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July 16, 2012

VIA MESSENGER

Mr. Donald S. Clark
Secretary
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room 135-H
Washington, DC 20580

Dear Mr. Clark:

Pursuant to Federal Trade Commission Procedure Rules 1.1 through 1.4, 16 C.F.R. §§ 1.1-1.4, the Generic Pharmaceutical Association, Inc. (“GPhA”) requests an advisory opinion addressing the Commission’s enforcement intentions regarding a voluntary program referred to as the Accelerated Recovery Initiative (“ARI”). The ARI is designed to obtain and provide to the United States Food and Drug Administration (“FDA”) key information that will enable the FDA’s Drug Shortage Program (“DSP”) more efficiently and effectively to accelerate the recovery of critical drugs in short supply. As explained in further detail below, GPhA expects that, with the key information provided by ARI, the FDA will be better positioned to prevent or eliminate shortages of critical, medically necessary drugs, thus helping patients/consumers receive the drugs they need, when they need them. ARI proposes to accomplish its mission by having a third-party vendor, IMS Health Incorporated (“IMS”), gather and provide to the FDA supply and expected product release information from manufacturers, thereby giving the FDA not only a better understanding of current and future market conditions for drugs in short supply but also an enhanced ability to work with manufacturers to expand the supply of these critical medications to patients in need. As competitively sensitive information collected by IMS will be available only to the FDA, and not to manufacturers or other stakeholders, this program is not expected to have any effect on product pricing or otherwise facilitate any unlawful agreements between or among its participants. Furthermore, the FDA has publicly stated its support for ARI announcing, through its spokeswoman Shelly Burgess, that the program would provide “exactly the data FDA needs. . . .”¹

¹ See Generics Industry’s Drug Shortage Plan wins FDA Support, Law 360, April 19, 2012, <http://www.law360.com/articles/331913/print?section=lifesciences> (attached hereto as Exhibit 1).

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I. Background on Critical Drug Shortages.

It is an unfortunate fact that certain prescription drugs face sporadic and critical supply shortages.² As noted by the United States Department of Health and Human Services (“HHS”), medically necessary,³ injectable drugs in particular have been disproportionately affected by “class-wide shortages.”⁴ In fact, recent studies by HHS and IMS Health Incorporated indicate that over eighty percent (80%) of the drugs on the FDA Drug Shortage List (“DSL”) (described at pg. 3 below) are generic injectable drugs, used by acute care patients being treated by providers in hospitals and out-patient facilities, and that as much as fifty percent (50%) of all generic, injectable drugs used in the United States are on the FDA Drug Shortage List.⁵

According to HHS, current drug shortages appear to be a consequence of a substantial expansion in the demand that has occurred over a short period of time, without a corresponding expansion in manufacturing capacity. The expansion in product demand and quantity, in turn, stems from both an increase in the overall volume of drugs used and an unusually high rate of patent expirations that began in 2008 and has continued through 2010.⁶

Furthermore, HHS has indicated that current shortages may not be completely resolved until new supply sources come on line as the manufacturing industry increases its capacity.⁷ However, the regulatory framework governing the industry delays by several years the ability of new suppliers to enter or the ability of existing suppliers to add production capacity. While the FDA continues to respond to the ever increasing drug shortages through, among other things, its Drug Shortage Program, and moving when possible to expedite its approval process for alternative supplies – see for example its approval of the temporary importation of certain cancer treatments as a case in point⁸ – additional actions are needed to stem the increasing tide of drug shortages. The HHS study concludes by recommending, among other things, that immediate responses to the problem of shortages should focus on increasing the extent of supply

² A “drug shortage,” as defined by the FDA, is present when “total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the current or projected demand at the user level.” *See* Economic Analysis of the Causes of Drug Shortages, ASPE Issue Brief dated October 2011 at note 1 (attached hereto as Exhibit 2).

³ A “medically necessary” drug, as defined by the FDA, is one “used to treat or prevent a serious medical condition for which there is no other alternative drug, available in adequate supply that is judged by medical staff to be an adequate substitute.” *Id.* Exhibit 2 at note 1.

⁴ *See* Exhibit 2 at pg. 1.

⁵ *See* Drug Shortages: A closer look at products, suppliers and volume volatility, November 2011, IMS Institute for Healthcare Informatics (attached hereto as Exhibit 3).

⁶ *See* Exhibit 2 at pg. 1.

⁷ *See* Exhibit 2 at pg. 2.

⁸ *See* Jennifer C. Dooren, *Suppliers for Cancer Drugs Get Approval*, Wall St. J., Feb. 22, 2012, at B3.

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responsiveness in the market. ARI is positioned to assist in facilitating this goal by putting key information in the hands of the FDA.

II. The FDA Drug Shortage Program and Drug Shortage List.

As a result of the increasing number and complexity of drug shortages, the FDA, through its Center for Drug Evaluation and Research (“CDER”) located in Rockville, Maryland, developed the Drug Shortage Program (“DSP”). The purpose of the DSP is to ensure the availability of safe and effective drugs to the American public by, among other means, monitoring critical drugs and medical countermeasures, including those in the Strategic National Stockpile, to ensure availability for emergency situations.⁹ The DSP also serves as a liaison with other FDA centers, other government organizations including the Center for Disease Control and the Department of Defense, and private industry.

The DSP uses publicly available information to notify suppliers and the public of present and upcoming shortages in an effort to mitigate or stem the shortage. The DSP makes use of the mandatory disclosures by manufacturers that must report the discontinuation of production of any sole-sourced production of a medically necessary product. *See* Section 506[c] of the Federal, Food, Drug, and Cosmetic Act 21 U.S.C. § 356c. However, all of the remaining information used by the DSP is supplied on a voluntary basis.¹⁰

The DSP posts this information on the FDA publicly available web site in the form of a list (the “DSL”), which currently includes the name of the drug, the formulation, the manufacturer, the anticipated time frame for the agent’s availability, phone numbers and other important communications from the manufacturer relating to the product shortage.¹¹ ARI incorporates information from this list as a starting point, and seeks to enhance the FDA’s ability to arrange production based solutions to mitigate or resolve the shortage at issue.

⁹ CEDR Manual of Policies and Procedures (“MAPP”), dated 02/03/2012, at pg 2 (attached hereto as Exhibit 4).

¹⁰ Under section 1001 of the recently enacted FDA Safety and Innovation Act, a drug manufacturer will now also be required to notify the Secretary of any expected “interruption ... that is likely to lead to a meaningful disruption in the supply of that drug ... and the reason for such ... interruption” six months prior to the expected interruption or as soon as practical.

¹¹ A copy of the most recent DSL is attached as Exhibit 5. It should be noted that section 1004 of the FDA Safety and Innovation Act now mandates that the Drug Shortage List contain the following information: 1) The name of the drug and its National Drug Code number; 2) The name of each manufacturer of the drug; 3) The reason for the shortage selecting from the following categories: A) Requirements related to complying with good manufacturing practices; B) Regulatory delay; C) Shortage of active ingredient; D) Shortage of an active ingredient compound; E) Discontinuation of the manufacture of the drug; F) Delay in shipping of the drug; G) Demand increase for the drug; and 4) The estimated duration of the shortage.

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III. GPhA and ARI.

GPhA is a trade association that represents manufacturers and distributors of finished dose generic pharmaceuticals, manufacturers and distributors of bulk pharmaceutical chemicals and suppliers of other goods and services to the generic drug industry. GPhA was founded in 2001, following the merger of three industry trade organizations: the Generic Pharmaceutical Industry Association, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance.¹² GPhA is a tax-exempt business league under Section 501(c)(6) of the Internal Revenue Code of 1986, as amended.

GPhA is run by a full-time staff and Executive team lead by its President and Chief Executive Officer, Ralph G. Neas.¹³ The Board of Directors consists of 15 industry representatives.¹⁴ Regular, or voting, membership in GPhA is open to any corporation, partnership or other legal entity that derives more than fifty percent (50%) of its net revenues in the United States from the commercialization, manufacture, sale and/or marketing of finished dose pharmaceutical products that are (1) products described in Abbreviated New Drug Applications filed with the U.S. Food & Drug Administration; (2) products sold as authorized generic drugs in the U.S., (3) biosimilar and biogeneric products, as described in Section 351(k) of the Public Health Service Act, as amended; and (4) Drug Efficacy Study Implementation (DESI) products.¹⁵

As members of the public who also are affected by shortages, the generic pharmaceutical industry is devoted to working with all stakeholders to minimize current shortages and mitigate factors that could contribute to future shortages. In accordance with this mission, GPhA has identified the following objectives for ARI:

- Collect and aggregate, via an independent third party under terms of strict confidentiality and with appropriate safeguards (as described further below), current and future production information for those products identified on the FDA Drug Shortage List that satisfy the ARI criteria outlined below;
- Through IMS, work with CDER's Drug Shortage staff to determine current and potential supply gaps, with a focus on those products where a shortage is expected to last longer than 90 days; and
- Through IMS, work with CDER's Drug Shortage staff to ensure the FDA's connectivity with key market participants in the supply chain of the critical drugs.

¹² Additional background information relating to GPhA can be found on its website at www.gphaonline.org.

¹³ A listing of GPhA's staff is attached hereto as Exhibit 6.

¹⁴ A listing of GPhA's Board members is attached hereto as Exhibit 7.

¹⁵ Attached as Exhibit 8 is a current GPhA membership listing. This list identifies both voting ("Regular") and non-voting ("Associate") members of GPhA.

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Pursuit of these objectives will involve IMS' collection and analysis of critical public and non-public production related information, and the provision of that information and analysis to the FDA. Thus, ARI will position IMS to become a clearinghouse of relevant information concerning the supply of critical drugs. As described in further detail below, IMS will not collect pricing or price-related information, and procedural safeguards will be put in place to protect confidential data and prevent the inappropriate uses of the collected information.

IV. Identification and Retention of an Independent Third Party Manager.

GPhA identified a number of companies capable of serving as a third party manager responsible for the collection of relevant information, and the aggregation and provision of that information to the FDA. Each of these companies was interviewed to determine their suitability to run ARI and, although several were well qualified, IMS emerged as the candidate best suited to supply the needed services. IMS has been providing information solutions to entities in the healthcare industry, including pharmaceutical providers, for more than 50 years and already tracks over 80% of global pharmaceutical sales activity accounting for more than 1.3 million products.¹⁶

GPhA and IMS have signed a preliminary non-disclosure agreement and are currently in discussions regarding the operation of ARI.¹⁷ Although ARI will be initiated as a GPhA program, ARI may ultimately operate as a stand-alone, non-profit entity.

IMS is expected, based on its experience and knowledge, to develop the mechanics of the program, including the type of information that it needs to collect, the analysis that it will conduct, and manner in which the information and analysis will be transmitted by IMS to the FDA. As a general overview, ARI, working through IMS, is expected to function as follows:

1. FDA, in consultation with GPhA, will identify/focus on a subset of medically necessary products on the DSL that are expected to be in short supply for more than 90 days, and provide this list of drugs to IMS¹⁸;
2. Through available market sources, including information from the DSL, IMS will identify and, with the assistance of GPhA, individually contact all of the manufacturers of the products identified in the subset above in an effort to sign them up to participate in ARI;

¹⁶ Additional background information relating to IMS can be found on its website at www.imshealth.com.

¹⁷ A draft of the non-disclosure agreement is attached as Exhibit 9.

¹⁸ Drugs meeting the following criteria are expected to be included in the subset of targeted products: 1) currently on the FDA Drug Shortage List; 2) currently listed on the ASHP Drug Shortage List (as no single agent can be substituted or no alternative for a particular indication); 3) it is either an ANDA product or a "grandfathered" product; 4) it is multi-source (i.e., there are potential alternative suppliers); and 5) having a projected shortage of longer than 90 days. In addition, the FDA will have discretion to add products to this list that it believes can benefit from ARI if circumstances warrant.

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3. Participation in ARI will be memorialized by a Participation and Confidentiality Agreement covering the voluntary disclosure of relevant information;¹⁹
4. Participating manufacturers will be expected to: a) provide IMS with their respective 90 to 180 day supply schedules/forecasts covering those products identified on the ARI list; b) to regularly update, on a monthly basis, the supply schedules provided to IMS; c) to provide IMS and the FDA with immediate notice of unanticipated changes to the existing supply schedule reflecting potential and/or expected production problems not previously disclosed on the DSL or otherwise (these communications will occur between IMS and each individual manufacturer, not in collaboration with any other manufacturer);
5. IMS, based on its industry knowledge and information received from manufacturers, will be expected to perform a “gap analysis” that analyzes and charts the anticipated supply and projected demand of the product and, when possible, note historical production levels for all current and former suppliers of the product at issue;
6. IMS will then transmit this analysis and information to the FDA; and
7. The FDA is expected to review this analysis transmitted from IMS along with related information regarding the drug at issue including time frames for expected approvals of additional manufacturers, new capacity, and potential closings of other related lines (information the FDA is in possession of), and then initiate contact with the other manufacturers of the drug at issue in an effort to increase production.

V. Competitive Considerations

A. Total Market Participation.

Total participation is key to identifying and understanding the cause of the potential shortage, and to finding a solution to prevent or stem the potential shortage, and GPhA seeks 100% participation in ARI by manufacturers of medically necessary products.²⁰ Despite the

¹⁹ A draft of the Participation and Confidentiality Agreement and Antitrust Guidelines is attached as Exhibit 10.

²⁰ According to HHS, the “[m]anufacture of generic, sterile injectable drugs is a somewhat concentrated market with 7 manufacturers making up a large percentage of the market. Most of the production of a given drug is by three or fewer manufacturers. Analysis of a sample of 33 generic sterile injectable oncology drugs shows that of 33 drugs, for 28 at least 90 percent of the total unit sales in 2010 was by 3 or fewer manufacturers. These manufacturers each operate a small number of facilities (1-10) at which injectable drugs can be produced. These facilities, in turn, each contain several manufacturing lines. A particular drug can be produced on one or more of these lines, in runs that may last hours to weeks. The same line may be used for multiple different drugs (produced in separate batches), however, certain drugs (including cytotoxic drugs) may only be produced on certain types of lines and in certain types of facilities, so the extent of substitution is limited. Moreover, there are costs in shifting from one drug to another on a specific line.” See Exhibit 2 at pg. 6.

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anticipated level of participation, for the reasons described below, GPhA does not believe ARI will result or enable any adverse consequences to competition for these products.

B. The Exchange of Sensitive Information Will be Limited and Controlled.

As previously noted, information to be collected by IMS under the auspices of ARI will not include price, price related information, or cost information of any kind. However, in order for the program to be successful, participants will be asked to voluntarily supply IMS with current and projected (up to 180 days) production schedules for certain medically necessary drugs already on the DSL. A number of protections/protocols will be established to ensure that the confidential nature of this information is preserved.

1. All participants will be required to enter into a separate confidentiality agreement with GPhA and IMS that is intended to safeguard the disclosure of this information;
2. Participants will supply information only to IMS, and not, directly or indirectly, to other participants;
3. IMS will establish appropriate internal protections including firewalls as needed to ensure that information received from participating manufacturers is not disclosed to other divisions within IMS;
4. IMS will not disseminate information to any of the participants but instead will use the information to help identify manufacturers with capacity to help stem or prevent the shortage;
5. IMS will transmit its analysis and conclusions only to the FDA and allow the FDA to communicate directly with manufacturers to determine whether they are willing to produce additional quantities of the medically necessary drug to prevent or stem the anticipated shortage; and
6. Reporting from IMS back to GPhA will be limited to the identification of drugs under review and will not include any of the competitively sensitive production/supply information provided by ARI participants or information about products (including the identification of any product) that is not already contained in the Drug Shortage List.

C. The Disclosure of Supply Information Should Not Affect Prices.

ARI will orchestrate the provision of supply related information to IMS, and subsequently to the FDA, that supplements the FDA's existing knowledge regarding drugs already in short supply. As the identification of these products is already publicly available on the DSL, it is unlikely that additional information relating to supply and capacity to produce the drug at issue could be used in a fashion that would have any impact on prices or otherwise result

in an agreement that would have any adverse effect on competition.²¹ Furthermore, the competitively sensitive information gathered by IMS will not be posted, in its raw or analyzed form, on the FDA website.

No price, cost or related information will be collected by IMS. Furthermore, all information collected by IMS under the auspices of ARI is subjected to a confidentiality agreement and will only be seen and analyzed by IMS and the FDA. Finally, how this information gets used, including the ultimate communication with manufacturers seeking to stem the drug shortage, is controlled by the FDA.

IV. Conclusion

In conclusion, we respectfully submit that the ARI Program is not likely to facilitate any sort of anticompetitive practice or effect. The benefits to patients are very significant—they will have greater access to the drugs they need.

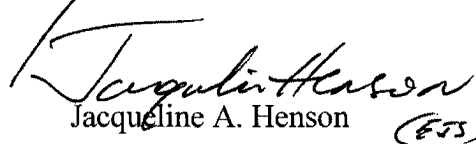
Pursuant to Federal Trade Commission Procedure Rule 1.4, 16 C.F.R. § 1.4, GPhA and ARI request that documents attached hereto as exhibits 8 and 9 be treated as confidential under Federal Trade Commission Procedure Rule 4.10, 16 C.F.R. § 4.10(a)(2), and § 6(f) of the Federal Trade Commission Act, 15 U.S.C. § 46(f). All information to be withheld is competitively sensitive information.

We look forward to feedback from the FTC. Please contact us if there is anything else we can provide that would be helpful to your analysis.

Sincerely,



E. John Steren



Jacqueline A. Henson (EJS)

²¹ The study from HHS, attached hereto as Exhibit 2, gives a succinct explanation of why shortages are a feature of the prescription drug market and why a shortage in product generally does not correspond to an increase in price. Although we have not performed any additional analysis, we believe that its findings also support the conclusion that ARI's efforts to gap short term supply shortages will not affect prices.