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

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.