UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Bureau of Competition
Health Care Division

August 8, 2012

E. John Steren
Ober, Kaler, Grimes & Shriver
1401 H Street NW, Suite 500
Washington, D.C. 20005

Re: Generic Pharmaceutical Association Advisory Opinion

Dear Mr. Steren:

This letter responds to your request on behalf of the Generic Pharmaceutical Association (GPhA) for an advisory opinion concerning its proposed "Accelerated Recovery Initiative." GPhA plans to adopt this program, known as the ARI, to help the Food and Drug Administration (FDA) respond to the unprecedented increase in shortages of critically important medicines that has occurred in recent years. It seeks to do so by providing the FDA with information that GPhA believes will enable agency staff "more efficiently and effectively to accelerate the recovery of critical drugs in short supply" and thereby to help ensure patients have access to the drugs they need.[1] A key element of the ARI is an agreement among competitors to compile competitively sensitive production information from manufacturers of shortage drugs.

Based on the information GPhA has provided, it appears that the proposed ARI program is not likely to harm competition. Although the manufacturer data that GPhA proposes to collect is competitively sensitive and the ARI would raise substantial antitrust concerns if this information were shared with competitors, the proposed program includes many safeguards designed to insure that such sharing does not occur. You have explained that GPhA has chosen an independent third party to collect and transmit the data to the FDA and that no other party, including GPhA, will have access to this information or any analysis derived therefrom. The program also includes various other features intended to minimize the risk that the ARI could serve to facilitate collusion among drug manufacturers. Accordingly, the Commission has no present intention to bring an enforcement action to challenge GPhA's proposed ARI program if it is implemented as described and the safeguards it contains are adhered to in practice.

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[1] Letter from E. John Steren to Donald S. Clark, Secretary, Federal Trade Commission (July 16, 2012) (hereinafter "Request Letter"). Pursuant to your July 13, 2012 email to Elizabeth Hilder, your request has been treated as one for a staff opinion under Rule § 1.1(b), 16 C.F.R. § 1.1(b).

Background

Shortages of medically necessary prescription drugs have become a matter of widespread public concern. Although drug shortages have occurred in the past, the extent of such shortages has increased dramatically in recent years. The FDA has reported that the number of drug shortages nearly tripled from 2005 to 2010 (rising from 61 drug products in 2005 to 178 in 2010).[2] In 2011, the number increased to 250.[3] You have advised that over 80 percent of the drugs on the FDA's published drug shortage list are generic injectables, that is, medications administered by injection or intravenously, generally in hospitals or outpatient clinics. The FDA has explained that: "Compared to oral drugs, sterile injectables are more complex and require more specialized processes and equipment to manufacture, leading to a higher likelihood of manufacturing problems."[4] The FDA has also observed that complex manufacturing processes, and the fact that relatively few companies manufacture any given injectable product, mean shortages of these drugs can take substantial time to resolve. Finally, the products involved are often ones that are critically important to patients. Cancer drugs are the largest category of injectables in shortage. Other products experiencing shortages include antibiotics, anesthesia drugs, drugs used in emergency medicine, and products used for intravenous feeding.[5]

The unprecedented extent of the current drug shortage problem has prompted congressional hearings;[6] proposed legislation;[7] government studies, reports, and workshops;[8] an

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[2] *See* FOOD & DRUG ADMIN., A REVIEW OF FDA'S APPROACH TO MEDICAL PRODUCT SHORTAGES 10 (2011). These figures do not include shortages of vaccines, immune globulin products, and other biologics. *See* Food & Drug Admin., Consumer Updates, "FDA Works to Lessen Drug Shortage Impact," *available at* http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm258152.htm.

[3] Ilisa B.G. Bernstein, Acting Director, FDA/CDER/Office of Compliance, FDA Update, Presentation to APhA Annual Meeting, Slide 41 (March 11, 2012), *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM299785.pdf.

[4] FOOD & DRUG ADMIN., A REVIEW OF FDA'S APPROACH TO MEDICAL PRODUCT SHORTAGES 13 (2011).

[5] *Id.* at 14-15.

[6] *See, e.g., Review of the Proposed Generic Drug and Biosimilars User Fees and Further Examination of Drug Shortages: Hearing Before H. Comm. on Energy and Commerce*, 112th Cong. (2012); *Drug Shortages: Why They Happen and What They Mean: Hearing Before the S.*

executive order;[9] FDA guidance to industry;[10] and numerous press reports describing the impact on patient care, particularly on cancer patients.[11] In June 2012, Congress enacted legislation that, among other things, will require more drug manufacturers to notify the FDA in advance of any discontinuance or significant disruption in production of a drug.[12] The statute also directs the

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Comm. On Fin., 112th Cong. (2011); *Prescription Drug Shortages: Examining a Public Health Concern and Potential Solutions: Hearing Before the S. Comm. On Health, Educ., Labor, and Pensions*, 112th Cong. (2011); *Examining the Increase in Drug Shortages: Hearing Before H. Comm. on Energy and Commerce*, 112th Cong. (2011); *Drug Shortage Crisis: Lives are in the Balance: Hearing Before H. Comm. On Oversight and Gov't Reform*, 112th Cong. (2011).

[7] *See* Drug Shortage Prevention Act of 2012, H.R. 3839, 112th Cong. (2012); Food and Drug Administration Safety and Innovation Act, S. 2516, 112th Cong. (2012); Food and Drug Administration Reform Act of 2012, H.R. 5651, 112th Cong. (2012), Gray Market Drug Reform and Transparency Act of 2012, H.R. 5853, 112th Cong. (2012); Preserving Access to Life-Saving Medications Act, S. 296, 112th Cong. (2011); Preserving Access to Life-Saving Medications Act of 2011, H.R. 2245, 112th Cong. (2011).

[8] *See, e.g.*, OFFICE OF THE ASST. SEC'Y FOR PLANNING AND EVALUATION, U.S. DEP'T OF HEALTH & HUMAN SERVS., ASPE ISSUE BRIEF, ECONOMIC ANALYSIS OF THE CAUSES OF DRUG SHORTAGES (Oct. 2011) (hereinafter "HHS Economic Analysis of Drug Shortages"); FOOD & DRUG ADMIN., A REVIEW OF FDA'S APPROACH TO MEDICAL PRODUCT SHORTAGES (2011) (hereinafter "FDA Drug Shortages Report"); U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-315T, DRUG SHORTAGES: FDA'S ABILITY TO RESPOND SHOULD BE STRENGTHENED (2011); FOOD & DRUG ADMIN., DRUG SHORTAGE WORKSHOP 12 (2011).

[9] Exec. Order No. 13588, 76 Fed. Reg. 68295 (Oct. 31, 2011).

[10] FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: NOTIFICATION TO FDA OF ISSUES THAT MAY RESULT IN A PRESCRIPTION DRUG OR BIOLOGICAL PRODUCT SHORTAGE (2012).

[11] *See, e.g.*, Michael Muskal, *FDA Acts to Increase Cancer Drug Supplies*, L.A. TIMES, Feb. 22, 2012, Part AA, at 5; Gardiner Harris, *Supply of a Cancer Drug May Run out in Weeks*, N.Y. TIMES, Feb. 11, 2012, § A, at 15; Rob Stein, *U.S. Drug Shortages Threatening Those Whose Lives Depend on Crucial Remedies*, N.Y. TIMES, May 2, 2011, § A, at A10; Jennifer Corbett Dooren, *U.S. News: Drug Shortages Distress Hospitals*, WALL ST. J., Feb. 1, 2011, § J, at A4.

[12] Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-114, § 1001(a), 126 Stat 993, (2012). The requirement applies to non-biological prescription drugs that are "life-

Comptroller General to conduct a study of drug shortages and make recommendations on how to prevent or alleviate such shortages.[13]

The FDA has undertaken a variety of activities to address the drug shortage problem. In the case of generic injectables, this often involves asking other manufacturers of the drug in shortage if they are willing and able to increase their production. Other FDA strategies include expediting regulatory reviews to accelerate approval of new sources of supply, new manufacturing lines, or new raw material sources. The FDA also exercises regulatory discretion, for example permitting controlled importation of equivalent products approved abroad but not in the United States.[14] In May 2012, the FDA reported that industry response to its October 2011 request to manufacturers for voluntary early notification of potential supply disruptions had enabled it to prevent 128 potential drug shortages over the six month period from November 2011 through April 2012.[15]

The Proposed Program

You have advised that the ARI is intended to assist the FDA in responding to drug shortages by providing the agency with information from manufacturers relating to their production and supply of designated shortage drugs. As described in your letter, GPhA plans to engage IMS Health Incorporated to collect information from manufacturers of shortage drugs about their current and projected production and supply schedules. IMS will use this data, along with market data it currently collects, to analyze whether, and to what extent, the anticipated supply of a given drug is likely to fall short of the projected demand over the next several months and then provide this information to FDA staff. The current focus of the program is on accelerating the recovery of critical drugs that are in short supply, but it is possible that the ARI program could also be used to assist the FDA to head off potential drug shortages.

Your letter states that the program will operate "under terms of strict confidentiality and with appropriate safeguards." Request Letter at 4. In particular, IMS will report the production

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supporting, life-sustaining, or intended for use in the prevention of a debilitating disease or condition." *Id.*

[13] *Id.* at § 1008(b).

[14] FDA Drug Shortages Report, *supra* note 8, at 20-21.

[15] Margaret Hamburg, Six Month Checkup: FDA's Work on Drug Shortages, FDA VOICE (May 3, 2012), *available at* http://blogs.fda.gov/fdavoice/index.php/2012/05/six-month-check-up-fdas-work-on-drug-shortages/.

information it collects and the analysis it performs only to the FDA and will not share it with any other party.

Based on the information you provided, we understand the details of the program to be as follows:

1. *Scope of the Program*: The FDA, with input from GPhA, will decide on the initial group of drugs to be addressed through the ARI program. GPhA anticipates that the initial focus of the program will be on a subset of drugs currently on the FDA's published list of drugs in shortage. Other criteria for inclusion in the ARI are expected to include at least the following: (a) the drug is expected to be in shortage for more than 90 days; (b) there is no therapeutic alternative (as defined by the American Society of Health-System Pharmacists' list); and (c) it is multi-source (that is, there are other manufacturers that might be able to increase their production).

The FDA would have discretion to include in the ARI program a drug that does not meet all of these criteria—for example, a drug that is not currently on the FDA drug shortage list but has the potential to go into shortage—where circumstances warrant. Drugs may move into and out of the ARI program as requested by the FDA and depending on the circumstances. Given the benefits of preventing potential drug shortages from becoming actual shortages, as the ARI program evolves there may be a focus on drugs that are not currently in shortage but present a potential for a shortage to develop.

2. *Manufacturer Participation*: IMS, with assistance from GPhA, will recruit drug manufacturers to participate in the program. All manufacturers of drugs covered by the ARI will be invited to participate, regardless of whether they are members of GPhA and regardless of whether they are manufacturers of branded or generic drugs. When a drug is added to the ARI program, manufacturers of that drug that are not already ARI participants will be invited to join the program. GPhA will not participate in recruitment of firms selling potential, rather than actual, shortage drugs. Participation in the ARI is voluntary and the program will be "non-exclusive," that is, participating firms will be free to participate in a similar program by some other sponsor (were one to be organized). In addition, nothing in the program would limit the ability of a firm to provide information directly to the FDA or to otherwise disclose its own ARI data for other legitimate purposes consistent with the antitrust guidelines.

Companies that choose to join must execute a participation agreement that requires them to pay annual ARI dues and to comply with specified confidentiality rules, antitrust guidelines, and prohibitions on misuse of the ARI process. The draft participation agreement you have submitted includes various commitments to be made by individual companies, GPhA, and IMS to ensure that the data participants submit is kept confidential and not shared or used in ways not contemplated by the program.

3. *IMS Activities*: The activities to be undertaken by IMS are designed to further the ARI's goal of providing the FDA with better information with which to address drug shortages. IMS will gather information from manufacturers of selected shortage drugs, perform a "gap analysis" for each drug included in the ARI program, and submit reports to the FDA. IMS will not use the information generated under the ARI for any other purpose.

IMS will contact manufacturers of ARI drugs that have signed a participation agreement and request current supply and production information and forecasts for the next 90-180 days for the drug or drugs in question. IMS will ask manufacturers to update this information on a monthly basis and to notify both IMS and the FDA immediately of unanticipated changes or potential supply disruptions. Requests for information from manufacturers about potential shortage drugs in the ARI program will be limited to those manufacturers that make or have made the drug in question. IMS will use the production and supply data it collects, along with its own forecasts of demand based on past demand data, to perform the gap analysis, that is, the projection of the extent of a likely supply shortfall. IMS will produce a monthly report to the FDA providing both a summary analysis for each drug along with a detailed breakdown by National Drug Code number.

IMS will provide the gap analysis and underlying data that IMS generates under the ARI program only to the FDA and will clearly mark each report as confidential. IMS will not provide information contained in these reports, or any data gathered from participants, to GPhA, ARI participants, or any other party. In addition, IMS will institute appropriate safeguards (e.g., firewalls) to limit internal access to this information to guard against the risk that knowledge of this confidential information could spill over into other aspects of IMS's business and be used for non-ARI purposes.

IMS communications with individual manufacturers under the ARI program will be limited to that which is necessary to gather the data needed to perform the gap analysis for an ARI drug. You have advised that "IMS will only be receiving supply/forecast data for the drugs at issue and will not be having an ongoing dialogue with the manufacturers, nor will it be requesting any additional information from these manufacturers."[16] All communications with manufacturers concerning their ability to increase their production or supply of a drug will continue to be undertaken by the FDA. IMS will not make recommendations to the FDA regarding how the agency should seek to address a given drug shortage. Instead, GPhA expects that the FDA will use the factual information IMS provides along with non-public information possessed by the agency to determine appropriate solutions to a shortage. Request Letter at 6.

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[16] Letter from E. John Steren to Elizabeth Hilder (July 30, 2012) (hereinafter "Request Supplement") Attachment Item 2.

IMS will not disclose competitively sensitive information to GPhA. IMS will submit monthly reports to GPhA, and GPhA expects it may share those reports with its members and the public at large. These IMS reports to GPhA will identify the number of drugs addressed in the most recent FDA report, the number of reports IMS sent to the FDA, and the number of drugs added or deleted from the ARI program during the prior month. The report may identify by name the specific drugs addressed in the most recent IMS report to the FDA, to the extent that the drug already appears on the FDA's drug shortage list. In no event, however, will IMS disclose to GPhA information that would identify any potential shortage drug that the FDA has requested IMS to analyze, unless the FDA has already publicly disclosed that information. In addition, IMS will not disclose information that would reveal the production and supply information submitted by manufacturers.

Legal Analysis

The key antitrust issue raised by the ARI arises from the fact that it involves an agreement among competitors to pool information about their output, both present and future. As a general matter, the antitrust laws do not prohibit trade associations from collecting data from competing sellers and collectively providing information and analysis to government officials.[17] Such activity, undertaken for a legitimate purpose, may serve to promote rather than injure competition and consumer welfare.

Under some circumstances, however, such data gathering programs can serve to facilitate collusion among competing sellers and thereby present a substantial risk of anticompetitive harm.[18] Trade association programs that involve sharing of competitively significant information among competitors have long been a subject of antitrust scrutiny, given their potential to

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[17] *See generally* U.S. Department of Justice and Federal Trade Commission, *Statements of Antitrust Enforcement Policy in Health Care* (1996), Statements 4, 5, and 6, *available at* http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm.

[18] Collusion may take the form of an actual agreement, actionable in its own right, or tacit coordination among firms in a concentrated market, which is not in itself unlawful. *See, e.g., Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 227 (1993). Sharing of information among competitors that makes it easier for them to collude in either form is sometimes referred to as a "facilitating practice." *See* VI PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 1407b, at 38 (2010) (defining as "an activity that makes it easier for parties to coordinate price or other behavior in an anticompetitive way.").

facilitate collusion among rivals.[19] Such programs are not per se unlawful unless part of a larger scheme to fix prices or other competitively significant terms of dealing. Instead, they are judged under the rule of reason, based on their likely effects on competition in light of the particular circumstances.[20]

Certain circumstances here raise the potential for competitive harm. As GPhA recognizes, the inventory and future production information it proposes to collect is competitively sensitive.[21] In addition, your letter notes that markets for the sale of generic injectables, which represent the vast majority of drugs in shortage, typically have few sellers. Such market concentration tends to make markets more susceptible to collusion.[22]

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[19] *See, e.g., American Column & Lumber Co. v. United States*, 257 U.S. 377 (1921) (trade association program to collect and report to members detailed information on sales, prices, and production, including forecasts of future production); XIII PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 2112a, at 63-64 (2005) ("The antitrust concern resulting from trade association provision of price and output information is facilitation of collusion or less formal coordination of output or price. The fact that the coordination is not the product of a Sherman §1 'agreement' does not preclude condemnation of a 'facilitating practice' that results from an agreement.").

[20] *See, e.g., United States v. Container Corp.*, 393 U.S. 333 (1969). *See also* S. DeSanti & E. Nagata, *Competitor Communications: Facilitating Practices or Invitations to Collude? An Application of Theories to Proposed Horizontal Agreements Submitted for Antitrust Review*, 63 ANTITRUST L. J. 93, 96-99 (1994).

[21] *See, e.g*, FED. TRADE COMM'N & DEP'T OF JUSTICE, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS 15 (April 2000) ("Other things being equal, the sharing of information relating to price, costs, output, or strategic planning is more likely to raise competitive concern than the sharing of information relating to less competitively sensitive variables. Similarly, other things being equal, the sharing of information on current operating and future business plans is more likely to raise concerns than the sharing of historical information.").

[22] *See, e.g., Todd v. Exxon Corp.*, 275 F.3d 191, 208 (2d Cir. 2001) ("Generally speaking, the possibility of anticompetitive collusive practices is most realistic in concentrated industries."); AREEDA & HOVENKAMP, *supra* note 18, ¶ 1407e, at 44. *See also* HHS Economic Analysis of Drug Shortages, *supra* note 8, at 14 (noting that "strategic behavior—behavior that takes into account the likely actions of both competitors and regulator—is a common response to an environment of constrained capacity with few participating firms. Such behavior can lead to increases in concentration and reductions in competition in the longer run.").

On its face, however, the proposed ARI program does not involve the exchange or sharing among competitors of the output information that the program would collect. Rather, the information would be collected and analyzed by a third party, IMS, which would share this information solely with the FDA. Moreover, you have emphasized that the program will operate "under terms of strict confidentiality and with appropriate safeguards." Request Letter at 4. GPhA has designed various aspects of the program to limit the potential that the ARI might result in harm to competition.

First, the role of GPhA itself is strictly limited to shield it from access to competitively sensitive information. GPhA is involved in developing the initial identification of drugs to be part of the ARI, will assist IMS in recruiting participants, and will provide financial support for the program. Aside from publicizing the program, no other activities by GPhA are specified. GPhA will receive monthly reports from IMS, which it may disseminate to its members and others, but these will provide no information relating to the production data that IMS has collected, nor will they identify potential shortage drugs that IMS has analyzed.

Second, GPhA has defined the obligations and activities of IMS to limit the risk that IMS would inadvertently facilitate anticompetitive behavior. IMS's duty to strictly limit disclosure of the production data gathered from ARI participants, and any information and analysis derived therefrom, solely to FDA staff is a binding commitment set forth in formal written agreements.[24] Likewise, the agreements make clear that IMS's use of the information is strictly limited to ARI program activities. You have also advised that IMS plans to institute appropriate internal safeguards to prevent misuse or improper disclosure of information generated under the ARI.

In addition, GPhA has defined IMS's role to be providing objective data and gap analysis reports to the FDA, not recommendations on how to address a given shortage.[25] The ARI does not provide a role for IMS to act as a representative of ARI participant companies in matters involving drug shortages. Nor does the ARI set up IMS as an intermediary between ARI participants and the FDA to broker solutions to a drug shortage or potential shortage. This carefully defined role for IMS helps to guard against the risk that the ARI could have the unintended effect of fostering collusion among competing sellers acting through IMS.

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[24] In addition, we understand that the FDA has established processes to ensure the confidentiality of competitively sensitive information it receives and that the FDA would treat confidential information received from IMS under the ARI program in the same manner.

[25] *See* Request Supplement, *supra* note 16, Attachment Item 1.

Third, GPhA has taken steps to discourage ARI participants from attempting to use the program for anticompetitive ends. The draft ARI participation agreement (Request Letter, Exhibit 10): (1) emphasizes the confidential nature of the production information to be collected; (2) advises companies of the need to ensure that their employees, agents, and consultants adhere to ARI program rules, which include confidentiality obligations embodied in the agreement and a set of antitrust guidelines that are provided along with the participation agreement; and (3) provides that participants that breach those obligations will be terminated from the program. Moreover, participants must make an express commitment not to use the ARI program activities to "exchange, discuss or agree on the price, output, cost, or other terms of competition, regarding any Shortage Drug or any other product or service." Exhibit 10, § 6(e). In addition, under the agreement, participants must indemnify GPhA, IMS, and other ARI participants for any losses resulting from breach of this commitment. *Id.* § 8.

These various safeguards are significant to the antitrust analysis. Just as with matters of price, collusion among drug manufacturers on output—such as agreements to limit supply or to allocate markets by ceding production of particular drugs to a single seller—would threaten substantial harm to consumers.[26] The safeguards GPhA has included, however, help to assure that the ARI is likely to operate in accordance with its legitimate purpose and limit the risk that the program would serve to facilitate collusion among actual or potential rivals.

The ARI's protections against disclosure of confidential information may also offer other benefits. For example, assurance to manufacturers that their confidential information will be protected may encourage greater participation in the program and thereby result in more useful information to support the FDA's efforts to combat drug shortages. In addition, safeguarding non-public information relating to the supply of critical drugs, particularly as to the potential for a shortage, may help to reduce the risk of actions that distort the supply chain, whether abusive conduct by other market participants that may seek to exploit a shortage for their own advantage, or the potential for hoarding by well-intentioned health care providers concerned about their patients.

Finally, it does not appear that the ARI program presents other risks to competition and consumers. As noted above, the program is "non-exclusive," that is, it involves no agreement among competitors to deal only through the ARI. It would not preclude ARI participants from also participating in another organization's program that sought to use similar data for legitimate

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[26] *See, e.g.*, AREEDA & HOVENKAMP, *supra* note 19, ¶ 2111d1, at 54 ("Output and price are the two elements of a firm's decision making most directly relevant to the degree of competition in a market.").

purposes. Nor would it have any effect on manufacturers' ability to use their own participant data in other business contexts.

Because anticompetitive effects appear unlikely, it is unnecessary to assess the likelihood or extent of any procompetitive benefits that may result from the ARI. Moreover, various details of the program remain to be developed, and we understand that GPhA is continuing to discuss with FDA staff how best to make the ARI complement the FDA's existing drug shortage activities. But we note that the stated goals of the ARI—helping to reduce market disruptions caused by drug shortages and thereby to increase patient access to critical medicines—suggest the potential for such benefits, as do the FDA's comments expressing interest in development of the program.[27]

Conclusion

In sum, it appears that the proposed ARI program is unlikely to harm competition. Although the supply and output data to be collected is competitively sensitive, and markets for the drugs in the ARI are likely to be susceptible to collusion, GPhA has designed the program to safeguard competitively sensitive information, with the aim of helping FDA to address extensive and unprecedented supply disruptions that threaten patient care. For these reasons, the Bureau of Competition has no present intention to recommend an enforcement action to challenge GPhA's proposed ARI program if it is implemented as described and the safeguards are adhered to in practice.

This letter sets out the views of the staff of the Bureau of Competition, as authorized by the Federal Trade Commission's Rules of Practice, and based on the facts as presented by the requesting entity. Under Rule § 1.3(c), 16 C.F.R. § 1.3(c), the Commission is not bound by this staff opinion and reserves the right to rescind it at a later time. In addition, this office retains the right to reconsider the questions involved and, with notice to the requesting party, to rescind or revoke the opinion if implementation of the proposed program results in substantial anti-competitive effects, if the program is used for improper purposes, if facts change significantly, or if it would be in the public interest to do so.

Sincerely,

Mark Meier

Markus H. Meier
Assistant Director

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[27] *See* Request Letter, Exhibit 1.