evaluation"? Respondents (or, more likely, their legal counsel) may be able to make their own judgments about how to answer these questions, but they will do so at the peril of court-ordered contempt for noncompliance. They may also reach very different judgments and thereby reduce the effectiveness and utility of the study to the FTC.

Other data specified in Requests 2 through 4 are freely available to the FTC, at least once it receives any agreements called for by Request 1. The Addendum to the FDA's annual Orange Book identifies companies, pharmaceuticals and patents. Any agreement relating to an ANDA will refer to the pharmaceuticals and companies in question, allowing the FTC to locate the relevant listings in the Orange Books. The Orange Book listings also identify any patents for these drugs, which the FTC can then peruse and print from the Patent Office's web site. See http://164.195.100.11/ netahtml/srchnum.htm.

In short, PhRMA believes that Request 1 sweeps far broader than agreements likely to affect when a generic product might begin to be marketed and the remainder of Requests 1 through 4 are both unnecessary and ambiguous. To focus the proposed study on the FTC's stated concern, PhRMA suggests that the FTC limit the study to collecting agreements between an innovator and a person that has filed an ANDA or may file an ANDA and in which the ANDA filer or potential ANDA filer commits to refrain from or delay its ANDA filing or the commercial marketing of a generic product in return for consideration from the innovator.

IV. The Notice and Proposed Study Do Not Comply with the Paperwork Reduction Act

In light of the proposed study's many and central problems, PhRMA has grave doubts that the study and Notice satisfy the requirements of the Paperwork Reduction Act ("PRA"), 44 U.S.C. § 3501 et seq.

The PRA requires the FTC to certify to the Office of Management and Budget ("OMB") that the study will have "practical utility." 44 U.S.C. § 3506 (c)(3)(A). OMB's implementing regulations make clear that this requires "the actual, not merely theoretical or potential, usefulness of information to or for an agency, taking into account its accuracy, validity, adequacy, and reliability, and the agency's ability to process the information it collects . . . in a useful and timely fashion." 5 C.F.R. § 1320(l) (emphasis added). As noted above, however, the FTC's recent investigations of agreements under the Hatch-Waxman Act have already provided the FTC a sophisticated understanding of the Act and of private agreements relating to ANDAs. The investigations have also sent a strong signal to the pharmaceutical industry about the FTC's concerns. Moreover, both the FDA and the FTC Staff believe that the FDA's proposed "use-it-or-lose-it" 180-day trigger for generic exclusivity will remedy the FTC's central concern about agreements between innovators and generic companies. The FTC's proposed study as a whole will thus offer no new insights into the past regulatory regime and will neither be necessary nor timely to evaluate the new one.

Even if some study were of some "practical utility," PhRMA believes that only the suggested narrowly defined collection of agreements between innovators and generic companies could be justifiable at all. The FTC Staff has already stated that documents and data going beyond agreements are not required to recognize any "competitive issues." Such additional documents and data, therefore, could only be of potential usefulness in the event that a further investigation is warranted, and do not satisfy OMB's definition of "practical utility." As discussed above, the specifications for additional documents and data also fail to use "unambiguous terminology" and are "unnecessarily duplicative of information otherwise