ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDER TO AID PUBLIC COMMENT

In the Matter of FRESENIUS MEDICAL CARE AG & CO. KGaA and DAIICHI SANKYO COMPANY, LTD. File No. 081-0146

I. Introduction

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Order ("Consent Agreement") from Fresenius Medical Care Ag & Co. KGaA ("Fresenius") and Daiichi Sankyo Company, Ltd. ("Daiichi"), which is designed to remedy the effects that would otherwise result from Fresenius's proposed acquisition of an exclusive sublicense from Daiichi's wholly owned subsidiary Luitpold Pharmaceuticals, Inc. ("Luitpold") to manufacture and supply Venofer in the United States (hereinafter "License Agreement"). Venofer is an intravenously-administered preparation of iron sucrose that is used primarily to treat iron deficiency anemia in patients with chronic kidney disease undergoing dialysis treatment.

Pursuant to a License, Distribution, Manufacturing and Supply Agreement dated July 8, 2008, Luitpold and Vifor (International) Inc. agreed to grant Fresenius an exclusive sublicense to distribute, manufacture and sell Venofer to independent outpatient dialysis clinics in the United States for a term of ten years with an option to extend the agreement for an additional ten years. Luitpold retains the right to sell Venofer in the United States to any other customer, including hospitals, doctor's offices, and hospital-based dialysis clinics. The transaction is purely vertical since Fresenius does not sell products that compete with Venofer.

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 enabling Fresenius to increase prices it charges its own clinics, which, in turn, would raise reimbursement rates that the Centers for Medicare & Medicaid Services ("CMS") pays for Venofer. The proposed Consent Agreement would remedy the alleged violations by limiting Fresenius's ability to inflate the intra-company transfer price it reports to CMS for Venofer as a mechanism to increase reimbursement rates.

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order.

II. The Parties

Fresenius is the world's largest provider of dialysis products and services to patients suffering from chronic kidney disease, a condition that affects 1.6 million people worldwide. Fresenius is already vertically integrated in that it provides dialysis services through its approximately 1,650 owned or managed dialysis clinics and supplies its own and other clinics with a broad range of dialysis-related products, such as hemodialysis machines, dializers and related disposable products.

Daiichi, through its wholly owned subsidiary Luitpold, licenses Venofer from Vifor (International) Inc., a Swiss pharmaceutical company that developed the product. Luitpold's subsidiary, American Regent, Inc., markets and distributes all of Luitpold's injectable products, including Venofer, to customers in the United States.

III. Intravenous Iron

Intravenous ("IV") iron is critical for the effective treatment of dialysis patients, the vast majority of whom suffer from chronic anemia. Without IV iron treatments, dialysis patients would suffer significantly higher mortality rates and a lower quality of life. In the United States, Luitpold's Venofer and Ferrlecit, which is manufactured by Watson Pharmaceutical Inc. ("Watson"), are the two IV iron products used most commonly to treat iron deficiency anemia in patients undergoing chronic hemodialysis. These second-generation IV iron drugs do not induce the side effects associated with first-generation IV iron products. Because of these side effects, sales of first generation IV irons in the United States are minimal.

The U.S. market for second-generation IV iron is highly concentrated. Luitpold and Watson are the only two suppliers of these drugs in the United States. In addition, entry into this market would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the effects of the proposed transaction.

IV. Reimbursement for Intravenous Iron

Approximately 80 percent of outpatient dialysis services, for patients of all ages, are reimbursed under the Medicare Part B end-stage renal disease ("ESRD") program, at an annual cost of $7.9 billion, of which $2.9 billion was for separately billable drugs, with IV iron payments accounting for $400 million. Medicare reimburses dialysis clinics based on the drug manufacturer's Average Sales Price ("ASP") plus six percent. ASP is calculated by averaging the prices paid by all customers, including any discounts or rebates. A clinic's profit depends not

just on how much it pays for the product but the difference between the clinic's acquisition price and the average sale price. An independent clinic, one not vertically integrated with the sale of the product, prefers, all other things equal, an acquisition price that maximizes the difference between its acquisition cost and the average selling price.

The reimbursement system will change, beginning as early as 2011 and completely by 2014. On July 15, 2008, Congress enacted the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA"), which will make substantial changes to the Medicare program relating to dialysis services and, once fully implemented, would eliminate the regulations that give rise to the concerns created by the proposed transaction. MIPPA mandates that CMS start a process of shifting from a system in which it pays separately for physician-administered drugs for dialysis patients to a system in which all the costs of providing care to dialysis patients would be bundled together into a single capitated payment, beginning on January 1, 2011 and phased in until full implementation is achieved on January 1, 2014. Once the change from a separately-billed, ASP-based payment for Venofer to a universal bundled payment for dialysis services is in effect, the adverse effects of the proposed transaction on reimbursement rates will disappear.

IV. Competitive Effects

Unremedied, the proposed transaction would give Fresenius, the largest provider of ESRD dialysis services in the United States, the ability to increase Medicare reimbursement payments for Venofer. After the transaction, the competitive market will no longer determine the price that Fresenius's clinics will pay for IV iron. Instead, the price Fresenius's clinics pay will become an internal transfer price, and that internal transfer price could become the price that Fresenius reports as the price it charges its own clinics for the product. Increasing the internal transfer price would, in turn, increase ASP and, hence, reimbursement to clinics, including Fresenius, for their use of Venofer. Unlike a "real" price increase, it would be costless for Fresenius to inflate its internal transfer price to CMS because it would not impact Fresenius's actual cost of providing Venofer to its patients, nor would it adversely affect demand. In fact, artificially raising ASP would increase the demand for Venofer among other dialysis clinics because it would cause reimbursement levels to go up.

V. The Consent Agreement

The proposed order reduces Fresenius's ability to report inflated intra-company transfer prices to CMS for Venofer. Under the proposed order, Fresenius would be restricted from reporting an intra-company transfer price higher than the level set forth in the order. That level is derived from current market prices. The order further provides that if a generic Venofer product receives final approval by the United States Food and Drug Administration, Fresenius would be required to report its intra-company transfer price at either (1) the level set forth in the order or (2) the lowest price at which Fresenius sells Venofer to any customer, whichever is lowest, until

December 31, 2011. On January 1, 2012, the order removes the lowest-priced-customer restriction, while the level set forth in the order remains in place. By 2012, at least 50 percent of ESRD dialysis services will be covered under the capitated reimbursement system implemented by MIPPA. The order also provides that if CMS implements regulations that eliminate the potential anticompetitive harm of this transaction, those regulations will supersede the order.

The order accomplishes two goals. First, it prevents the acquisition from driving up ASP and reimbursement rates by requiring Fresenius to report its transfer price in line with current market conditions. Second, it is designed to capture potential near-term changes in the market caused by generic entry, should it occur, and to ensure that the price Fresenius reports to CMS reflects the competitive impact of such future generic competition. When fully implemented, the reimbursement methodology of the new bundled pricing system will eliminate the concerns raised by the transaction. Therefore, the price-adjustment provision expires as the reimbursement mechanism changes.[1]

The order also prohibits Luitpold and Fresenius from sharing confidential business information relating to the manufacture, sale, or distribution of Venofer, as Luitpold will continue to sell Venofer to non-dialysis clinics, and requires the parties to provide notice to the Commission prior to modifying the License Agreement. Finally, to enable the Commission to ensure compliance with the order, the proposed order provides that the Commission may appoint a Monitor Trustee. The Commission has not determined to appoint a monitor at this time, however, because currently it does not appear that compliance with the order would be time consuming or require particular expertise. Nevertheless, should it become necessary or appropriate, the proposed order requires Fresenius and Daiichi to execute an agreement conferring upon the Interim Monitor all of the rights and powers necessary to permit the monitor to satisfy his responsibilities.

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.

[1] The Commission is grateful to CMS staff for assisting the Commission as it considered the competitive implications of the proposed transaction and crafted an appropriate remedy.