ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

In the Matter of Fresenius Medical Care AG & KGaA and NxStage Medical, Inc., File No. 171-0227

INTRODUCTION

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Fresenius Medical Care AG & KGaA ("Fresenius") and NxStage Medical, Inc. ("NxStage") designed to remedy the anticompetitive effects resulting from Fresenius's proposed acquisition of NxStage. The proposed Decision and Order ("Order") contained in the Consent Agreement requires the parties to divest all rights and assets related to NxStage's bloodline tubing set business to B. Braun Medical, Inc. ("B. Braun").

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will review the comments received and decide whether it should withdraw, modify, or make the Consent Agreement final.

Under the terms of the Agreement and Plan of Merger dated August 7, 2017, Fresenius will acquire NxStage in a transaction valued at approximately $2.0 billion (the "Acquisition"). The Commission's Complaint alleges 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 substantially lessening competition in the U.S. market for bloodline tubing sets. The proposed Consent Agreement will remedy the alleged violation by preserving the competition that otherwise would be lost in this market because of the proposed Acquisition.

THE PARTIES

Fresenius, headquartered in Bad Homburg, Germany, is a vertically integrated business specializing in the development, manufacture, and distribution of in-center dialysis equipment, in-home dialysis equipment, and dialysis-related consumables. In addition to being one of the largest providers of dialysis services, Fresenius is the largest manufacturer and distributor of dialysis equipment and related products in the United States.

Headquartered in Lawrence, Massachusetts, NxStage is a medical technology company specializing in the development, manufacturing, and marketing of products for treatment of chronic kidney disease and acute kidney failure. NxStage operates through three primary segments: (1) System One, home and critical care dialysis; (2) ancillary products; and (3) in-center kidney care dialysis clinics.

THE RELEVANT PRODUCT AND STRUCTURE OF THE MARKET

Clinicians use bloodline tubing sets for every hemodialysis treatment performed. During hemodialysis therapy, the hemodialysis machine pulls blood from the patient, filters it through a dialyzer to remove toxins, then returns the filtered blood back to the patient. Bloodlines are plastic tubes that complete the extracorporeal blood circuit by continuously carrying blood from the patient to the dialyzer and then back to the patient's body. They consist of a plastic tube with other plastic components such as connectors, injection ports, clamps, and pressure chambers that assist with the hemodialysis treatment. Manufacturers configure bloodline tubing to fit connection points on the hemodialysis machine. Hemodialysis machines have either "open" or "closed" architecture. An open architecture hemodialysis machine has universal connections that are compatible with multiple bloodline brands, whereas a closed architecture hemodialysis machine requires proprietary bloodlines specifically manufactured for its connection points. There are no viable alternatives to bloodline tubing sets for hemodialysis equipment.

Fresenius, NxStage, and Nipro are the only competitively significant suppliers of bloodline tubing sets in the United States. Fresenius is the leading supplier with 59 percent of the market. NxStage accounts for an additional 23 percent of the market, and Nipro has a share of 16 percent. The remaining 2% share of the market consists of smaller firms supplying proprietary bloodlines for closed architecture hemodialysis machines.

THE RELEVANT GEOGRAPHIC MARKET

The United States is the relevant geographic market in which to analyze the effects of the proposed Acquisition. These products are medical devices regulated by the U.S. Food and Drug Administration ("FDA"). Medical devices sold outside of the United States, but not approved for sale in the United States, do not provide viable competitive alternatives for U.S. consumers.

COMPETITIVE EFFECTS OF THE ACQUISITION

The proposed Acquisition would likely result in substantial competitive harm to consumers in the relevant market. The parties are two of only three significant suppliers of bloodline tubing sets used in open architecture hemodialysis machines in the United States. Eliminating the head-to-head competition between Fresenius and NxStage in this highly concentrated market would allow the combined firm to exercise market power unilaterally, resulting in higher prices, reduced innovation, and less choice for customers in this market.

ENTRY CONDITIONS

Entry in the relevant market would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed Acquisition. New entry would require significant investment of time and money for product research and development, regulatory approval by the FDA, developing clinical history supporting the long-term efficacy of the product, and establishing a U.S. sales and service infrastructure. Such development efforts are difficult, time-consuming, and expensive, and often fail to result in a competitive product reaching the market.

THE CONSENT AGREEMENT

The Consent Agreement eliminates the competitive concerns raised by the proposed Acquisition by requiring the parties to divest to B. Braun all assets and rights to research, develop, manufacture, market, and sell NxStage's bloodline tubing sets. Additionally, to ensure that the divestiture is successful and maintain continuity of supply, the proposed Order requires the parties to supply B. Braun with bloodline tubing sets for a limited time while B. Braun is establishing its own manufacturing capability. The provisions of the Consent Agreement ensure that B. Braun becomes an independent, viable, and effective competitor in the U.S. market in order to maintain the competition that currently exists.

B. Braun is well positioned to restore the competition that otherwise would have been lost due to the proposed Acquisition. Headquartered in Germany with U.S. offices based in Bethlehem, Pennsylvania, B. Braun develops, manufactures, and markets a variety of medical products in eighteen therapeutic areas, including hemodialysis, and the company has a track record for quality, service, and consistency. B. Braun's existing hemodialysis business includes products that are highly complementary to the divestiture assets.

The parties must accomplish the divestitures and relinquish their rights to B. Braun no later than ten days after consummating the proposed Acquisition. If the Commission determines that B. Braun is not an acceptable acquirer, or that the manner of the divestiture is not acceptable, the proposed Order requires the parties to unwind the sale of rights to B. Braun and then divest the products to a Commission-approved acquirer(s) within six months of the date the Order becomes final.

To ensure compliance with the Order, the Commission has agreed to appoint a Monitor to ensure that Fresenius and NxStage comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the rights and assets to B. Braun. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

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