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-
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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

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 AoA oi on ADMAso r