COMMENTS ON PROPOSED INFORMATION AND DOCUMENT REQUESTS

AUTHORIZED GENERIC DRUG STUDY

FTC Project No. P062105

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I. INTRODUCTION AND OVERVIEW

These comments, submitted on behalf of an undisclosed client, address the Federal Trade Commission's Comment Request with respect to FTC Project No. P062105,[1] requesting observations on the relevance and burden of proposed requests for documents and information to be issued in connection with a planned study by the FTC of the competitive effects of authorized generic drugs.[2]

These comments are addressed principally to

- "whether the proposed collections of information are necessary for the proper performance of the functions of the FTC, including whether the information will have practical utility," and
- "ways to enhance the quality, utility, and clarity of the information to be collected."[3]

A main purpose of the proposed study is to determine the extent, if any, to which the expectation of price competition from authorized generics during the 180-day marketing exclusivity period decreases the incentive of generic manufacturers to enter the market and gain exclusivity by filing paragraph IV certifications—and, in consequence, deters market entry to the detriment of consumers.

To answer this question, the Comment Request calls for production of extensive information and documents relating to the recent history of generic entry. Production of

[1] 71 Fed. Reg. 16779 (Apr. 4, 2006). Citations below are to the Comment Request as found on the Commission's web site, http://www.ftc.gov/os/2006/03/P062105AuthorizedGenericDrugStudyFRNotice.pdf.

[2] The term "authorized generic drug" is defined in the Comment Request at 2-3. The Comment Request summarizes the relevant provisions of the Hatch-Waxman Act and other regulatory background. This comment assumes familiarity with this regulatory background and with the specialized terminology and abbreviations used in the Comment Request.

[3] Comment Request at 5.

this information will be burdensome for the pharmaceutical companies, and its review will burden the Commission's staff. Yet the practical utility of the information will be limited, because of a recent material change in the regulatory environment: the enactment of Section 6003 of the Deficit Reduction Act of 2005.

Among other things, the new provision, effective in 2007, amends the definition of "best price," for purposes of calculating the Medicaid rebate, to include prices charged for authorized generics sold by an affiliate or other licensee of the NDA holder. The purpose, and the likely effect, of this amendment is to fundamentally reduce the incentives of branded firms to introduce authorized generics. Thus, the purported "problem" that gave rise to the proposed study will likely disappear, or be substantially reduced, without any further regulatory or legislative action. And the regulatory environment will be materially altered, so that the information sought will be of little practical utility to any possible Commission action or change in statutory law.

Moreover, it is undisputed that, where authorized generics have been introduced, there has often been vigorous, but non-predatory, price competition, of great benefit to consumers. We believe, however, that there no instances where fear of such price competition has deterred any generic firm from filing an ANDA prior to patent expiration.

The most efficient way to address the central question—the purported entry-deterring effect of fear of price competition from authorized generics—is to begin by posing interrogatories to generic firms calling on them to identify instances of claimed deterrent effect. Such information will help the Commission to refine its list of drugs to be included within the study and otherwise to proceed expeditiously, without undue burden to itself or to the responding parties.

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II. THE CENTRAL QUESTION

Meaningful comment on the relevance and burden of the proposed information requests depends on a correct understanding of the purpose of the study. Is the study intended to produce a general, academic description of the authorized generics business, *sans* particularized initial working hypotheses? Or is the study, instead, aimed at examining specific "competitive effects" and testing specific working hypotheses? If so, what competitive effects—either desirable or undesirable—are to be investigated, and what working hypotheses are to be tested? And to what end?

The main purpose of the proposed investigation may be gleaned from the words of the Comment Request, the documents it cites as background for the proposed investigation, and the political context in which the Comment Request was issued.

The Comment Request states, at 3,

> In recent years and with increasing frequency, brand-name drug manufacturers have begun to market authorized generic drugs at precisely the same time that a paragraph IV generic is beginning its period of 180-day marketing exclusivity. The likely effects of this practice on generic competition have been subject to some debate. In the short run, the entry of an authorized generic drug may benefit consumers by creating additional competition that lowers generic prices further than if only the paragraph IV generic were marketed. Many generic manufacturers assert, however, that in the long run, consumers will be harmed because an expectation of competition from authorized generics will significantly decrease the incentives of generic manufacturers to pursue entry prior to patent expiration. For a generic manufacturer, the additional competition from an authorized generic may result in significantly less profit during the period of 180-day exclusivity than if the generic manufacturer had no authorized-generic competition during that time.
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> Currently, there is no publicly available, comprehensive economic study that assesses the likely short- and long-run effects of entry by authorized generics on generic competition. [footnote omitted]

In short, the main economic question is this:

To what extent, if any, does the expectation of price competition from authorized generics during the 180-day marketing exclusivity period (the "exclusivity period") decrease the incentive of generic manufacturers to enter the market and gain exclusivity by filing paragraph IV certifications, and, in consequence, deter market entry to the detriment of consumers?

Clearly, this question was central to the concerns of Senators Grassley, Leahy, and Rockefeller, when they wrote the letter cited by the Commission (*see* Comment Request at 5) as one of the communications giving rise to the proposed investigation. The three Senators referred to the exclusivity period and then went on to state,

> We have heard concerns that the practice of "authorized" generics could have a negative impact on competition for both blockbuster and smaller drugs, because the generic industry would be less inclined to invest in their production. Consequently, if the generic industry were to be less incentivized to produce such generic drugs to compete with name brand drugs, it is possible that fewer generic drugs would come to market and the prices for certain drugs would remain high for consumers.[4]

This same question is the principal concern of Commissioner Leibovitz, who observed,

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[4] http://www.senate.gov/~rockefeller/news/2005/pr051205a.html. Representative Waxman expressed exactly the same concern in his September 20, 2005, remarks to the Generic Pharmaceutical Association:

> Brand-name drug companies have increasingly been putting "authorized generics" onto the market just as the first generic competitor is set to begin its 180 days of exclusive marketing. As you know, the Hatch-Waxman Amendments created this incentive for generic companies who challenge patents on the brand name drug—in exchange for undertaking the costs and risks of patent litigation, the successful challenger is given 6 months of marketing without any other generic competition.
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> Of course, the practice of using authorized generics substantially reduces the value of the 180-day exclusivity to the generic drug manufacturer who challenged the patent. The practice raises the serious possibility that generic drug manufacturers may stop challenging patents—at least in the substantial numbers they have up until now.

http://www.waxman.house.gov/news_files/news_statements_generic_pharmaceutical%20_association_9.20.05.htm.

> The introduction of an authorized generic will likely diminish the incentives for generic firms to challenge patents and incur substantial development and litigation costs. And, of course, one of the reasons for a brand foregoing short-term profits on one product may be to chill the incentives of generics to develop competing products in the future.
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> My sense is that the impact on generic firms' incentives will vary. It is quite possible that for blockbuster drugs, the pot of gold for generics will still be large enough so that they will fight to be first to file and first to market. But we could very well see fewer generic applications for smaller drugs—the ones that won't earn several hundred million dollars a year in revenues. This could lead to fewer generic products on the market, which could then result in less competition down the road. That would be bad for consumers.[5]

Targeted Investigation or General Contribution to the Economic Literature?

In sum, the study called for by Senators Grassley, Leahy, and Rockefeller, Representative Waxman, and Commissioner Leibovitz would not be an expansive, broadly conceived academic exercise, but would instead investigate specific alleged competitive effects flowing from the sale of authorized generics, particularly during the exclusivity period.

In the Comment Request the Commission refers to the congressmen's requests,[6] states that it proposes to undertake "such a study,"[7] but goes on to describe the exercise in more expansive terms:

> Among other things, the proposed study will examine actual wholesale prices (including rebates, discounts, etc.) for brand-name and generic drugs, both with and without competition from authorized generics; business reasons (including profitability assessments) that support authorized generic entry; factors (including product development and litigation costs) relevant to the decisions of generic firms about whether and under what circumstances to seek entry prior to patent expiration; and licensing agreements with authorized generics. These data will enable the proposed study to *make new contributions to the economic literature on the effects of generic drug entry on prescription drug prices* and, in particular,

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[5] Remarks by Commissioner Leibovitz to the Antitrust in Health Care Conference, May 12, 2005, http://www.ftc.gov/speeches/leibowitz/050512healthcare.pdf.

[6] Comment Request at 3, last full paragraph.

[7] *Id.*, second to last line on the page.

the role of the 180-day period of exclusivity in generic competition prior to patent expiration.[8]

Each and every item in the proposed request for documents and information might, conceivably, lead to the Commission's learning information that might "make new contributions to the economic literature"—no matter how burdensome the collection of such information might be, no matter how tangentially relevant (or totally irrelevant) it might be to the central question identified above, no matter how far removed the data might be from the subject of possible legislation to remedy the perceived problem, and no matter how much delay an expansive investigation might cause in the congressmen's receiving an answer to the question they asked.

Accordingly, in these comments we do not attempt to address what documents and information might or might not contribute in some abstract way to the economic literature. Instead, we focus on the central concerns raised by those who prompted the proposed investigation.

Lawful, Non-Predatory Competition. The Commission assumes—correctly, indeed, indisputably—that an NDA holder may lawfully permit its product to be sold under a chemical name, rather than a brand name, and in generic trade dress.[9] Indeed, authorized generics are economically indistinguishable from the practice of selling private label products, common in a wide variety of industries. The price competition occasioned by the entry of an authorized generic has the same effect that may result from other forms

[8] *Id.*, at 4 (emphasis added).

[9] *See* Comment Request at 2, citing Teva Pharm. Indus. v. FDA, 410 F.3d 51 (D.C. Cir. 2005), where Judge Ginsburg demonstrated conclusively that nothing in the Hatch-Waxman Act bears on the right of an NDA holder to sell its product under the chemical name of the pharmaceutical, or to employ generic trade dress.

of lawful price competition. A brand name manufacturer might, for example, introduce a new patented, branded product with similar therapeutic effect and sell that product at a highly competitive price. Or it might simply lower the price of the original branded product.

Conspicuous by its absence—in the Comment Request, the documents cited in the Comment Request, or in related materials such as statements by the Generic Pharmaceutical Association[10]—is any allegation or concern that authorized generics are being sold at predatory prices.

Likewise conspicuous by its absence is any allegation or concern that price competition between authorized generics and paragraph IV generics may be weak or ineffectual—and, therefore, that consumers might enjoy only a minimal benefit from the presence of authorized generics. To the contrary, all the concerns about the presence of authorized generics have been based on the assumption that the introduction of authorized generics often leads to substantial, albeit non-predatory, price competition.

Thus, the only specific anticompetitive competitive effect that has been claimed to arise from the introduction of authorized generics is the alleged entry-deterring effect said to flow from anticipated price competition. We submit that the relevance and burden of the proposed requests for documents and information should be judged largely by reference to this crucial question. Then issue is discussed in greater detail below.

In part IV we briefly address the broader concerns, raised by some, that price competition is harmful because it purportedly "weakens" the generic industry.

[10] *See* http://www.gphaonline.org/AM/Template.cfm?Section=Issues&TEMPLATE=/CM/HTMLDisplay.cfm&CONTENTID=1932 (stating the association's position on authorized generics).

III. ENTRY DETERRENCE?

As discussed above, we understand that the central question to be investigated is this: To what extent, if any, does the expectation of price competition from authorized generics during the exclusivity period decrease the incentive of generic manufacturers to enter the market and gain exclusivity by filing paragraph IV certifications? Based on this understanding, our comments

- point out that recent changes in the law mean that the extensive historical data and information laid out in the Comment Request will shed little light on the future role of authorized generics—which is very much in question,
- suggest a different approach toward getting at this central question, in a way intended to focus efficiently on the main area of contention and minimize the burden both to the Commission and to the responding parties, and
- urge that the information requests be revised in several ways to improve their utility and reduce their burden.

A. A Change in the Law

Information and data on past market conditions is often a good predictor of future market conditions. Sometimes, however, conditions change, in a way that greatly reduces the predictive value of historical data.

We believe that Section 6003 of the Deficit Reduction Act of 2005 is such a material change. Among other things, the new provision, effective in 2007, amends the definition of "best price," for purposes of calculating the Medicaid rebate, to include prices charged for authorized generics sold by an affiliate or other licensee of the NDA holder.[11]

[11] The 2005 act, among other things, amends Section 1927 of the Social Security Act, 42 U.S.C. § 1396r-8, by adding the following additional subclause to (c)(1)(C)(ii) (definition of "best price"):

> (IV) in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act , shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, health maintenance organization.

According to the summary of the legislation in the Congressional Record, the intent of the change is to "Close Authorized Generics Loophole" by

> Improved regulation of authorized generic drugs. This section requires CMS [Centers for Medicare and Medicaid Services] to include the best price of an authorized generic in the calculation of the best price for the branded drug.[12]

The "loophole" to which Senator Grassley made reference was CMS's prior practice of disregarding the prices charged for authorized generics when calculating "best price," even though authorized generics are able to take advantage of the branded pharmaceutical's NDA for purposes of FDA regulation.

Where, as is often the case, a branded pharmaceutical is sold at a much higher price than its generic counterparts, this change in the law will create a powerful disincentive for branded manufacturers to compete on price through the use of authorized generics—a disincentive that did *not* exist during the historical period covered by the Comment Request.

In short, the data and information outlined in the Comment Request will become obsolete just at the time the Commission is collecting and analyzing it. Insofar as the 2005 legislation actually closes the "authorized generics loophole," as intended—and there is ample reason to think that the intended result will be achieved—any fear of price competition by authorized generics, and any concomitant disincentive to file ANDAs, will greatly diminish. Even for purposes of an academic "contribution to the economic literature," the data and information will be of limited utility, except for historical purposes.

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[12] 152 CONG. REC. S12071 (Oct. 31, 2005) (material placed in the record by Sen. Grassley).

Accordingly, we submit, the preferable course is to proceed cautiously, along the lines indicated in III.A., above; make a reasoned, fact-based preliminary determination as to whether the claimed disincentive appears real at all; and wait to observe the effect of the 2005 legislation before proceeding to a full-blown inquiry into pricing of authorized generics.

B. Getting at the Central Question

We believe that the Comment Request materially underestimates the burden of compliance. However, be that as it may, there is no dispute that the burden will be quite substantial—not only for the responding parties, but also for the Commission, whose staff must spend the effort and resources to understand the material they receive.

Plainly, the origin of the proposed investigation lies in claims by generic firms that authorized generic competition has deterred them from filing ANDAs; the study is intended to determine whether that claim is true or false, so that, if it is true, Congress may consider legislation to address the issue.

We believe that there are no documented instances where fear of authorized generics has deterred all generic firms from filing an ANDA and seeking to enter the market prior to patent expiration. In any event, if any of the generic firms that have called for this investigation were in fact deterred by fear of price competition, they know they were deterred, and as to which drugs they were deterred.

The Comment Request states, at 5, that documents and information will be sought with respect to a "list of specific drug products that the FTC will provide." There is no indication as to which drugs—or how many—will be on the list. Nor does the Comment Request identify the criteria that the Commission will use in compiling the list.

It is possible that the Commission will receive (or has already received) confidential representations from generic firms identifying the drugs as to which they claim that fear of price competition by authorized generics served as a barrier to entry, and that these are the drugs as to which information will be sought. Notwithstanding any such information, the most straightforward way to achieve the objective of the study is to begin by posing an interrogatory to generic firms, along these lines:

> Identify any patented pharmaceutical product as to which your company considered filing an ANDA, but ultimately decided not to make such a filing, where the decision not to file was based in whole or in part on concerns about competition from an authorized generic.

To the extent the generic firm responds affirmatively, the Commission might, as part of its initial request, call for relevant decisional documents as to these identified products.

With initial responses in hand from the approximately 100 generic companies from which the Commission proposes to seek information, the Commission would then be in a position to evaluate, on a considered basis, whether and how to go forward. The Commission would, in other words, know whether there is any colorable instance of deterrence to be investigated. And, if the answer is yes, the Commission would be in a position to issue a second round of focused interrogatories and document requests, targeting those products in which real deterrence might have occurred and those companies likely actually to have knowledge relevant to the investigation.

C. Other Comments

As noted above, there is tension between (i) an effort to answer a specific question about alleged disincentives to file ANDAs and (ii) an intent to conduct a broad industry study so as to make a contribution to the economic literature. Data useful for the

latter purpose might be of little utility for the former. Even if one assumes an intent to conduct a broad, academic type study, any comment as to the utility of specific data and information would be facilitated by knowing exactly what effects are to be studied and what working hypotheses are to be tested. Likewise, our ability to comment usefully on burden would be enhanced by knowing how many drugs will be on the FTC's list. All that said, we have the following specific observations on the data and information requests.

1. **Drugs Covered by the Study.** Consistent with our understanding of the proper purpose of the study, the "list of specific drugs" as to which information is sought should be limited, at least initially, to those where a credible claim exists that fear of price competition from authorized generics prevented *any* generic entry.

2. **Types of Documents.** We suggest that language in the request for decisional documents should be changed from "any documents, including studies, surveys, analyses, and reports (both internal and external)" to "all studies, surveys, analyses, and reports (both internal and external)." This amended language would still require an extensive document search, including search of emails, but the burden of production would be reduced by eliminating documents containing only incidental references to the relevant subjects—while otherwise responsive documents containing substantive discussion of relevant topics would continue to be picked up.

3. **Information about Responsive Documents.** Depending on the volume of documents, the burden of production could be greatly reduced, without any material loss of utility to the Commission, by requiring simply that the documents be produced as they are maintained in the ordinary course of business, with an index sufficient to show the individual from whose files each responsive document was taken.

4. **Cost Data.** Cost data would be germane to ascertaining the validity of any allegations of predatory pricing, but we know of no such allegations. We do not know of any other compelling reason to collect such data, even for purposes of contributing in a meaningful way to the economic literature. Collecting the information sought would be extremely burdensome. Analyzing it would greatly burden the Commission. Accordingly, we urge omission of cost data.

5. **IMS Data.** It would be burdensome and duplicative for some 190 subjects of the information requests to negotiate separately with IMS for contractual clearance to produce the data, and then to turn over large volumes of duplicative data, all from the same source. We believe that a reasonable alternative would be for the Commission to deal directly with IMS and obtain the data it needs directly from IMS.

IV. PRICE COMPETITION THAT "WEAKENS THE GENERIC INDUSTRY"?

There is some suggestion in the public discourse that, by selling authorized generics in a lawful, price-competitive manner, and thereby taking sales and profits away from generic firms, brand name firms "weaken" the generic industry. Perhaps the thought is that reduced profits (as compared to a but-for world with no authorized generic competition) makes it harder and more costly for the generic firms to attract capital; the reduced access to capital harms the generic firms in vague and unspecified ways; and somehow injury to consumers and to competition results from this alleged weakening.

If investigation discloses—contrary to our present belief—that fear of price competition from authorized generics has in fact been a significant deterrent to entry, it would

be appropriate to examine both the indirect and the direct effects of that deterrent effect.[13] If, on the other hand, the suggestion is to study whether—in the absence of any entry-deterring effect—vigorous, non-predatory, otherwise lawful price competition is somehow bad for the country, we have the following observations.

First, insofar as price competition by authorized generics "weakens" generic firms, it strengthens the incentives of brand name firms to do research and development. Conversely, any attempt artificially to "strengthen" generic companies by taking profits out of the pockets of brand name pharmaceutical companies would weaken the latter's R&D incentives. Accordingly, any investigation of whether price competition is good or bad for the country would need to take brand name R&D incentives into account. Such an investigation would create a major burden to the Commission as well as the parties investigated, and would likely be inconclusive.

Second, authorized generics are hardly an unqualified evil for the generic industry. (a) Selling authorized generics under a license is often a good way to increase sales and profits. (b) Adding a licensed authorized generic can fill out a generic firm's product line and therefore help to make its product line as a whole more attractive to customers; in many cases, taking a license may help a generic firm to enter a market it otherwise could not have entered. (c) Licensing an authorized generic may be an efficient and advantageous way for a generic firm to settle patent litigation.

In short, any complete investigation of the proposition that "price competition by authorized generics weakens the generic industry" would have to account not only for the

[13] In their letter, *supra* note 5, Senators Grassley, Leahy, and Rockefeller said, "We also ask that the study look into the long term impact of the practice of 'authorized' generics on competition in the drug market and on the price of drugs, as well as on the viability of the generic drug industry. "

detriment to generic firms selling traditional generics but also the benefit to generic firms that license authorized generics. Such an investigation would create a major burden for the Commission as well as the parties investigated, and would likely be inconclusive.

Finally, a party may not be heard to argue in an antitrust tribunal that limitations on price competition are legally "reasonable" because non-predatory price competition produces some socially undesirable result.[14] This fundamental rule of antitrust law does not, of course, prevent Congress from enacting ad hoc regulations governing competition, in derogation of the letter or spirit of the antitrust laws. Nor does it inhibit Congress's ability to legislate in ways consciously intended to take profits from one category of firms more profitable and another category less profitable. But antitrust principles do suggest that the Commission, a prime enforcer of the antitrust laws, should be skeptical of any argument that price competition itself is bad, and should hesitate before undertaking any investigation purporting to determine whether price competition is good or bad.

[14] United States v. National Soc'y of Prof'l Eng'rs, 435 U.S. 679 (1978).