ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

In the Matter of Grifols S.A., and Grifols Shared Services North America, Inc.
File No. 181-0081, Docket No. C-4654

INTRODUCTION

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Grifols S.A. and its subsidiary Grifols Shared Services North America, Inc. (collectively "Grifols"). The purpose of the Consent Agreement is to remedy the anticompetitive effects resulting from Grifols' proposed acquisition of Biotest US Corporation ("Biotest US") from The Biotest Divestiture Trust. The proposed Decision and Order ("Order") contained in the Consent Agreement requires Grifols to divest plasma collection centers in three local geographic markets in the United States to Kedplasma LLC ("KedPlasma"), a subsidiary of Kedrion Biopharma Inc. ("Kedrion"). Grifols is also prohibited from acquiring any ownership interest in ADMA Biologics ("ADMA"), which had been partially owned by Biotest US, without prior notification.

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

THE ACQUISITION

Pursuant to an agreement dated December 22, 2017, Grifols proposed to acquire all of the outstanding voting securities of Biotest US from The Biotest Divestiture Trust, which included the outstanding securities of ADMA owned by Biotest US. Grifols and Biotest US subsequently modified the acquisition agreement to exclude the outstanding securities of ADMA and revalued the acquisition. The acquisition and the modified acquisition (collectively, "the Acquisition") are subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

The Commission's Complaint alleges that the 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 (1) eliminating actual, direct, and substantial competition between Grifols and Biotest US in three local markets for the collection of human source plasma; (2) increasing the ability of the merged entity unilaterally to decrease donation fees for the collection of human source plasma in each local market; (3) reducing incentives to improve service or quality in each local market for the collection of human source plasma; and (4) increasing the likelihood that Grifols would unilaterally exercise market power in the U.S. market for hepatitis B immune globulin ("HBIG"). The proposed Consent Agreement would remedy the alleged violations by preserving the competition that would otherwise be eliminated as a result of the proposed Acquisition.

THE PARTIES

Headquartered in Barcelona, Spain, Grifols is a vertically integrated global healthcare company. Grifols specializes in the collection of plasma, and the development and production of several plasma-derived products. Grifols operates or manages approximately 192 plasma collection centers throughout the United States and sells a wide variety of plasma-derived blood products, including HBIG. In 2016, Grifols had net revenues of approximately $4.3 billion.

Biotest US is a wholly owned subsidiary of The Biotest Divestiture Trust headquartered in Boca Raton, Florida. Through its subsidiary, Biotest Pharmaceutical Corporation, Biotest US owns a network of 22 U.S. plasma collection centers. Prior to the signing of the Consent Agreement, it also owned 41 percent of the stock of ADMA. ADMA develops, manufactures and sells human blood plasma-derived products in the United States, including HBIG. In 2017, Biotest US generated approximately $187 million in revenues.

RELEVANT MARKETS AND STRUCTURE OF THE MARKETS

Plasma Collection Centers

Grifols and Biotest are the only two companies with plasma collection centers in three geographic areas in the United States: (1) Lincoln, Nebraska; (2) Augusta, Georgia; and (3) Youngstown, Ohio. Donated plasma is a critical input for a variety of medical products that are used to treat diseases or conditions in multiple therapeutic areas, including pulmonology, hematology, immunology, infectious disease, and trauma. Plasma collection centers are often located near universities, military installations, and other areas with a sufficient number of potential donors. Centers typically compensate donors by paying them a per-donation fee. Donors choose their donation center based on proximity, convenience, quality of the facility, and the donor fee. Plasma centers typically compete on these dimensions to attract individuals interested in selling their blood.

The relevant geographic markets for the provision of plasma collection services are local due to the limited distance individuals are willing or able to travel to donate plasma. Donors typically will not travel more than 25 minutes, or 15 to 20 miles, to donate plasma, though each plasma collection center's draw area may differ based on the ease of travel and transportation and the density of population. In each of the geographic areas of concern, Grifols and Biotest operate plasma collection centers very close to each other, and the next-closest alternative is quite distant. In Lincoln, Nebraska, Grifols and Biotest are less than a mile apart and the closest alternative plasma collection centers are an hour away in Omaha. Likewise, in Augusta, Georgia, they are approximately six miles apart and in Youngstown, Ohio, they are approximately nine miles apart, and for each market the alternatives are located over an hour away.

Hepatitis B Immune Globulin

HBIG is a plasma-derived product used as a prophylaxis to treat healthcare professionals or patients exposed or potentially exposed to hepatitis B, and to prevent recurrence of hepatitis B in hepatitis B-positive liver transplant patients. There are no viable substitutes for HBIG. The market for HBIG is highly concentrated. There are three HBIG products sold in the United States: ADMA's Nabi HB, Saol Therapeutics' ("Saol") HepGam B, and Grifols' HyperHep. ADMA's Nabi HB is the market leader, while Saol's HepGam B and Grifols' HyperHep are the second and third leading product lines, respectively.

The relevant geographic market in which to analyze the proposed Acquisition's effects in the HBIG market is the United States. Plasma-derived products, such as HBIG, must be approved by the U.S. Food and Drug Administration ("FDA") for sale in the United States. The FDA further requires that these products be made solely from plasma collected in the United States in FDA-approved collection centers and manufactured in FDA-approved plants. Plasma-derived products not approved for sale in the United States are not viable alternatives for U.S. consumers.

COMPETITIVE EFFECTS OF THE ACQUISITION

Plasma Collection Centers

In the three geographic areas at issue—Lincoln, Nebraska; Augusta, Georgia; and Youngstown, Ohio—the proposed Acquisition raises competitive concerns because, post-Acquisition, Grifols would own all of the plasma collection centers in each area, which would affect its incentives to offer competitive donor fees and/or quality of service. Thus, the proposed Acquisition would likely result in diminished service, quality, and longer wait times for donors in each market. In addition, Grifols likely would be able to exercise market power by unilaterally decreasing donor fees at one or both of the plasma donor centers in each geographic area.

Hepatitis B Immune Globulin

The proposed Acquisition would significantly increase market concentration and eliminate substantial competition between the first- and third-largest suppliers of HBIG in the United States. Prior to the parties' restructuring the transaction, Grifols would have acquired an approximately 41 percent ownership stake in ADMA, one of its two rivals in the United States HBIG market. This ownership stake would have given Grifols the incentive to increase significantly the price of its HBIG product because it would recapture sufficient revenues through its stake in ADMA to offset any sales lost due to Grifols' price increases.

ENTRY

Plasma Collection Centers

Entry into the plasma collection service markets in Lincoln, Nebraska; Augusta, Georgia; and Youngstown, Ohio is not likely to occur in a timely and sufficient manner to deter or counteract the likely anticompetitive effects of the Acquisition. New entry is unlikely due to the scarcity of qualified donors necessary to justify opening a new plasma collection center in each of these geographic areas.

Hepatitis B Immune Globulin

Entry into the HBIG 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, and establishment of 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. These obstacles make entry in the HBIG more challenging and less likely to avert the anticompetitive effects of the proposed Acquisition.

THE CONSENT AGREEMENT

The proposed Consent Agreement eliminates the competitive concerns raised by the proposed Acquisition by: (1) requiring Grifols to divest its plasma collection centers in Lincoln, Nebraska; Augusta, Georgia; and Youngstown, Ohio to Kedplasma; (2) prohibiting Grifols from obtaining ownership or control of any ADMA stock; and (3) requiring Grifols to provide prior notice to the Commission if it seeks to repurchase any of the divested plasma collection centers or any ownership interest in ADMA.

Kedplasma is a well-qualified acquirer of Grifols' plasma collection centers. Kedplasma is a subsidiary of Kedrion, a leading manufacturer of protein products and the fifth-largest producer of plasma proteins worldwide. Kedrion currently operates plasma collection centers in the United States, Germany, and Hungary. In the United States, Kedplasma operates 15 plasma collection centers and it anticipates opening two additional centers in 2018 (none of which currently competes or will compete with the to-be-divested Grifols' plasma collection centers).

The proposed Consent Agreement contains several provisions designed to ensure the successful divestiture of the plasma collection centers to Kedplasma. Grifols is required to obtain the consents of all third parties that are necessary to permit Grifols to divest the plasma collection centers to the buyer. This provision ensures that the buyer will have the assets necessary to continue operating the business of the divested centers in a competitive manner. In addition, the Consent Agreement requires Grifols to provide Kedplasma with the opportunity to interview and hire employees affiliated with the divested centers, as well as with information about each employee. Next, the Consent Agreement requires Grifols to provide all employees with reasonable financial incentives to remain in their positions until the buyer assumes control

of each divested center. This will ensure that the buyer has access to personnel who are familiar with the centers' donors and their donation schedules, and donation policies necessary to preserve the marketability, viability, and competitiveness of each center. Finally, the Consent Agreement requires Grifols to maintain the centers and prevent the destruction, deterioration, or impairment of the equipment and assets of the centers until they are divested to ensure that they remain competitive.

Before entering the Consent Agreement, and in consultation with Commission staff, Biotest US transferred ownership of all ADMA stock to its parent, The Biotest Divestiture Trust. Because Grifols is not acquiring The Biotest Divestiture Trust, it will neither acquire the ADMA stock previously held by Biotest US nor any other ownership interest in ADMA. To prevent Grifols from reacquiring the interest in ADMA, the proposed Consent Agreement explicitly prohibits Grifols from directly or indirectly acquiring any ownership interest in ADMA or obtaining any rights to nominate or obtain representation on the Board of Directors of ADMA. It also requires Grifols to provide notification prior to any future acquisition of ownership interest in ADMA or any of the other divested plasma collection center assets.

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 the Order to Maintain Assets, or to modify their terms in any way.