PROPOSED FTC STUDY OF AUTHORIZED GENERICS

On April 4, 2006, the FTC published notice of its intention to conduct an extensive study of the economic effects of authorized generic pharmaceuticals. See 71 Fed. Reg. 16,779 (April 4, 2006). The initial stage of the study would involve detailed information requests, akin to subpoenas, to as many as 80 brand-name pharmaceutical manufacturers -- probably including any brand-name pharmaceutical manufacturer that has faced or soon will face generic competition -- and an even larger number of generic manufacturers. All pharmaceutical companies should be aware of the following issues:

- The FTC Study as proposed will cover a wide-range of pharmaceutical products that have faced generic competition since January 1, 1999, and is not limited only to products for which an authorized generic was launched;
- Targeted companies would be required to search for and submit a wide-range of detailed marketing and financial data for each product covered by the FTC Study;
- The FTC is accepting comments on the proposed study through June 5, 2006. Companies should consider filing comments aimed at reducing the burden of the proposed study; and
- Companies likely to be included in the FTC study may wish to consider whether they possess responsive materials and whether any modifications to their document retention programs are appropriate.

Background

A typical generic drug is sold pursuant to an Abbreviated New Drug Application (“ANDA”), a special approval procedure authorized by the Hatch-Waxman Act. An “authorized generic,” however, relies on the original New Drug Application (“NDA”) filed by the brand-name drug company. Courts have upheld FDA’s position that brand-name drug companies may authorize third parties to sell authorized generics under an NDA at any time, including during the 180-day exclusivity period afforded the first ANDA filer. See Teva Pharma. Indus. v. FDA, 410 F.2d 51 (D.C. Cir. 2005).

To date, most studies of authorized generics have found that they are procompetitive, in that they add a competitor and reduce total drug costs, thus benefiting consumers. Opponents of authorized generics assert that they may reduce the long-run incentives for generic drug manufacturers to develop generic versions of brand-name pharmaceuticals prior to patent expiration. The FTC Study proposes to examine “both the likely short-term competitive effects of authorized generic drug entry and, to the extent possible, the likely long-term impact of entry by authorized generic drugs on competition by generic manufacturers.” 71 Fed. Reg. at 16,780.

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1 The FTC notice of its proposed study cites two such prior studies, but questions the underlying data used. See ’71 Fed. Reg. at 16,780 n. 4.
Proposed Information Requests

The FTC proposes to issue requests for information referred to as “Special Orders.” Each Special Order issued to a branded or generic company will specify particular products covered by the data requests. The text of the requests, which are different for branded and generic companies, is attached as Exhibit A. The requested data fall into two principal categories. First, the FTC has asked for internal business documents “prepared or reviewed by or for any senior vice president (or equivalent position) with product line responsibility” for the specified drug product that address how to respond to generic competition. This request could cover a wide-range of materials, including documents covered by attorney-client privilege. Second, the FTC proposes to request very detailed monthly data on sales, cost of goods sold, and prices for each product identified in the Special Orders.

Next Steps

The Commission must obtain approval from the Office of Management and Budget (“OMB”) under the Paperwork Reduction Act before issuing the Special Orders. As noted above, the FTC is accepting public comments on its proposal through June 5, 2006. OMB approval will be requested after the public comment period closes, with the possibility that the Special Orders could issue this fall.

Consider Filing Comments

As currently envisioned, the FTC Study could impose significant burdens on the companies required to respond. Although FTC Staff may be amenable to case-by-case modifications to address particular burdens, there likely will be pressure to treat all recipients more or less equally, in accord with whatever standard requests are issued following the comment period and OMB approval. Companies that anticipate receiving a Special Order should seriously consider filing comments encouraging the FTC to narrow the scope of the proposed requests. In particular, comments might:

- Question whether the burdens associated with the proposed study are worthwhile in light of recent developments. Recent legislation modifying the calculation of “Average Manufacturer Price” and “Best Price” for purposes of Medicaid reimbursements may impact the economics of authorized generics. The FTC Notice does not reference this recent change, which may lessen the need for the proposed study in its present form.

- Propose reductions in the scope of materials requested by the study. The wide-ranging request for internal documents may not be necessary to conduct the contemplated economic analysis of authorized generics. Submission of the cost and pricing data alone, without the more burdensome search for internal evaluations or analyses, should serve the FTC’s stated purposes with less burden on the industry.

- Seek to clarify that a privilege log need not be created for any documents withheld on the grounds of attorney-client privilege. Production of a privilege log is an expensive, time-consuming exercise that seems unnecessary in this case.

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2 “Special Order” refers to the FTC’s investigatory authority under Section 6(b) of the FTC Act, 15 U.S.C. § 46(b). The Special Orders will consist of interrogatories and document requests and be generally similar in form to subpoenas or other forms of compulsory process.
Retention of Potentially Responsive Documents

The FTC Notice asserts that destruction of any documentary evidence that may be responsive to the proposed FTC Study may be subject to criminal prosecution. Companies that anticipate receiving a Special Order should consider what actions may be appropriate in light of the FTC's announced intention to issue the Special Orders.

* * *

Please contact us if you have any questions about the proposed FTC study or how we might assist you in filing comments in response to the FTC's Notice or submitting a response to the Special Orders you may receive if and when the FTC Study gets underway.

If you have any questions concerning the material discussed in this client alert, please contact any of the following attorneys:

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<thead>
<tr>
<th>Antitrust</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>David Meyer</td>
<td>202.662.5582</td>
<td><a href="mailto:dmeyer@cov.com">dmeyer@cov.com</a></td>
</tr>
<tr>
<td>George Chester</td>
<td>202.662.5198</td>
<td><a href="mailto:gchester@cov.com">gchester@cov.com</a></td>
</tr>
<tr>
<td>James Dean</td>
<td>202.662.5651</td>
<td><a href="mailto:jdean@cov.com">jdean@cov.com</a></td>
</tr>
<tr>
<td>Theodore Voorhees</td>
<td>202.662.5236</td>
<td><a href="mailto:tvoorhees@cov.com">tvoorhees@cov.com</a></td>
</tr>
<tr>
<td>David Addis</td>
<td>202.662.5182</td>
<td><a href="mailto:daddis@cov.com">daddis@cov.com</a></td>
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<tr>
<th>Food &amp; Drug</th>
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<th>Email</th>
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<tbody>
<tr>
<td>Peter Safir</td>
<td>202.662.5162</td>
<td><a href="mailto:psafir@cov.com">psafir@cov.com</a></td>
</tr>
<tr>
<td>Richard Kingham</td>
<td>+44.(0)20.7067.2018</td>
<td><a href="mailto:rkingham@cov.com">rkingham@cov.com</a></td>
</tr>
<tr>
<td>Michael Labson</td>
<td>202.662.5220</td>
<td><a href="mailto:mlabson@cov.com">mlabson@cov.com</a></td>
</tr>
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<tr>
<th>Pharmaceutical Investigations</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mark Lynch</td>
<td>202.662.5544</td>
<td><a href="mailto:mlynch@cov.com">mlynch@cov.com</a></td>
</tr>
<tr>
<td>Ethan Posner</td>
<td>202.662.5317</td>
<td><a href="mailto:eposner@cov.com">eposner@cov.com</a></td>
</tr>
<tr>
<td>Aaron Marcu</td>
<td>212.841.1078</td>
<td><a href="mailto:amarcu@cov.com">amarcu@cov.com</a></td>
</tr>
<tr>
<td>Eric Holder</td>
<td>202.662.5372</td>
<td><a href="mailto:eholder@cov.com">eholder@cov.com</a></td>
</tr>
<tr>
<td>Geoffrey Hobart</td>
<td>202.662.5281</td>
<td><a href="mailto:ghobart@cov.com">ghobart@cov.com</a></td>
</tr>
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This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

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Exhibit A

INFORMATION REQUESTED BY PROPOSED FTC SPECIAL ORDERS

In addition to routine questions about the name, address, organization chart(s), and incorporation date of the responding company and its subsidiaries, and the name, business address, and official capacity of the official supervising the company’s response, the FTC will ask the three different company types to provide answers to the following questions for a list of specific drug products that the FTC will provide:

Brand-Name Companies

1. For each identified drug product, submit any documents, including studies, surveys, analyses, and reports (both internal and external), that are dated after January 1, 1998 and were prepared or received by or for any senior vice president (or equivalent position) with product line responsibility for the specified drug product or any officer(s) or director(s) of the company (or, in the case of unincorporated entities, individuals exercising similar functions) that evaluated, considered, analyzed, or discussed how to respond (including through pricing changes) to (a) future or current generic competition, (b) the expiration of the patent(s) claiming the identified drug product or its use, (c) whether to license or otherwise market the identified drug product as an authorized generic drug product, and/or (d) whether to refrain from marketing an authorized generic, including but not limited to, agreements to do so. This request includes documents that discuss future generic entry for either specified products or responses to generic entry in general. For each such document, indicate (if not contained in the document itself) the date of preparation and the name and title of each individual who prepared the document, and group the documents by identified drug product. If the company licensed or otherwise authorized the marketing of the identified drug product as an authorized generic, provide the license agreement with the authorized generic company and the supplemental application the company filed with the FDA pursuant to 21 U.S.C. 356a(b) that had the effect of allowing the company to license or otherwise market the identified drug product as an authorized generic.

2. For each identified drug product, provide the following information:
   a. A detailed description of the product, including its brand name or identification number, its common name, and its biological or chemical class; its application status at the FDA for each of its indication(s) or end use(s), and intended indication(s) or end use(s), including the date the New Drug Application was filed and approved, and the date the product was first marketed in the United States, as both a brand-name drug and, if applicable, an authorized generic;
   b. A detailed description of every SKU of the product as both a brand-name drug and, if applicable, an authorized generic, including product form, dosage strength, bottle or box size, route of administration, and the date first marketed in the United States;
   c. The identification number of each SKU of each product;
   d. A list of all patents listed in the Orange Book for each drug product whether owned, licensed, or controlled by the company, including patent or patent
application number, title, priority date, inventor, date filed, date issued, date of patent expiration, status, and a copy of all relevant claims.

3. For each SKU listed in response to Specification 2c above, state for every month from a full calendar year preceding generic entry to the present, for sales in the United States (e.g., if generic entry occurred in July 2002, the company is to provide the following information for every month beginning January 1, 2001):

   e. The company’s total sales, net of discounts, rebates, promotions, returns and chargebacks, to all customers in units, total prescriptions, and dollars;

   f. The company’s total sales, net of discounts, rebates, promotions, returns and chargebacks, to hospitals, clinics and long-term care facilities, including but not limited to independent cancer care centers and pain centers, in units, total prescriptions, and dollars;

   Prescription drugs distributed through hospitals, clinics and long-term care facilities may have different pricing structures than those distributed through retail and mail-order pharmacies.

   g. The company’s standard or actual cost of goods sold in dollars, reported by material cost, labor cost, manufacturing cost, distribution cost, API cost, overhead cost, other cost, and variances;

   h. The company’s prices, including: (1) List price; (2) average wholesale price; (3) wholesale acquisition cost; (4) price to Medicare; (5) price to Medicaid; (6) the maximum allowable cost; and (7) average manufacturer price (“AMP”) as defined by, and reported to, the Centers for Medicare and Medicaid Services.

Authorized Generic Company Questions

1. For each identified drug product that is licensed to, or otherwise marketed by, the company:

   a. Provide any documents, including studies, surveys, analyses, and reports (both internal and external), that are dated after January 1, 1998 and were prepared or received by or for any senior vice president (or equivalent position) with product line responsibility for the specified drug product or any officer(s) or director(s) of the company (or, in the case of unincorporated entities, individuals exercising similar functions) that evaluated, considered, analyzed, or discussed whether or how to proceed with generic entry, including discussion related to whether to file an ANDA containing a paragraph III or IV certification (regardless of whether the company filed such ANDA), whether or when to launch commercial marketing, and the impact that entry by an authorized generic drug would have on generic entry by an ANDA drug product. This request includes documents that discuss future generic entry for either specified products or responses to generic entry in general. For each such document, indicate (if not contained in the document itself) the date of preparation and the name and title of each individual who prepared each such document;
b. Provide a copy of the license agreement, or other marketing authorization, with the brand-name company.

2. For each identified drug product that is licensed to, or otherwise marketed by, the company, provide the following information:
   a. A detailed description of every SKU of the product, including product form, dosage strength, bottle or box size, route of administration, and the date first sold in the United States;
   b. The identification number of each SKU of each product.

3. For each SKU of each relevant product listed in response to Specification 2b above, state for every month from the date of first commercial marketing to the present, for sales in the United States:
   a. The company’s total sales, net of discounts, rebates, promotions, returns and chargebacks, to all customers in units, total prescriptions, and dollars;
   b. The company’s total sales, net of discounts, rebates, promotions, returns and chargebacks, to hospitals, clinics and long-term care facilities, including but not limited to independent cancer care centers and pain centers, in units, total prescriptions, and dollars;
   c. The company’s standard or actual cost of goods sold in dollars, reported by material cost, labor cost, manufacturing cost, distribution cost, API cost, overhead cost, other cost, and variances;
   d. The company’s prices, in each relevant area, including: (1) List price; (2) average wholesale price; (3) wholesale acquisition cost; (4) price to Medicare; (5) price to Medicaid; (6) the maximum allowable cost; and (7) average manufacturer price (“AMP”) as defined by, and reported to, the Centers for Medicare and Medicaid Services.

Independent Generic Company Questions

1. For each identified product, and for any other brand drug product for which the company has evaluated, considered, analyzed, or discussed whether or how to proceed with generic entry, submit the following:
   a. Any documents, including studies, surveys, analyses, and reports (both internal and external), that are dated after January 1, 1998 and were prepared or received by or for any senior vice president (or equivalent position) with product line responsibility for the specified drug product or any officer(s) or director(s) of the company (or, in the case of unincorporated entities, individuals exercising similar functions) that evaluated, considered, analyzed, or discussed whether or how to proceed with generic entry, including discussion related to (a) whether to file an ANDA containing a paragraph III or IV certification (regardless of whether the company filed such ANDA), (b) whether or when to launch commercial marketing, and/or (c) the impact that entry by an authorized generic drug would have on generic entry by the company’s ANDA drug product. This request includes documents that discuss future generic entry for either specified products or responses to generic entry in general. For each such document, indicate (if not contained in the document itself) the date of preparation and the name and title of
each individual who prepared each such document. Submit a copy of the ANDA application for each identified drug product;

b. Any documents sufficient to show the identified product's development costs, costs to file ANDA, and patent-related litigation costs.

2. For each identified product, state the following:

a. A detailed description of the product, including its brand name or identification number, its common name, and its therapeutic class; its application status at the FDA for each of its indication(s) or end use(s), and intended indication(s) or end use(s), including the date the application was filed and approved, and the date the product was first sold in the United States;

b. A detailed description of every SKU of the product, including product form, dosage strength, bottle or box size, route of administration, and the date first sold in the relevant area;

c. The identification number of each SKU of each product.

3. For each SKU listed in response to Specification 2c, state for every month from the date of first commercial marketing to the present, for sales in the United States:

a. The company's total sales, net of discounts, rebates, promotions, returns and chargebacks, to all customers in units, total prescriptions, and dollars;

b. The company's total sales, net of discounts, rebates, promotions, returns and chargebacks, to hospitals, clinics and long-term care facilities, including but not limited to independent cancer care centers and pain centers, in units, total prescriptions, and dollars;

c. The company's standard or actual cost of goods sold in dollars, reported by material cost, labor cost, manufacturing cost, distribution cost, API cost, overhead cost, other cost, and variances;

d. The company's prices, in each relevant area, including: (1) List price; (2) average wholesale price; (3) wholesale acquisition cost; (4) price to Medicare; (5) price to Medicaid; (6) the maximum allowable cost; and (7) average manufacturer price ("AMP") as defined by, and reported to, the Centers for Medicare and Medicaid Services.

For All Three Company Types

The FTC will request IMS Health (IMS) data if the company obtains such information in the regular course of business, as follows:

If the company obtains IMS Health (IMS) data in the regular course of business, provide for each identified drug product, for every month from January 1999 (or date of first commercial marketing, where applicable) to the present for sales in the United States:

a. IMS Retail Perspective data, or the equivalent thereof, by product form, by strength, and by diagnosis, for total sales in dollars and units, by customer channel, including, but not limited to independent pharmacies, chain pharmacies, mass merchandisers, proprietary stores, and food stores with pharmacies;
b. IMS Provider Perspective data, or the equivalent thereof, by product form, by strength, and by diagnosis, for total sales in dollars and units, by customer channel, including, but not limited to, non-federal hospitals, federal facilities, mail order, and long-term care facilities, clinics, and closed wall HMOs;

c. IMS National Prescription Audit data, or the equivalent thereof, by product form, by strength, and by diagnosis, for newly dispensed prescriptions, refill dispensed prescriptions, total dispensed prescriptions, total units, and total dollar sales;

d. IMS Retail Method of Payment Report, or the equivalent thereof, by product form, by strength, and by diagnosis, for total sales in dollars and units, by customer channel, including, but not limited to, private managed care, and public managed care;

e. IMS Integrated Promotional Services Total Promotion Report, by product form, for total dollars spent for: (1) Detailing; (2) physician and pharmacist marketing; (3) medical and other journal advertising; and (4) any other promotional spending, including, but not limited to, direct consumer advertising;

f. Any other IMS data, or the equivalent thereof, used in the ordinary course of business;

g. All supporting definitions and materials for any IMS data provided.