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FEDERAL TRADE COMMISSION

[File No. 151 0074]

Pfizer Inc. and Hospira, Inc.; Analysis of Proposed Consent Orders to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent orders--embodied in the consent agreement -- that would settle these allegations.

DATES: Comments must be received on or before September 23, 2015.

ADDRESSES: Interested parties may file a comment at https://ftcpublic.commentworks.com/ftc/pfizerhospiraconsent online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "Pfizer Hospira Consent, File No. 151 0074" on your comment and file your comment online at https://ftcpublic.commentworks.com/ftc/pfizerhospiraconsent by following the instructions on the web-based form. If you prefer to file your comment on paper, write "Pfizer Hospira Consent, File No. 151 0074" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania

Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Kari A. Wallace, Bureau of Competition, (202-326-3085), 600 Pennsylvania Avenue, NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR § 2.34, notice is hereby given that the above-captioned consent agreement containing consent orders to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, have been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for August 24, 2015), on the World Wide Web, at http://www.ftc.gov/os/actions.shtm.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before September 23, 2015. Write "Pfizer Hospira Consent, File No. 151 0074" on your comment. Your comment - including your name and your state - will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Website, at http://www.ftc.gov/os/publiccomments.shtm. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Website.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or

foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which . . . is privileged or confidential," as discussed in Section 6(f) of the FTC Act, 15 U.S.C. § 46(f), and FTC Rule 4.10(a)(2), 16 CFR § 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR § 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at https://ftcpublic.commentworks.com/ftc/pfizerhospiraconsent by following the instructions on the web-based form. If this Notice appears at http://www.regulations.gov/#!home, you also may file a comment through that website.

If you file your comment on paper, write "Pfizer Hospira Consent, File No. 151 0074" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR § 4.9(c).

(Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Website at http://www.ftc.gov to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before September 23, 2015. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see http://www.ftc.gov/ftc/privacy.htm.

Analysis of Agreement Containing Consent Orders to Aid Public Comment

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Pfizer Inc. ("Pfizer") and Hospira, Inc. ("Hospira") that is designed to remedy the anticompetitive effects resulting from Pfizer's acquisition of Hospira. Under the terms of the proposed Consent Agreement, the parties are required to divest all of Pfizer's rights and assets related to generic acetylcysteine inhalation solution and all Hospira's rights and assets related to clindamycin phosphate injection, voriconazole injection, and melphalan hydrochloride injection to Alvogen Group, Inc. ("Alvogen").

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the proposed Consent Agreement or make final the Decision

and Order ("Order").

Pursuant to an Agreement and Plan of Merger executed on February 5, 2015, Pfizer proposes to acquire Hospira for approximately $16 billion (the "Proposed Acquisition"). The Commission alleges in its Complaint that the Proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by lessening current competition in the markets for generic acetylcysteine inhalation solution and clindamycin phosphate injection and future competition in the markets for voriconazole injection and melphalan hydrochloride injection in the United States. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the Proposed Acquisition.

I. The Products and Structure of the Markets

The Proposed Acquisition would reduce the number of current suppliers in the markets for generic acetylcysteine inhalation solution and clindamycin phosphate injection, and reduce the number of future suppliers in the markets for voriconazole injection and melphalan hydrochloride injection.

Generic acetylcysteine inhalation solution is a mucolytic therapy used to treat certain respiratory disorders. Acetylcysteine liquefies mucus in the lungs, which then can be coughed or suctioned out. Patients inhale the solution through a nebulizer mask, facemask, mouthpiece, tent, or intermittent positive pressure-breathing machine. Only three companies—Fresenius Kabi, partnered with Gland Pharma Ltd. and Pfizer; Hospira; and American Regent, Inc.—supply generic acetylcysteine inhalation solution in the United States. The branded version of this product, Mucomyst, is no longer available. Fresenius/Gland/Pfizer is the market leader with an

approximately 69% share and Hospira has an approximately 22% share.

Clindamycin phosphate injection is an antibiotic used to treat lung, skin, blood, bone, joint, and gynecological infections in hospitals. Currently, only four companies supply the product in the United States: Pfizer, Hospira, Sagent Pharmaceuticals, and Fresenius Kabi. While Pfizer's clindamycin phosphate product is a branded version, the price of Pfizer's product is competitive with the generic products. Customers, therefore, play the branded and the generic products against each other to negotiate prices. Pfizer and Hospira have a combined approximate market share of more than 80%.

Voriconazole injection is an antifungal medication used to treat significant fungal infections in hospitals. Pfizer currently sells its Vfend brand voriconazole injection product priced competitively with the only generic version in the United States, which is offered by Sandoz. Hospira is one of a limited number of suppliers capable of entering the voriconazole injection market in the near future.

Melphalan hydrochloride injection is a chemotherapy agent used to treat multiple myeloma and ovarian cancer. There are currently two melphalan hydrochloride injection products available in the United States: the branded version, which was originally developed and marketed by Glaxo Smith Kline and is now supplied by ApoPharma USA, Inc. ("ApoPharma"), and the generic version, sold by Mylan N.V. ("Mylan"). ApoPharma prices its branded version of the product competitively with the generic version offered by Mylan. Pfizer and Hospira are developing melphalan hydrochloride injection products, and are two of a limited number of suppliers capable of entering the market in the near future.

II. Entry

Entry into the four markets described earlier would not be timely, likely, or sufficient in

magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including approval by the United States Food and Drug Administration ("FDA"), is costly and lengthy.

III. Effects

In markets for pharmaceutical products used primarily in hospitals, like the products here, branded drug manufacturers are typically unable to command a premium price for their products because of the reimbursement structure for drugs administered in hospitals. Hospitals typically would not be reimbursed for using a premium-priced branded injectable product, when lower-priced therapeutically equivalent products are available. As a result, brand manufacturers of sterile injectable or inhalation products may lower their prices and compete directly with generic manufacturers' products. Customers tend to gravitate to the lowest-priced product, regardless of whether the drug was approved by the FDA as a brand or a generic product.

Like true generic pharmaceutical markets, these multi-source pharmaceutical products generally are commodities, and prices often are inversely correlated with the number of competitors in each market. As the number of suppliers offering a therapeutically equivalent drug increases, the price for that drug decreases due to the direct competition between the existing suppliers and each additional supplier. The Proposed Acquisition would eliminate the current competition between two of the three competitors in the market for generic acetylcysteine inhalation solution, resulting in a duopoly and likely price increases. Similarly, in the market for clindamycin phosphate solution, the Proposed Acquisition would eliminate competition between two of only four current competitors, leading to higher prices.

In addition, the Proposed Acquisition likely would cause significant anticompetitive harm to consumers by eliminating future competition that would otherwise have occurred if Pfizer and

Hospira remained independent. The evidence shows that anticompetitive effects are likely to result from the Proposed Acquisition due to the elimination of an additional independent entrant in the currently concentrated markets for voriconazole injection and melphalan hydrochloride injection, which would have enabled customers to negotiate lower prices. Customers and competitors have observed—and pricing data confirms—that the price of these pharmaceutical products decreases with new entry even after several other suppliers have entered the market. Thus, absent a remedy, the Proposed Acquisition will likely cause U.S. consumers to pay significantly higher prices for voriconazole injection and melphalan hydrochloride injection.

IV. The Consent Agreement

The proposed Consent Agreement effectively remedies the competitive concerns raised by the acquisition in all four markets at issue by requiring Pfizer to divest all its rights to generic acetylcysteine inhalation solution and Hospira to divest all of its rights and assets related to clindamycin phosphate injection, voriconazole injection, and melphalan hydrochloride injection to Alvogen. Alvogen is a private, global pharmaceutical corporation that develops, manufacturers, sells, and distributes generic pharmaceuticals in the United States and in 33 other countries around the world. The parties must accomplish these divestitures and relinquish their rights no later than ten days after the Proposed Acquisition is consummated.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Acquisition. If the Commission determines that Alvogen is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires the parties to unwind the sale of rights to Alvogen and then divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The proposed Consent Agreement and Order contain several provisions to help ensure that the divestitures are successful. Alvogen will acquire Pfizer's acetylcysteine inhalation ANDA and stream of revenue associated with the product and will assume Pfizer's role in the contractual relationships with the third parties. Pfizer/Hospira will supply Alvogen with the clindamycin phosphate injection products for three years while the company transfers the manufacturing technology to Alvogen or its designee. Similarly, Pfizer/Hospira will transfer the third-party development and contract manufacturing agreements for voriconazole injection and melphalan hydrochloride injection to Alvogen. The proposed Order also requires Pfizer and Hospira to provide transitional services to Alvogen to assist it in establishing its manufacturing capabilities and securing all of the necessary FDA approvals. These transitional services include technical assistance to manufacture clindamycin in substantially the same manner and quality employed or achieved by Hospira, and advice and training from knowledgeable employees of the parties.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark
Secretary.

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