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

Bureau of Competition
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Direct Dial
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September 15, 2010

Ms. Joanne Lewers
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1500 K St. N.W.
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Dear Ms. Lewers:

This letter responds to your request for a staff Advisory Opinion on behalf of the Rx-360 International Pharmaceutical Supply Chain Consortium ("Rx-360").[1] Rx-360 seeks guidance concerning the law enforcement intentions of the Federal Trade Commission's Bureau of Competition ("BC") with respect to Rx-360's proposed implementation of two supplier audit programs, the Rx-360 Audit Sharing Program and the Rx-360 Joint Auditing Program. Under each of these programs, pharmaceutical manufacturers will be able to share information about the quality and safety of ingredients purchased from common suppliers ("auditees"). The Rx-360 Joint Auditing Program additionally will permit manufacturers to share the costs of sponsoring quality and safety audits of common suppliers. Because it appears that the audit programs (1) do not require exchanges of competitively significant information, (2) contain protections to reduce Rx-360 members' ability to use the programs for anticompetitive ends, (3) protect auditees from concerted misuse of the audit programs, and (4) are intended and likely to promote efficiency, quality, and safety, FTC staff has no present intention to recommend to the Commission that it challenge the implementation of either program.

In forming this intention, we relied entirely on a review of the written materials and other representations you have given to FTC staff. Should there be information that we are unaware of that qualifies, modifies, or contradicts any of these materials or representations or that calls in to question the conclusions we have drawn from them, or should the proposed activities materially change in the future, we may change our law enforcement recommendation accordingly.

Summary of Representations and Written Materials

We understand that Rx-360 is a not-for-profit international consortium created by

[1] Letter from Joanne Lewers, Counsel to Rx-360, to Donald S. Clark, Secretary of the Commission, requesting an FTC staff Advisory Opinion (July 26, 2010).

members of the biotech and pharmaceutical industries and incorporated in the Commonwealth of Pennsylvania. Its mission, as you describe it, is to protect patient safety by assuring the quality and safety of the supply chain, including the authenticity of materials within the supply chain.

According to your request letter, globalization of distribution for both drug components—such as raw materials, active pharmaceutical ingredients ("APIs"), and excipient ingredients—and finished products has provided opportunities for the introduction of counterfeited, adulterated, and contaminated materials. In turn, the growth and globalization of the pharmaceutical supply chain presents a challenge for manufacturers to monitor the quality and safety of production at their supplier sites, which for any given drug manufacturer may number in the hundreds or even thousands around the world.

You state that FDA regulations and guidance require pharmaceutical manufacturers either to perform on-site audits of suppliers or to test all lots of components shipped to a manufacturer to ensure that suppliers meet the necessary standards for providing safe, high-quality materials. Audits may be performed by a pharmaceutical manufacturer's in-house auditors or by third-party auditors hired by the pharmaceutical manufacturer. These audits focus on the quality, safety, and authenticity of ingredients in the pharmaceutical supply chain; they are not, and should be distinguished from, financial audits.

We understand that primary responsibility for ensuring the quality and safety of pharmaceutical components rests with the finished product manufacturers. In this regard, drug manufacturers follow a risk-based approach to auditing, meaning that sites generally are audited once every several years. Sites that are deemed a "low risk" may be audited less often. Some suppliers, however, may receive a multitude of requests from finished product manufacturers to conduct audits, many of which may be duplicative. As a result, some suppliers may spend significant effort and resources making their facilities available for audits of facilities and processes that may have only recently been examined by other manufacturers.

You state that Rx-360 was formed in 2009 to provide a more cost-effective means of conducting audits and using audit data. You further state that membership in Rx-360 is open to any entity whose activities relate to the research, development, or manufacture of pharmaceutical or biotechnology products. These include research-based pharmaceutical companies, generic pharmaceutical companies, biotechnology companies, and suppliers of ingredients, components, and services to the pharmaceutical and biotechnology industries. Auditors and consultants are permitted to participate in some Rx-360 Working Groups as "Observers," assisting in the development of Rx-360 standards. To avoid conflicts of interest, they will not be permitted to participate in some other activities, such as the Auditor Qualification Working Group, which will select auditors for assignments.[2]

[2] Representations made by Joanne Lewers, Counsel to Rx-360, via e-mail to Theodore Gebhard (August 10, 2010).

According to your request letter, Rx-360 proposes to:

- Share publicly-available information on proposed or new legislation and regulation that impacts the pharmaceutical supply chain;
- Share publicly-available information on counterfeits, cargo thefts, and adulterated products in the pharmaceutical supply chain;
- Develop voluntary standards for assuring the quality, safety, and authenticity of supplies and suppliers;
- Develop and implement audit standards and audit training and certification programs;
- Create or obtain the infrastructure necessary to share data regarding quality, safety, and authenticity of supplies and suppliers that could adversely impact patient health or welfare; and
- Fund the further development of new technologies for securing and detecting adulteration in the supply chain.

You state that these activities will require the sharing of information already within the public domain. But you further state that the activities will also require the sharing of certain non-public information—subject to certain confidentiality obligations (summarized below). Thus, Rx-360 will become a clearinghouse for both public and non-public information related to the global pharmaceutical supply chain.

The Proposed Rx-360 Audit Programs

Rx-360 intends to implement two audit programs. The Rx-360 Audit Sharing Program will allow Rx-360 members to share existing supplier quality and safety audits conducted by Rx-360 members or on their behalf. The Rx-360 Joint Auditing Program will allow Rx-360 members to conduct joint quality audits of pharmaceutical suppliers going forward.

(1) Rx-360 Audit Sharing Program

We understand that participation in the Rx-360 Audit Sharing Program is entirely voluntary. Existing audit reports will be shared only following submission of the audit report to Rx-360 by the audit sponsor and with the consent of the audited supplier (the "auditee"). Program participants will be required to execute a confidentiality agreement with Rx-360 to protect each audited supplier from unwarranted disclosure of its confidential and proprietary information. You have included a copy of that agreement in Appendix C of your request letter. Further, each existing audit report will be redacted by the auditee to protect trade secrets, confidential business information, and other competitively sensitive information. Redaction will follow the Rx-360 audit sharing redaction policy as set out in Appendix D to your request letter. The redacted reports will then be provided to the Rx-360 Secretariat. Once the Secretariat determines that the report is appropriately redacted, the Secretariat will enter the audit report into

a secure database and set access permissions so that only Rx-360 members authorized by the auditee can view the report. The report will be blinded as to audit sponsor, and there will be no way for an Rx-360 member to identify which other members have been given access to the report. Audit reports will remain accessible to authorized members for up to 48 months from the date of the audit. At present, the duties of the Secretariat are performed by outside legal counsel.

You state that the redacted audit reports may be used by those permitted access to help make unilateral decisions about which suppliers to select. This process is similar to what many companies now accomplish through use of vendor questionnaires.

(2) Rx-360 Joint Auditing Program

We understand that under the Rx-360 Joint Auditing Program, one or more Rx-360 members would be able to request that the Consortium sponsor the audit of a particular supplier. You describe the procedures for development and execution of audit plans in your request letter and appendices, especially Appendices G and H, and other correspondence. In brief, you explain that an audit includes meetings with auditee management and other pertinent personnel, on-site observation of the auditee's facilities and operations, and review of the auditee's records and procedures. You further state that an audit focuses on such things as materials controls and supply chain security, calibration and validation of critical equipment, methods, and processes, manufacturing processes, and documentation and records systems.[3]

You state that the audit process begins when an individual Rx-360 member submits a request to the Secretariat for a particular audit to be conducted. The Secretariat then surveys the Rx-360 membership to determine whether other members want to act as joint sponsors of the audit. The identity of the original requesting sponsor and other participating sponsors initially would be known only to the Secretariat. The target supplier would then be contacted to request an audit. At that time, the names of the requesting firms would be disclosed to the supplier. The supplier may either agree or decline to be audited. The supplier may also exclude any requesting company from participating as a joint sponsor.

According to your letter, a third-party auditing firm would be engaged to conduct the audit. The third-party auditor will be selected on the basis of objective minimum requirements. These selection standards would include, for example, an auditor's prior experience, knowledge of pertinent regulatory and best-practices requirements, and ability to communicate in written and spoken English. Other minimum criteria are set out in Appendix F. The services agreement with the auditor will require that, among other things, the auditor maintain the confidentiality of information learned in the course of performing services. The identity of each member interested in auditing a particular supplier would not be disclosed to other companies interested in auditing that supplier.

We understand that after conducting the audit, the auditor will categorize each of its

[3] Representations made by Joanne Lewers, Counsel to Rx-360, via e-mail to Theodore Gebhard (August 11, 2010).

observations as either "critical" or "other." A critical observation, as defined by Rx-360, indicates a system failure that has produced or creates a significant risk of producing a product that is harmful to consumers or that may adversely affect the safety, identity, strength, or purity of the product. You explain in your letter that critical observations require immediate corrective action by the supplier, and will be immediately reported to the auditee and the audit sponsors—even prior to issuance of a draft audit report.

Following an oral review of its findings with the supplier, the auditor will prepare a draft audit report for review by the audit sponsors. The auditor will send the draft audit report to the Secretariat, who in turn will forward a copy to each of the audit sponsors. You represent that to ensure fairness, the auditee will be permitted to contest the accuracy of any observations in the draft audit report, including critical observations. Resolution of disputes in this regard will be made by a decision of the majority of the joint sponsors of the audit. Those decisions will also determine what is ultimately included in the final audit report and posted into the Rx-360 database.

You state that if the audit report identifies any critical observations, the Rx-360 Secretariat will choose a "lead sponsor" to follow-up on implementation of corrective actions with the audited supplier. The lead sponsor will report its findings concerning corrective action to the Secretariat, who in turn will report them to each of the other sponsors. Notwithstanding the above, Rx-360 will not approve or disqualify any supplier based on the findings of a joint audit. Instead, each Rx-360 member that participates in a joint audit will independently utilize the audit findings. Each sponsor retains the right to decide on its own whether an observation has been properly classified as "critical." And each individual sponsor will be free to pursue directly with the supplier any corrective actions it deems necessary.

You explain that, at all times, the auditee will determine which Rx-360 members may obtain access to the audit data. The auditee even may deny access to the audit report to one or more of the joint sponsors—an outcome considered unlikely except where the auditee determines that a joint sponsor is to some extent a competitor of the auditee. Once the final audit is completed and posted on the Rx-360 database, other members of Rx-360 will be able to purchase access to it, again provided the auditee agrees to allow access to such companies. We understand, however, that other suppliers will not have access to an audited supplier's report.

You also state that the Rx-360 programs are not the only means by which audits will be conducted going forward. Instead, the Rx-360 programs are merely options for manufacturers to consider as part of their audit process. For example, members retain the option to conduct audits outside of the Rx-360 program framework.

You submit that none of the information that will be shared relates to costs or prices. Furthermore, as a safeguard to ensure that there is no sharing of competitively significant information, the Rx-360 Secretariat will review audit reports before they are shared to affirm that any information regarding costs, product specifications, quantities, and any other information that may be considered competitively significant has been redacted from the report.

Finally, you state that the Rx-360 Joint Auditing Program is expected to enable manufacturers and suppliers to achieve efficiencies by reducing costly, duplicative, and disruptive audits at common suppliers. These efficiencies, in turn, will enable manufacturers to focus their auditing resources on (1) other suppliers that produce product-specific components, (2) new suppliers, and (3) suppliers that the manufacturer may not have previously been able to audit in the past to the desired frequency. Suppliers also may enjoy cost savings insofar as the number of on-site audits of their facilities is reduced.

Analysis

The Rx-360 audit programs feature the sharing of information among members, some or all of whom may be competitors.[4] The exchange of competitively significant information among competitors may facilitate anticompetitive ends, such as improving the ability of rivals to reach a consensus to limit competition. Group behavior by downstream firms, as here, also raises the possibility of anticompetitive concerted action on the part of manufacturers against one or more upstream suppliers. It is appropriate therefore to consider the risk that Rx-360's proposed audit programs pose in respect to these possibilities. In so doing, we conclude that they do not raise significant risk.

Under the antitrust laws, the legality of information exchanges among competitors is governed by the rule of reason. The rule of reason balances the potential for competitive harm against efficiencies or other procompetitive effects, if any, that the information exchange generates.[5] Among other factors, a rule of reason analysis may inquire into market structure and the nature of the exchanged information to assess whether the exchange is likely to reduce the vigor of competition.[6] A rule of reason analysis, however, need not always go so far as to

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[4] Without first performing a formal market definition exercise it is not possible to know whether or to what extent Rx-360 members are actual competitors in one or more relevant U.S. markets. For purposes of this analysis, we assume that the members are competitors, at least respecting some relevant U.S. pharmaceutical markets.

[5] *United States v. United States Gypsum Co.*, 438 U.S. 422, 441 n.16 (1978) (information exchanges among competitors do not always produce anticompetitive effects, but can also have procompetitive consequences by increasing efficiency. Thus, such exchanges—when not evidence of actual agreements to limit competition—should be subject to the rule of reason).

[6] *Id. See also United States v. Container Corp.*, 393 U.S. 333 (1969), where the Supreme Court condemned a price exchange agreement, without detailed proof of actual market effects, largely because of the nature of the information exchanged, the structure of the market, and the absence of a benign justification for the price information exchange.

The Bureau's analytical framework for evaluating agreements among competitors to achieve joint goals is set out in the FTC/DOJ Guidelines for Collaborations Among Competitors (2000). Specifically, except where an agreement among competitors is *per se* unlawful, the agencies ordinarily will not challenge collaborations where the effect is competitively benign or, on balance, procompetitive.

require a full scale market definition exercise.[7] Rather, as the Commission's *Polygram* opinion establishes, under some circumstances it is appropriate to perform a "truncated rule of reason" or "quick look" in which the Commission considers the capacity of the conduct at issue to facilitate competitive harm against its tendency or ability to further plausible and cognizable procompetitive ends, such as reducing costs.[8]

Based on the information that you have provided us and as summarized above, it does not appear that the Rx-360 audit programs involve practices of the kind that appear likely, even absent an efficiency justification, to restrict or facilitate restriction of competition and decrease output in any relevant market. To the contrary, the shared information may permit Rx-360 members to achieve cognizable efficiencies redounding to the public's benefit. Our assessment is based on a number of factors.

First, the goals of the audit programs do not appear to be either directly or indirectly anticompetitive. Neither do they require exchanges of information about potentially competitively significant parameters such as price, output rates, costs, or capacity.[9] Given the absence of information exchanges respecting a significant competitive parameter, Rx-360 member collaborative efforts are not likely to facilitate marketplace coordination that limits competitive vigor.[10]

Second, your procedures appear to contain several safeguards that further lessen risks of competitive harm. For example, the identity of audit sponsors will be protected, even from each other; audit reports will be redacted to exclude trade secrets, confidential business information, and the audit sponsor's name; the Rx-360 database will contain only those audit reports that both the audit sponsor(s) and the auditee have agreed to disclose to members on an individual basis; each Rx-360 member that participates in a joint audit will independently utilize the audit findings; participation in Rx-360 is voluntary, and all members retain the option to sponsor audits of suppliers independently of Rx-360; and outside legal counsel to Rx-360 will monitor, on an ongoing basis, members' compliance with Rx-360's antitrust "Policy & Guidance," a copy of which you have provided with your request in Appendix B. Each of these features cabins the

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[7] The FTC/DOJ Horizontal Merger Guidelines provide a thorough description of a full scale market definition exercise. *See* Horizontal Merger Guidelines: U.S. Department of Justice and Federal Trade Commission (August 19, 2010), http://www.ftc.gov/os/2010/08/100819hmg.pdf

[8] *Polygram Holdings, Inc.* 136 F.T.C. Decisions 310 (2003) (guided by the Supreme Court's decision in *California Dental Ass'n v. FTC,* 526 U.S. 756 (1999)).

[9] Your request letter states that neither the Audit Sharing Program nor the Joint Audit Program will require the obtaining or sharing of competitively significant data such as prices, output rates, costs, or other dimensions on which Rx-360 members compete in the marketplace.

[10] *See* Section 3 of the Collaboration Guidelines, *esp.* section 3.31(b).

audit programs in ways that appear to reduce members' ability to use the programs for anticompetitive ends.[11]

Third, auditees appear to be protected from possible concerted misuse of the audit programs. For example, as previously noted, audit reports are not accessible to any given Rx-360 member from the Rx-360 database unless the auditee has provided its approval of release of the audit report to that member. Additionally, the audits themselves are conducted by third-party audit firms selected on the basis of objective standards related to an auditor's capacity to perform quality and safety audits. After an audit is completed, Rx-360 will have no role in approving or disqualifying any supplier based on an audit's results; rather, each Rx-360 member will render its own judgment on the audit report and determine whether the auditee needs to make adjustments in order to maintain a supply relationship with the member.

Fourth and finally, there appear to be cognizable cost-savings associated with the audit programs, as well as consumer benefits. It appears that the Joint Audit Program will enable manufacturers to reduce the costs of duplicative audits at common suppliers and more productively allocate audit resources. For example, the Joint Audit Programs may allow individual manufacturers to refocus their resources on suppliers that produce product-specific components for those individual manufacturers. Suppliers too could enjoy cost savings by dint of fewer independently-sponsored on-site audits. These savings, or at least some portion of them, may be passed through the pharmaceutical supply chain to consumers. In addition, consumers might be better assured of the quality and safety of the components and processes used to manufacture pharmaceuticals.

Conclusion

On the basis of these features, FTC staff concludes that the Rx-360 audit programs likely do not raise significant competitive concerns. Staff believes that the nature of the shared data is likely competitively benign and, in any event, the programs are sufficiently cabined in other respects to eliminate substantially any risk that the shared data would facilitate anticompetitive effects in either output or input markets. The programs appear, moreover, to have important, cognizable cost-saving and safety enhancing features. For these reasons, BC staff has no present intention to recommend that the Commission undertake an enforcement action against the Rx-360 audit programs upon their implementation. This opinion of FTC staff is predicated on the accuracy of the information that you have provided to us. In accordance with normal practice, the Bureau of Competition reserves the right to reconsider the questions involved and, with notice to the requesting party, to rescind the opinion if actual conduct respecting the Rx-360 audit programs proves to be anticompetitive in any purpose or effect or if facts change significantly in the future such that it would be in the public interest to bring an enforcement action.

[11] For example, retention of independent decision-making lessens concerns about the potential for competitive harm. *See esp.* section 3.34 of the Collaboration Guidelines.

The views of FTC staff contained herein are provided as authorized by Rule 1.1(b) of the Commission's Rules of Practice, 16 C.F.R. § 1.1(b). Under Commission Rule 1.3(c), 16 C.F.R. § 1.3(c), the Commission is not bound by this staff opinion.

Sincerely,

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