definition of "qualified residential mortgages," which would not be subject to the rule's requirements.

- **Proposed Rules Regarding Remittance Transfers**

Members will discuss the Board's proposed rule under Regulation E (Electronic Fund Transfer Act) that would create new disclosures and protections for consumers who send remittance transfers to recipients in foreign countries.

Reports by committees and other matters initiated by Council members also may be discussed.

Persons wishing to submit views to the Council on any of the above topics may do so by sending written statements to Jennifer Kerslake, Secretary of the Consumer Advisory Council, Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, Washington, DC 20551. Information about this meeting may be obtained from Ms. Kerslake at 202–452–6470.

Board of Governors of the Federal Reserve System, June 3, 2011.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 2011–14065 Filed 6–7–11; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

[File No. 101 0153]

Grifols, S.A. and Talecris Biotherapeutics Holdings Corp.; Analysis of Agreement Containing Consent Orders to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before July 1, 2011.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "Grisfols-Talecris, File No. 101 0153" on your comment, and file your comment online at *https://ftcpublic.commentworks.com/ftc/grifols-talecris,* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex D), 600 Pennsylvania Avenue, NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Jeffrey Perry (202–326–2331), FTC, Bureau of Competition, 600 Pennsylvania Avenue, NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 the Commission Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for June 1, 2011), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.* A paper copy can be obtained from the FTC Public Reference Room, Room 130–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326–2222.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before June 10, 2011. Write "Grifols-Talecris, File No. 101 0153" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential," as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/grifols-talecris* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write "Grifols-Talecris, File No. 101 0151" on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex D), 600 Pennsylvania Avenue, NW., Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c), 16 CFR 4.9(c).

appropriate. The Commission will consider all timely and responsive public comments that it receives on or before July 1, 2011. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

Analysis of Agreement Containing Consent Order to Aid Public Comment

I. Introduction

The Federal Trade Commission ("Commission") has accepted from Grifols, S.A. ("Grifols") and Talecris Biotherapeutics Holdings Corp. ("Talecris"), subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") and Decision and Order, and has issued a Complaint and the Order to Maintain Assets ("OMA") contained in the Consent Agreement. The Consent Agreement is designed to remedy the anticompetitive effects resulting from Grifols' proposed acquisition of Talecris (the "Acquisition"). Under the Consent Agreement, Grifols will: (i) Divest the fractionation facility currently owned by Talecris in Melville, New York, to Kedrion S.p.A. ("Kedrion"); (ii) divest plasma collection centers to Kedrion; (iii) divest to Kedrion Talecris' Koate DVI plasma-derived Factor VIII ("pdFVIII") business, including the Koate brand name, in the United States; and (iv) for a seven-year period, manufacture immune globulin ("Ig"), albumin, and Koate for Kedrion to sell in the United States.

The proposed Consent Agreement has been placed on the public record for 30 days to solicit 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 proposed Consent Agreement and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make it final.

On June 6, 2010, Grifols entered into an agreement to acquire Talecris for approximately $3.4 billion in cash and stock. The Commission's Complaint alleges that the Acquisition violates Section 5 of the FTC Act, as amended, 15 U.S.C. 45, and if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the FTC Act by lessening competition in the U.S. markets for Ig, albumin, and pdFVIII (the "Relevant Products").

II. The Parties

Grifols is a public company, headquartered in Barcelona, Spain. Its bioscience division develops and manufactures human blood plasma-derived products with manufacturing facilities in Barcelona and Los Angeles, California. Grifols entered the U.S. market in 2002, when it acquired the assets of a U.S. manufacturer, Alpha Therapeutics Corporation, and 42 plasma collection centers from SeraCare. Since then, Grifols has acquired additional plasma centers and is now vertically integrated, making it the second largest plasma collector in the world. Grifols employs approximately 6,000 people worldwide and had global 2009 revenues of $1.3 billion.

Talecris is also a public company—owned in part by the private investment firm Cerberus Capital Management, L.P. ("Cerberus")—that specializes in the development, manufacture, and worldwide sale of human blood plasma-derived products. Talecris began its U.S. operations in 2005, when Cerberus acquired Bayer AG's global plasma business and Precision Pharma in the same year. Talecris is headquartered in Research Triangle Park, North Carolina, with additional regional headquarters in Canada and Germany. Like Grifols, Talecris is a vertically integrated company, owning numerous plasma collection centers, as well as manufacturing facilities in Clayton, North Carolina, and Melville, New York. It employs approximately 5,000 people worldwide and had global 2009 revenues of approximately $1.5 billion.

III. Market Structure and Relevant Products

A. Relevant Geographic Market

The relevant geographic market in which to analyze the Acquisition's effects is the United States. Plasma-derived products must be FDA-approved for sale in the United States, which 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. Thus, plasma products not approved for sale in the United States do not provide viable competitive alternatives for U.S. consumers in the face of an increase in price for U.S. products.

B. Relevant Product Markets

i. Ig

Ig is a plasma protein replacement therapy largely used to treat immune deficient patients. The relevant product market for Ig includes all brands, concentrations (*i.e.,* 5% and 10%), formulations (*i.e.,* liquid and lyophilized/powder), and means of administration (*i.e.,* intravenous and subcutaneous). Because intravenous Ig ("IVIG") accounts for the overwhelming majority of Ig sales in the United States, industry participants often refer to the Ig market as the IVIG market. Although IVIG is available in two concentrations (5% and 10%), they are therapeutically equivalent. The main difference is one of convenience: A 10% IVIG requires less volume, meaning treatment typically takes less time. Ig has numerous FDA-approved indications (*e.g.,* primary immunodeficiencies and Chronic Inflammatory Demyelinating Polyneuropathy), and there is a significant amount of off-label use.

Hospitals, physicians, and patients would not switch, and historically have not switched, from Ig products to non-Ig products in response to a small but significant and non-transitory increase in price ("SSNIP"). Although Ig products differ somewhat (*e.g.,* based on sucrose levels, immunoglobulin A content, or concentration), ample evidence demonstrates that the brands and products are largely interchangeable. Grifols and Talecris account for approximately 8.4% and 22.8% of the U.S. Ig market, respectively, and their merger would leave three manufacturers with nearly 100% of current U.S. Ig sales.

ii. Albumin

Physicians use albumin to expand blood volume, prime heart valves during cardiac surgery, treat burn victims, and replace proteins in treating liver failure. In the United States, the parties compete in the sale of two different albumin concentrations: 5% and 25% liquid. The 5% and 25% concentrations have different clinical uses, but if a 5% product is unavailable, hospitals can dilute a 25% product to a 5% concentration if necessary. On the manufacturing side, there are no significant costs associated with shifting production between 5% and 25% albumin, and manufacturers can make such changes in a matter of days. Because competitive conditions—including the number and identity of suppliers—for 5% and 25% albumin solutions are the same, it is appropriate to analyze albumin as a single market comprising both 5% and 25% products.

In most circumstances where it is used, albumin has no viable substitutes. While starches and salines can act as volume expanders like 5% albumin, those non-albumin products cannot substitute for albumin in the great majority of uses and do not meaningfully constrain albumin prices and, hence, are not included in the relevant product market. Even for those

few indications for which there might be a potential alternative therapy, hospitals generally prefer albumin and would not switch from albumin to another product in response to a SSNIP. Grifols and Talecris have U.S. albumin market shares of approximately 13% each, and the Acquisition would leave only four meaningful competitors in that market.

iii. pdFVIII

Physicians use pdFVIII to treat bleeding disorders, namely Hemophilia A and von Willebrand Disease ("VWD"). While both pdFVIII and its non-plasma counterpart, recombinant Factor VIII ("rFVIII"), can be used to treat Hemophilia A, rFVIII and pdFVIII have limited interchangeability and, hence, limited ability to constrain each other's prices. For instance, although rFVIII is the standard of care for previously untreated patients with Hemophilia A (due to the perception that pdFVIII carries an increased risk of viral transmission), evidence suggests that patients using rFVIII are more likely to develop inhibitors—antibodies that impede the treatment's effectiveness. Thus, for some Hemophilia A patients, pdFVIII is the only viable treatment. Likewise, patients with severe VWD are treated with pdFVIII products containing von Willebrand Factor ("VWF"). No recombinant products contain VWF, so those patients also may have no choice but to use pdFVIII.

Clinical considerations, not price, determine whether a particular patient is given pdFVIII or rFVIII, and hospitals would not switch from pdFVIII to rFVIII in response to an increase in the price of pdFVIII. Grifols and Talecris account for approximately 23% and 3.6% of the U.S. pdFVIII market, respectively, and their merger would leave only three meaningful competitors in that market.

IV. Industry Background and the Acquisition's Effects

A decade ago, there was robust competition in the plasma-derived products industry. After supply increases in the early 2000s led to lower prices, suppliers reduced production and plasma collection capacity and began to vertically integrate, placing plasma collection almost entirely in the control of the few remaining firms in the market. Manufacturers also engaged in horizontal consolidation, leading to an industry dominated by three large firms, including Talecris. In the years that followed that consolidation, the Ig market in particular experienced a tightening of supply and dramatic year-over-year price increases.

The relevant markets have characteristics that allow manufacturers to promote stability and rational, coordinated behavior. *Firs*t, the markets are transparent, with firms monitoring each other's collections, output, pricing, and future expansion plans. *Second,* firms have engaged in signaling to limit supply levels and maintain higher prices. *Third,* if a firm were to "break ranks" from a coordinated scheme, the other manufacturers can detect any "cheating" over the course of the long manufacturing period and inflict punishment in other geographic markets. *Fourth,* the relevant markets are characterized by highly inelastic demand, increasing the firms' incentives to coordinate because even a small change in supply can have a large effect on price.

The Acquisition would substantially lessen competition in the relevant markets. It would eliminate actual, direct, and substantial competition between Grifols and Talecris. Moreover, given that each of the relevant markets already is highly concentrated, the Acquisition would facilitate successful coordinated interaction among the few remaining meaningful competitors, leading to reduced supply and higher prices for consumers. In addition, the Acquisition increases the likelihood that consumers would experience lower levels of innovation and service in the markets for the Relevant Products.

V. Entry Conditions

Neither new entry nor expansion sufficient to deter or counteract the Acquisition's anticompetitive effects is likely to occur within two years. The barriers to entering the plasma fractionation industry are extraordinary, with costs reaching hundreds of millions of dollars. Indeed, the barriers are so immense that *de novo* entry is unrealistic in less than five years. For example, an entrant must develop a product and secure all necessary regulatory approvals, with the required clinical trials alone taking up to three years. Additionally, the time and capital investment required to build and obtain regulatory clearance for a fractionation facility are significant, taking four to eight years and costing $100 million or more. Finally, entrants must navigate a substantial body of intellectual property in the field, including trade secrets relating to purification and safety, and must incur substantial product research and development costs before bringing a product to market. Accordingly, new entry by a domestic or foreign firm would not be timely, likely, or sufficient to counteract the Acquisition's anticompetitive effects.

VI. The Consent Agreement

The proposed Consent Agreement requires Grifols to divest certain assets to Kedrion and take other actions to alleviate the Acquisition's effects. In particular, the Consent Agreement expedites the entry of an additional competitor into each of the relevant markets, making a potential industry-wide coordinated scheme more difficult, and limiting the combined firm's ability to raise prices.

Kedrion possesses the resources and ability to be an effective competitor and meaningful constraint on any potential coordination in the industry. Created in 2001, Kedrion is the seventh largest fractionator in the world. Specializing in the development, production, and distribution of plasma-derived products, Kedrion actively sells plasma-derived products in more than 30 countries. Kedrion currently sells IVIG in a number of European and other markets and has started the process for FDA approval of its own IVIG product for sale in the United States. Kedrion also expects final FDA approval to sell a new albumin product in the United States in 2011. It currently operates two plants in Italy and is nearing completion of an expansion to its manufacturing facility in Godollo, Hungary.

Under the Consent Agreement, Grifols will enter into a sale-and-leaseback agreement with Kedrion for Talecris' Melville fractionation facility. Specifically, Kedrion will acquire the Melville facility and lease it back to Grifols for three to four years to ensure continuity of operations; at the end of the lease term, Kedrion can assume Melville operations and fractionate its own plasma. Additionally, Grifols will divest to Kedrion plasma collection centers and sell Kedrion an initial supply of raw plasma, ensuring that Kedrion will have an independent and reliable source of raw plasma.

In addition, Grifols will manufacture and supply Kedrion with FDA-approved and established IVIG, albumin, and pdFVIII products. Kedrion will market and sell private-label versions of Talecris' Gamunex IVIG and Plasbumin albumin for a period of seven years. And Grifols will transfer to Kedrion all commercial agreements and rights to sell Koate pdFVIII in the U.S. market, making Kedrion the sole provider of Koate in the United States. Kedrion will also have the option to purchase the rights to manufacture Koate for sale in the United States.

Through the Consent Agreement, Kedrion will have immediate market access and the ability to supply customers with established products in

all three product markets. Kedrion's presence in the U.S. market will add incremental supply of these life-saving products while still allowing the combined firm to take full advantage of the Acquisition's expected efficiencies. In addition, Kedrion will also have the opportunity to hire Grifols and Talecris employees to facilitate its entry and ensure continuity in the manufacture and sale of its products. By eliminating many of the industry's immense barriers to entry, the Consent Agreement will facilitate Kedrion's current and future entry with its own IVIG and albumin products and position Kedrion to replace the competition lost as a result of the Acquisition.

To ensure that the Commission remains informed about the status of the proposed divestitures, the Consent Agreement also requires the parties to file periodic reports with the Commission until the divestitures are accomplished. Furthermore, the OMA requires that the parties maintain all assets scheduled to transfer to Kedrion and authorizes the Commission to appoint a monitor to oversee the various agreements between Kedrion and Grifols. Under the OMA, Grifols and Talecris must maintain the full economic viability, marketability, and competitiveness of the proposed divested business and assets. This includes, among other things, retaining all rights, title, and interest in the divested assets, maintaining operations in their regular course, and not interfering in Kedrion's hiring of designated Grifols and Talecris employees. If Grifols does not comply with the OMA or any of the Consent Agreement's other terms, the Commission may appoint a divestiture trustee to divest the assets and enter into a product manufacturing agreement with a Commission-approved acquirer.

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

By direction of the Commission, Commissioner Kovacic recused and Commissioner Brill issuing a separate concurring statement.

Donald S. Clark,

Secretary.

Concurring Statement of Commissioner Julie Brill

I concur in the Commission's decision to issue a complaint against Grifols challenging its acquisition of Talecris. I write separately to express my view that whether to resolve this matter through the proposed consent order is a close call, though I ultimately concur in that decision as well.

The vitally important plasma protein industry has seen considerable consolidation in recent years. Today, only four significant active competitors remain as to immune globulin ("Ig"), the largest product by sales at issue in this merger: Grifols, Talecris, CSL and Baxter.[1] In the meantime, prices have increased substantially. Just two years ago, when CSL tried to buy Talecris, the Commission alleged that these "price increases have been caused by the consolidation of competitors and the resulting increases in concentration."[2] The industry has operated as a tight oligopoly in the words of a 2007 Department of Health and Human Services report, carefully controlling supply, avoiding robust price competition, and engaging in signaling of future competitive moves.[3]

One outgrowth of the supply limitations and coordinated behavior described in the Commission's CSL complaint has been the difficulty safety-net providers have had in obtaining Ig under the 340B Drug Pricing Program. This Congressionally mandated program is designed to provide pharmaceuticals at reduced prices to health care providers serving indigent and other at-risk patients. All too often, however, plasma-derivative manufacturers have not made their products available at statutorily-mandated prices.[4] This subverts Congress's goal of ensuring access to life-saving pharmaceuticals and increases costs to the health care system overall.

Against this backdrop, almost any merger in this industry would merit the significant scrutiny this one has received at the FTC. Although Grifols is today one of the smaller firms in the U.S. market, with a roughly 9% share of Ig sales, it recently launched a new 10% concentration intravenous Ig product that could threaten the industry-leading products offered by Talecris, Baxter and CSL. In addition, as alleged in the Commission's current complaint, the Ig market is highly concentrated and the change in market concentration effected by this merger easily raises a presumption of enhanced market power under the antitrust agencies' 2010 Merger Guidelines.[5] Finally, as also alleged in the complaint, the risk of post-merger coordinated behavior is very real, given the history of coordination in this industry and the fact that the immediate post-merger U.S. Ig market will consist of three firms of roughly equal size. Given these and other significant facts, I strongly support issuance of the Commission's complaint.

Whether the consent order does enough to remedy competition concerns is a much closer call. On the one hand, the consent allows for the near-term introduction of product into the market from a new competitor, Kedrion. The consent should also facilitate Kedrion's entry into the U.S. market with its own Ig product in several years. On the other hand, Grifols will keep 67 of Talecris's 69 plasma collection centers, as well as its own 80 centers, while divesting two to Kedrion. In addition, the Melville, NY, manufacturing plant that Grifols is divesting to Kedrion is a smaller facility that is not currently outfitted to purify fractionated plasma into finished product. While Grifols will fractionate and purify a "Designated Amount of [finished] Product" for Kedrion for several years under the consent order, Kedrion may need to build or purchase a new facility in order to effectively compete over the longer term.[6]

In the end, given the particular facts and circumstances of this matter, I support the consent because it provides some degree of immediate, sure relief to consumers. I expect, though, that the Commission, other Federal and State agencies, and affected purchasers will closely monitor these markets, both as to future proposed consolidations and potential coordinated behavior, including behavior that may adversely impact indigent and other at-risk patients through the critical 340B program.

[FR Doc. 2011–14082 Filed 6–7–11; 8:45 am]

BILLING CODE 6750–01–P

[1] A fifth competitor, Octapharma, withdrew its Ig product from the market in September 2010 due to safety concerns. As the Commission alleges in its complaint, "its future competitive significance is uncertain."

[2] Compl. ¶ 33, *FTC* v. *CSL Ltd.*, No. 09–1000 (D.D.C., filed May 28, 2009), available at *http://www.ftc.gov/os/caselist/0810255/091110cslcerberusunsealedcmplt.pdf.*

[3] *Id.* ¶¶ 37–44.

[4] See, *e.g.,* Public Hospital Pharmacy Coalition, "Access to IVIG by Safety Net Hospitals Participating in the 340B Drug Discount Program" (Sept. 2006), available at *http://www.phpcrx.org/public/documents/pdfs/IVIG_report.pdf.*

[5] The Ig market share and HHI figures in the Commission's complaint date from 2009 and are thus conservative, as they count Octapharma as a market participant, which it currently is not.

[6] *Compare In re Polypore Int'l, Inc.,* 2010–2 Trade Cas. ¶ 77,267, 2010 FTC LEXIS 97, at *108–110 (F.T.C. 2010) (requiring divestiture of second manufacturing plant to ensure that divestiture assets constituted viable ongoing business).