

Complaint

IN THE MATTER OF

**GRIFOLS, S.A. AND TALECRIS BIOTHERAPEUTICS
HOLDINGS CORPORATION**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5(A) OF THE FEDERAL TRADE COMMISSION ACT AND SEC. 7
OF THE CLAYTON ACT

Docket No. C-4322; File No. 101 0153
Filed, May 31, 2011 — Decision, July 20, 2011

This consent order addresses the proposed \$3.4 billion acquisition by Grifols, S.A. ("Grifols"), of Talecris Biotherapeutics Holdings Corp. ("Talecris"). The complaint alleges that the acquisition, if consummated, would substantially lessen competition in the U.S. markets for Ig, albumin, and pdFVII. Ig is a protein replacement therapy largely used to treat immune deficient patients. Albumin is a plasma-derived substance used to expand blood volume, prime heart valves during cardiac surgery, treat burn patients, and replace proteins in treating liver failure. Under the consent order, Grifols is required to divest Talecris's Melville facility, plasma-derived business, and plasma collection centers, to a pre-approved buyer. Grifols is also required to toll manufacture Ig, albumin and PdFVII for the pre-approved buyer for seven years.

Participants

For the *Commission*: Katherine Ambroggi, Alexander Ansaldo, Maria DiMoscato, Karen Espaldon, Peggy Bayer Femenella, Michelle Fetterman, Ken Field, Peter Herrick, Victoria Jeffries, Albert Kim, Jeremy Morrison, Paul Nolan, Eric Rohlck, Jennifer Schwab, and Nicholas Widnell.

For the *Respondents*: William Baer, Deborah Feinstein, and Frank Liss, Arnold & Porter LLP; and Alicia Batts and Rhett Krulla, Proskauer Rose LLP.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act ("FTC Act"), and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that Respondent Grifols, S.A. ("Grifols"), a corporation subject to the jurisdiction of the Commission, has

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agreed to acquire Respondent Talecris Biotherapeutics Holdings Corp. ("Talecris"), a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent Grifols is a public company, headquartered in Barcelona, Spain. With its primary production facilities in Barcelona and Los Angeles, California, Grifols develops, manufactures, and sells human blood plasma-derived products. Grifols also owns a network of U.S. plasma collection centers to supply its production facilities. Grifols employs approximately 6,000 people worldwide and had global 2009 revenues of \$1.3 billion, roughly one-third of which came from sales in the United States.

2. Respondent Talecris is a public company – owned in part by the private investment firm Cerberus Capital Management, L.P. – that specializes in the development, manufacture, and sale of human blood plasma-derived products. Talecris is headquartered in Research Triangle Park, North Carolina, with additional regional headquarters in Canada and Germany. Talecris has production facilities in Clayton, North Carolina, and Melville, New York, and like Grifols, Talecris owns a network of U.S. plasma collection centers to supply those facilities. Talecris employs approximately 5,000 people worldwide and had global 2009 revenues of approximately \$1.5 billion, roughly two-thirds of which came from sales in the United States.

3. The plasma-derived products manufactured and sold by Respondents are life-sustaining and life-enhancing biologics indicated for, among other things, the treatment of primary immune deficiency diseases, neurological conditions, severe burns, liver failure, and blood coagulation disorders.

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II. THE ACQUISITION

4. Pursuant to an Agreement and Plan of Merger dated June 6, 2010, Grifols agreed to acquire Talecris for \$3.4 billion in cash and stock (the "Acquisition"). The Acquisition would combine two of the largest manufacturers of life-sustaining plasma-derived products.

III. JURISDICTION

5. Respondents, and each of their relevant operating subsidiaries and parent entities are, and at all relevant times have been, engaged in activities in or affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12. The Acquisition constitutes an acquisition under Section 7 of the Clayton Act.

IV. THE RELEVANT PRODUCTS

6. The relevant product markets in which to analyze the Acquisition are: (i) Ig, (ii) albumin, and (iii) plasma-derived Factor VIII ("pdFVIII").

A. Ig

7. Ig is a widely used drug that can be administered intravenously ("IVIG" or "IGIV") or subcutaneously ("SCIG"). IVIG, the more predominant form, has numerous indications approved by the U.S. Food and Drug Administration ("FDA"), and as many as 150 off-label uses. The most common uses involve the treatment of Primary Immunodeficiency Diseases and neurological conditions – *e.g.*, Guillain-Barré Syndrome and Chronic Inflammatory Demyelinating Polyneuropathy.

8. There are no substitutes for Ig for certain indications. For other indications, physicians and hospitals regard Ig as far superior to all potential substitutes.

9. Ig constitutes a relevant product market in which to analyze the Acquisition's effects.

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B. Albumin

10. Albumin is used as a blood volume expander and to prime heart valves during surgery, treat burn victims, and replace proteins in treating liver failure.

11. There are no good substitutes for albumin. Physicians and hospitals regard albumin as far superior from a clinical standpoint to any potential alternatives, such as hetastarch and saline products.

12. Albumin constitutes a relevant product market in which to analyze the Acquisition's effects.

C. Plasma-Derived Factor VIII

13. pdFVIII is an essential protein responsible for blood coagulation (*i.e.*, clotting), and products containing pdFVIII are FDA-approved to treat individuals with either Hemophilia A or von Willebrand Disease, or in some instances, both.

14. Recombinant Factor VIII ("rFVIII") is made from non-human sources and can also be used to treat Hemophilia A. Due to perceived differences in safety, rFVIII is the standard of care for previously untreated Hemophilia A patients.

15. For certain treatments, neither rFVIII nor any other product is a clinical substitute for pdFVIII. For example, rFVIII products do not contain von Willebrand Factor and therefore cannot be used to treat von Willebrand disease. Purchasers and patients would not switch from pdFVIII to rFVIII in response to a small but significant and non-transitory increase in price of pdFVIII.

16. pdFVIII constitutes a relevant product market in which to analyze the Acquisition's effects.

V. THE RELEVANT GEOGRAPHIC MARKET

17. The United States is the relevant geographic market in which to analyze the Acquisition's effects. To compete in the

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relevant product markets in the United States, a firm must establish a local sales force, service infrastructure, and reputation among purchasers.

18. Like pharmaceutical products, Ig, albumin, and pdFVIII must be FDA-approved for sale in the United States. To obtain approval, the products must be made from plasma collected in the United States at FDA-approved collection centers. These products must also be manufactured at FDA-approved facilities.

19. Performing the necessary clinical trials and navigating the FDA approval process for plasma and plasma-derived products takes well in excess of two years. Thus, Ig, albumin, and pdFVIII currently sold outside of the United States are not viable competitive alternatives for U.S. customers, who cannot and do not turn to these products even in the event of a price increase for products currently available in the United States.

VI. MARKET STRUCTURE

20. Under the 2010 Department of Justice and Federal Trade Commission Horizontal Merger Guidelines ("Merger Guidelines") and relevant case law, the Acquisition is presumptively unlawful in the Ig and albumin markets. Under the Herfindahl-Hirschman Index ("HHI"), which is the standard measure of market concentration under the Merger Guidelines, an acquisition is presumed to enhance market power if it increases the HHI by more than 200 points and results in a post-acquisition HHI that exceeds 2,500 points. The Acquisition creates market concentration levels well in excess of these thresholds for Ig and albumin.

- a. Based on 2009 sales volume, the combined firm would have approximately 31.2% of the Ig market and face meaningful competition from only two firms: Baxter International, Inc. ("Baxter") and CSL Limited ("CSL"). As of 2009, Baxter and CSL commanded approximately 35% and 25% of the Ig market, respectively, meaning the three largest suppliers would control more than 91% of the market after the Acquisition. According to 2009 sales volume, the

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Acquisition would increase the HHI in the Ig market by 383 points, from 2,518 to 2,901.

- b. In September 2010, another Ig supplier, Octapharma AG ("Octapharma"), withdrew its Ig product from the U.S. market because of concerns about serious adverse events. Before the withdrawal, Octapharma accounted for approximately 8.8% of the Ig market. Now, Octapharma is not selling any Ig in the United States, and its future competitive significance is uncertain.
- c. In addition, the Acquisition would also increase concentration in the albumin market by 333 points, from 2,743 to 3,076, leaving only four meaningful competitors.

21. Under the Merger Guidelines, acquisitions that increase the HHI by between 100 and 200 points and result in a post-acquisition HHI that exceeds 2,500 points raise potentially significant competitive concerns and often warrant scrutiny. Here, the Acquisition would increase the HHI in the pdFVIII market by 166 points, from 3,491 to 3,657, leaving only three meaningful competitors controlling nearly 100% of the market.

VII. ENTRY CONDITIONS

22. Entry into the relevant markets would not be timely, likely, or sufficient to prevent or defeat the Acquisition's likely anticompetitive effects.

23. The manufacturing process for plasma-derived products is complex and highly regulated and involves technical know-how and proprietary processes involving (i) plasma collection, (ii) plasma testing, (iii) fractionation (*i.e.*, precipitation of solids by manipulation of solution pH, temperature, etc.), (iv) finishing or purification, (v) quality control, and (vi) lot release.

24. Currently, the U.S. markets for Ig, albumin, and pdFVIII are controlled by a handful of vertically integrated manufacturers, each of which has its own plasma collection, fractionation, and purification facilities. To be successful, a new entrant must

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develop and produce a product that is at least on par with the incumbent products in terms of safety, efficacy, and reliability. A new entrant – including existing manufacturers outside the United States – also must establish a U.S. sales force, plasma supply, support, manufacturing capability, and a reputation for safety, efficacy, and reliability.

25. Building the necessary facilities and infrastructure to manufacture Ig, albumin, and pdFVIII takes years and costs tens of millions of dollars. In particular, entry into the relevant product markets *de novo* requires a massive commitment of time and resources.

VIII. INDUSTRY BACKGROUND AND THE ACQUISITION'S EFFECTS

26. Historically, the plasma-derived products industry has operated as a tight oligopoly, characterized by a high level of transparency and coordination. Absent relief, Grifols' acquisition of Talecris would eliminate a significant threat to that dynamic.

- a. A decade ago, there was robust competition in the plasma-derived products industry. After supply increases in the early 2000s led to lower prices, producers "rationalized" 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 underwent horizontal consolidation, leading to an industry dominated by three large firms – Baxter, CSL, and Talecris – and two smaller ones – Grifols and Octapharma. In the years that followed, the market saw supply shortages and dramatic year-over-year price increases.
- b. Signaling among suppliers – *i.e.*, intentional sharing of competitive information for purposes of securing accommodating reactions from other firms – allows them to gain real time insight into each other's strategies and plans. Sensitive competitive information is widely available from a vast array of reports, market

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analyses, discussions with downstream purchasers, and the suppliers themselves, as firms collect and catalog an extraordinary wealth of timely "competitive intelligence."

- c. The industry's primary trade group, the Plasma Protein Therapeutics Association ("PPTA"), facilitates this free exchange of competitive intelligence. The PPTA regularly publicizes aggregated plasma collection, inventory, and throughput data for IVIG, albumin, and pdFVIII, among other products.
- d. Manufacturers routinely use PPTA data and other competitive intelligence to calibrate their own collections, output, and pricing decisions and avoid "irrational" behavior, such as oversupplying the market or starting a price war. When this information is combined with the long production cycle for plasma-derived products, suppliers have little opportunity to "cheat" by increasing output, without being detected and potentially punished by other suppliers well in advance of realizing any benefits from such cheating.

27. The Acquisition would substantially lessen competition in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. eliminating actual, direct, and substantial competition between Respondents for the sale of Ig, albumin, and pdFVIII in the United States;
- b. enabling the combined firm and other firms selling Ig, albumin, and pdFVIII to engage more successfully and completely in coordinated interaction that harms consumers;
- c. increasing the likelihood that U.S. consumers would be forced to pay higher prices for Ig, albumin, and pdFVIII; and

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- d. increasing the likelihood that consumers would experience lower levels of innovation and service in the U.S. markets for Ig, albumin, and pdFVIII.

IX. VIOLATIONS CHARGED

28. The allegations of Paragraphs 1 through 27 above are incorporated by reference as though fully set forth here.

29. The Acquisition constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

30. The Acquisition, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this Complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C., this thirty-first day of May, 2011.

By the Commission, Commissioner Kovacic recused.

DECISION AND ORDER

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition of Talecris Biotherapeutics Holdings Corp. ("Respondent Talecris") by Grifols, S.A. ("Respondent Grifols"), and Respondent Grifols and Respondent Talecris having been furnished thereafter with a copy of a draft Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent Grifols and Respondent Talecris with violations of Section 7 of the Clayton

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Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent Grifols and Respondent Talecris, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondent Grifols and Respondent Talecris of all the jurisdictional facts set forth in the aforesaid draft Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent Grifols and Respondent Talecris that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent Grifols and Respondent Talecris have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order").

1. Respondent Grifols is a corporation organized, existing and doing business under and by virtue of the laws of Spain with its office and principal place of business at Avinguda de la Generalitat, 152, Parque empresarial Can Sant Joan, 08174 Sant Cugat del Valles, Barcelona, Spain, and with its office and principal place of business in the United States located at 2410 Lillyvale Avenue, Los Angeles, CA 90032.
2. Respondent Talecris is a corporation organized, existing and doing business under and by virtue of the

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laws of Delaware, with its office and principal place of business located at 4101 Research Commons, 79 T.W. Alexander Drive, Research Triangle Park, North Carolina 27709.

3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. "Grifols" means Grifols, S.A., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Grifols, S.A. (including Talecris, after the Acquisition Date), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. "Talecris" means Talecris Biotherapeutics Holdings Corp. its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Talecris Biotherapeutics Holdings Corporation, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. "Commission" means the Federal Trade Commission.
- D. "Acquisition" means Respondent Grifols' acquisition of Talecris.
- E. "Acquisition Date" means the date on which the Acquisition is consummated.

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- F. "Acquirer" means the Person specified by name in this Order, or the Person approved by the Commission, to acquire the Divested Business pursuant to Paragraph II or Paragraph VI of this Order.
- G. "Branded Supply Date" means the date that is one hundred twenty (120) days after the Acquisition Date.
- H. "Confidential Business Information" means competitively sensitive, proprietary, and all other information, solely Relating To the Divested Business, that is not in the public domain, owned by or pertaining to a Person or a Person's business, and includes, but is not limited to, all customer lists, price lists, contracts, cost information, marketing methods, technologies, processes, or other trade secrets.
- I. "Contract Manufacturing Agreement" means the agreement that has been approved by the Commission and become a part of the Divestiture Agreement, under which Respondent Grifols and Kedrion have agreed to, among other things, various terms regarding the Manufacturing of Products by Respondent Grifols and the sale of Products by Kedrion.
- J. "Designated Amount of Products" means the confidential amount of liter equivalent Products included in Confidential Exhibit A to this Order.
- K. "Designated Employee" means the named employee, or person filling a particular job description, listed in Confidential Exhibit B to this Order.
- L. "Designated Melville Employee" means the named employee, or person filling a particular job description, listed in Confidential Exhibit B-1 to this Order.
- M. "Development" means all research and development activities, including, without limitation, the following: test method development; stability testing; process development; manufacturing scale-up;

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development-stage manufacturing; quality assurance/quality control development; statistical analysis and report writing; and conducting experiments for the purpose of obtaining any and all product approvals or certifications. "Develop" means to engage in Development.

- N. "Divested Business" means:
1. The Melville Facility;
 2. The Grifols Plasma Centers;
 3. Grifols Plasma;
 4. The Contract Manufacturing Agreement; and
 5. All assets, tangible and intangible, property, facilities, equipment, contracts, and all other requirements necessary to fulfill Grifols' obligations under the Contract Manufacturing Agreement, the Product Agreement, and the Divestiture Agreement.
- O. "Divestiture Agreement" means all the divestiture agreements, licenses, assignments, and other agreements entered into by Respondent Grifols and Kedrion for the sale of the Melville Facility, the Grifols Plasma Centers, Grifols Plasma, the Products Supply Agreements, and all other agreements, leases, transfers, and licenses required by this Order. The Divestiture Agreement is attached as Confidential Exhibit C to this Order.
- P. "Effective Date" means the date on which the divestitures, licensing, and assignments pursuant to Paragraph II or Paragraph VI of this Order, are consummated.
- Q. "FDA Approval Date" means the date on which the FDA grants all approvals necessary for Kedrion to market and sell Private Label Albumin Product and

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Private Label IVIG Product. In the event the FDA approves the marketing and sale by Kedrion of one of the two products before the other, the FDA Approval Date shall be the latter of those two approval dates.

- R. "Grifols Plasma" means normal source plasma, approved by the U.S. Food & Drug Administration ("FDA"), supplied by Grifols, which meets the specifications set forth in Exhibit B to the Contract Manufacturing Agreement.
- S. "Grifols Plasma Centers" means the plasma collection facilities owned and operated by Respondent Grifols at the locations identified in Exhibit D to this Order.
- T. "Kedrion" means Kedrion S.p.A. a corporation organized, existing and doing business under and by virtue of the laws of Italy with its international headquarters located at Loc. Ai Conti, 55051 Castelrechhio Pascoli, Barga (Lucca), Italy and its principal place of business in the United States located at Parker Plaza, 40 Kelby Street, Fort Lee, NJ 07024.
- U. "Manufacture" or "Manufactured" means some or all of the fractionation, purification, formulation, filling, packaging, inspecting, validating and testing of Products, and does not include the commercialization activities including, but not limited to, pricing and price-reporting, sales, marketing, and/or distribution.
- V. "Melville Facility" means the facility owned and operated by Talecris at 155 Duryea Road, Melville, New York 11747, and all machinery, fixtures, equipment, vehicles, transportation and storage facilities, furniture, tools, supplies, stores, spare parts, and other tangible property located at or Relating To that facility.
- W. "Melville Lease Agreement" means any agreement between Respondent Grifols and Kedrion for the lease of the Melville Facility.

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- X. "Melville Lease Termination Date" means the date on which Respondent Grifols terminates its lease of the Melville Facility from Kedrion pursuant to the Melville Lease Agreement.
- Y. "Patents" means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case existing as of the Acquisition Date, and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, Related To any product of or owned by Respondent Grifols as of the Acquisition Date.
- Z. "Person" means any natural person, partnership, corporation, association, trust, joint venture, government, government agency, division, or department, or other business or legal entity.
- AA. "Plasma Sales Agreement" means an agreement between Grifols and Kedrion under which Grifols will sell blood plasma to Kedrion.
- BB. "Products" means:
 - 1. Private Label IVIG Product, Koate, or Private Label Albumin Product, in each case that is intended for human use, Manufactured by Grifols, pursuant to instructions by Kedrion and under the terms and conditions of the Contract Manufacturing Agreement; and
 - 2. Fraction V Paste or Cryoprecipitate, derived from plasma, Manufactured by Grifols for Kedrion pursuant to the Contract Manufacturing

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Agreement, and delivered as intermediates to Kedrion by Grifols.

- CC. "Relating To" or "Related To" means pertaining in any way to, and is not limited to that which pertains exclusively to or primarily to.
- DD. "Remedial Agreement" means the following:
1. the Divestiture Agreement if such agreement has not been rejected by the Commission pursuant to Paragraph II of this Order; and
 2. any agreement between Respondent Grifols and a Commission-approved Acquirer (or between a Divestiture Trustee and a Commission-approved Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets to be granted, licensed, delivered or otherwise conveyed, that have been approved by the Commission to accomplish the requirements of this Order.
- EE. "Third Party(ies)" means any Person other than Respondent Grifols, Talecris, Kedrion, or the Acquirer.
- FF. "Trade Dress" means the current trade dress of a particular product or Person including, without limitation, product packaging, logos, and the lettering of the product trade name, brand name, or corporate name.
- GG. "Trademark(s)" means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common

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law rights, and the goodwill symbolized thereby and associated therewith, for Koate.

[Albumin Definitions]

- HH. "Albumin Manufacturing Agreement" means an agreement between Kedrion and Respondent Grifols, that has been approved by the Commission and become a part of the Divestiture Agreement, under which Respondent Grifols will provide Private Label Albumin Product and Fraction V for Kedrion.
- II. "Albumin Product" means an albumin factor derived from human blood plasma and used, among other things, as a blood volume expander.
- JJ. "Designated Amount of Talecris Albumin Product" means the minimum amount of Talecris Albumin Product to be produced by Respondent Grifols during the Contract Manufacturing Agreement and made available for sale by Kedrion, attached in Confidential Exhibit E-1.
- KK. "Fraction V" means plasma protein factor that predominantly contains albumin.
- LL. "Fraction V Paste" means a plasma intermediate used in the Manufacture of Albumin Product.
- MM. "Plasbumin" means branded Talecris Albumin Product and includes Plasbumin®-5, Albumin (Human) 5%, USP (PDF); Plasbumin®-20, Albumin (Human) 20%, USP (PDF); and Plasbumin®-25, Albumin (Human) 25%, USP (PDF).
- NN. "Private Label Albumin Product" means an Albumin Product identical to, and manufactured according to the FDA-approved process used in the production of, the Talecris Albumin Product.

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- OO. "Talecris Albumin Customer Contracts" means contracts between Talecris and Third Parties, including group purchasing organizations and hospitals, for the sale and purchase of, at a minimum, the Designated Amount of Talecris Albumin Product, including but not limited to, the contracts identified in Confidential Exhibit E.
- PP. "Talecris Albumin Product" means the Albumin Product Developed, manufactured and sold by Talecris in the United States under the brand name Plasbumin.

[IVIG Definitions]

- QQ. "IVIG Product" means an intravenous immune globulin derived from human blood plasma.
- RR. "Designated Amount of Talecris IVIG Product" means minimum amount of Talecris IVIG Product to be produced by Respondent Grifols during the Contract Manufacturing Agreement and made available for sale by Kedrion, and designated in Confidential Exhibit F-1.
- SS. "Gamunex" means branded Talecris IVIG Product.
- TT. "Private Label IVIG Product" means intravenous immune globulin derived from human blood plasma identical to, and manufactured according to the FDA-approved process used in the production of, the Talecris IVIG Product.
- UU. "Talecris IVIG Customer Contracts" means contracts between Talecris and Third Parties, including group purchasing organizations and hospitals, for the sale and purchase of at least the Designated Amount of Talecris IVIG Product including, but not limited to, the contracts identified in Confidential Exhibit F.

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- VV. "Talecris IVIG Product" means the IVIG Product Developed, manufactured and sold by Talecris in the United States under the brand name Gamunex.

[Koate Definitions]

- WW. "Cryoprecipitate" means a product derived from fresh frozen plasma containing coagulation factors.
- XX. "Factor VIII Product" means an antihemophilic factor derived from Cryoprecipitate used in the treatment of, among other things, hemophilia A.
- YY. "Koate" means the Factor VIII Product sold under the Talecris registered brand name Koate.
- ZZ. "Koate Option, License and Sale Agreement" means the agreement between Respondent Grifols and Kedrion granting to Kedrion, among other things, the exclusive rights to sell branded Koate in the United States and the option to acquire non-exclusive rights to manufacture branded Koate in the United States, Italy, and Hungary.
- AAA. "Koate Customer Contracts" means all contracts between Talecris and a third party for the purchase and sale of Koate in the United States including, but not limited to, the contracts identified in Confidential Exhibit G.
- BBB. "Koate Intellectual Property" means all of the following Related To Koate:
1. all Talecris intellectual property used in the Development, manufacturing, storage, distribution and sale of Koate including, but not limited to:
 - a. Koate Manufacturing Copyrights;
 - b. Software;

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- c. computer programs;
 - d. Patents including, but not limited to, the right to obtain and file for Patents and Koate Sales and Manufacturing Copyrights, and registrations thereof;
 - e. licenses including, but not limited to, licenses to third-party Software if transferable and sub-licenses to Software modified by Respondent Talecris;
 - f. know-how (including, but not limited to, flow sheets, process and instrumentation), diagrams, risk analysis, certificates of analysis, goodwill, technology (including, but not limited to, equipment specifications), drawings, utility models, designs, design rights, techniques, data, inventions, practices, recipes, raw material specifications, process descriptions;
 - g. technical information (including, but not limited to, material and final product specifications);
 - h. protocols (including, but not limited to, operational manuals);
 - i. quality control information and methods, and other confidential or proprietary technical, business, Development and other information;
 - j. trade secrets; and
 - k. all rights to limit the use or disclosure thereof trade names, service marks, logos, and the modifications or improvements to such intellectual property; and
2. rights to sue and recover damages or obtain injunctive relief for infringement, dilution,

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misappropriation, violation or breach of any of the foregoing.

- CCC. "Koate Manufacturing Copyrights" means copyrights in all process development data and reports Relating To the research and development of Koate, or of any materials used in the research, Development, manufacture, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks Relating To Koate; all copyrights in analytical and quality control data; and all correspondence with governmental agencies.
- DDD. "Koate Sales Copyrights" means rights to all original works of authorship of any kind directly Related To the sale of Koate in the United States, and any registrations and applications for registrations thereof, including, but not limited to, the following: all such rights with respect to all promotional, marketing, sales, and advertising materials, educational and training materials for the sales force, and sales forecasting models; marketing or sale of Koate including copyrights in all raw data, statistical programs developed (or modified in a manner material to the use or function thereof (other than through user preferences)) to analyze research data, market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information; all copyrights in records, including customer lists, sales force call activity reports, vendor lists, and sales data.

II.

IT IS FURTHER ORDERED that:

- A. Within ten (10) days of the Acquisition Date, Respondent Grifols shall divest the Melville Facility, the Grifols Plasma Centers, and Grifols Plasma, enter into the Contract Manufacturing Agreement, the Product Agreement, the Koate Option, License and

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Sale Agreement, assign or extend rights and obligations under the Koate Customer Contracts, the Talecris Albumin Customer Contracts, and the Talecris IVIG Customer Contracts, absolutely and in good faith, to Kedrion, pursuant to, and in accordance with, the Divestiture Agreement. The Divestiture Agreement (which shall include, among other things, the sale and purchase agreements for the Melville Facility, the Grifols Plasma Centers, and Grifols Plasma, the assignments, licenses, supply agreements, and all other agreements between Respondent Grifols and Kedrion) between Respondent Grifols and Kedrion shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Kedrion, or to reduce any obligations of Respondent Grifols under such agreements, and such agreements, if approved by the Commission, shall be incorporated by reference into this Order and made a part hereof.

Provided, however, that Respondent Grifols shall be allowed, pursuant to the Divestiture Agreement, to enter into a Melville Facility Lease Agreement with Kedrion under which, for a period of no more than four (4) years from the Acquisition Date, Respondent Grifols will lease back the Melville Facility from Kedrion. Such agreement, if approved by the Commission, shall be a part of the Divestiture Agreement and incorporated into this Order and made a part hereof.

Provided, however, if, at the time the Commission determines to make this Order final, the Commission notifies Respondent Grifols that Kedrion is not an acceptable Acquirer then, after receipt of such written notification: (1) Respondent Grifols shall immediately notify Kedrion of the notice received from the Commission and shall as soon as practicable effect the rescission of the Divestiture Agreement; and (2) Respondent Grifols shall, within one-hundred-fifty

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(150) days from the date this Order becomes final, divest the Divested Business, enter into manufacturing and distribution agreements, assign or extend rights and obligations under customer contracts, and divest any other assets or enter into any other relief required to satisfy the purposes of this Order, absolutely and in good faith, at no minimum price, to or with an Acquirer, that receives the prior approval of the Commission, and in a manner that receives the prior approval of the Commission;

Provided further, however, that if Respondent Grifols has complied with the terms of Paragraphs II.A., II.B., and II.C. before the date on which this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent Grifols that the manner in which the divestiture and assignments were accomplished is not acceptable, the Commission may direct Respondent Grifols, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture and assignments including, but not limited to, entering into additional agreements or arrangements, as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Prior to the Effective Date, Respondent Grifols shall secure all consents and waivers from all Third Parties, other than the FDA, including customers whose contracts are being assigned or extended to Kedrion pursuant to Paragraph II.A., that are necessary to permit Kedrion to sell Private Label Albumin Product, Private Label IVIG Product, and Koate.

Provided, however, Respondent may satisfy this requirement by certifying that the Acquirer has executed all such agreements directly with each of the relevant Third Parties.

- C. Respondent Grifols shall Manufacture the Designated Amount of Products, as set forth in Confidential

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Exhibits A, E-1, and F-1, annually for Kedrion to market and sell such Products, and Kedrion will take or pay for such Designated Amount of Products Manufactured by Grifols for seven (7) years beginning the day after the FDA Approval Date or the Effective Date, whichever date is later;

Provided, however, that in the event Kedrion is not approved by the FDA to market and sell Private Label Albumin Product or Private Label IVIG Product by the Branded Supply Date, then, for purposes of Paragraph II.C., Respondent Grifols shall: (1) Manufacture Plasbumin and Gamunex for Kedrion; (2) supply Kedrion with sufficient inventory of Plasbumin and Gamunex so it can begin supplying customers with Plasbumin and Gamunex no later than three days after the Branded Supply Date, and (3) continue to supply Kedrion with Plasbumin and Gamunex so it can market and sell in the amounts set forth in Confidential Exhibits A, E-1, and F-1 of this Order.

Provided further, however, that in the event Respondent Grifols is required to supply Kedrion with Plasbumin and Gamunex, the requirements of Paragraph II.C. shall begin no later than the Branded Supply Date, and continue until the earlier of (a) the FDA Approval Date, or (b) seven (7) years after the Branded Supply Date. In the event the Branded Supply Date occurs before the Effective Date, then, for purposes of section (b) of this proviso, it shall be seven (7) years after the Effective Date. If FDA Approval is granted for Kedrion to market and sell the Private Label Albumin Product or the Private Label IVIG Product, then Respondent Grifols shall begin supplying Kedrion those private label products pursuant to Paragraph II.C. in place of Plasbumin or Gamunex, respectively.

Provided further, however, that in no event shall the seven (7) year obligations of Paragraph II.C. extend

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longer than seven (7) years after the Branded Supply Date or the Effective Date, whichever is later.

Provided further, however, that respondent grifols and respondent talecris, with assistance from the monitor, shall use all reasonable efforts to expedite all fda approvals necessary for kedrion to market and sell private label albumin product and private label ivig product.

- D. Respondent Grifols shall divest or otherwise transfer to Kedrion:
1. The exclusive right to sell Koate in the United States;
 2. The exclusive rights to the use of all Trade Dress, brand names, Trademarks, and Koate Sales Copyrights Relating To Koate in the United States, including the exclusive rights to use the brand name Koate and its derivatives in the United States;
 3. All sales and promotional materials used in the United States for the sale of Koate in the United States;
 4. At Kedrion's option and within five (5) years of the Acquisition Date, a non-exclusive license to Koate Intellectual Property for use in Koate at a price agreed to in the Divestiture Agreement;
 5. The right to sell the Private Label Albumin Product, or Plasbumin, if required pursuant to the Order, in the United States;
 6. The right to rebrand and use all current Talecris marketing materials Relating To Talecris Albumin Product;

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7. The right to sell the Private Label IVIG Product, or Gamunex, if required pursuant to the Order, in the United States; and
 8. The right to rebrand and use all current Talecris marketing materials Relating To the Talecris IVIG Product.
- E. Respondent Grifols shall include, as part of the Divestiture Agreement, any service agreement in which Respondent Grifols contemplates providing services or assistance it will provide Kedrion for the duration of the period described in Paragraph II.C., including scope of services, term, prices, and personnel involved.
- F. Any Remedial Agreement that has been approved by the Commission between Respondent Grifols (or a Divestiture Trustee) and a Commission-approved Acquirer shall be deemed incorporated into this Order, and any failure by Respondent Grifols to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- G. Respondent Grifols shall not terminate any agreement that is part of the Divestiture Agreement before the end of the term approved by the Commission without:
1. the written agreement of Kedrion or the Acquirer and thirty (30) days prior notice to the Commission; or,
 2. in the case of a proposed unilateral termination by Respondent Grifols due to an alleged breach of an agreement by the Kedrion or the Acquirer, sixty (60) days notice of such termination. *Provided, however,* such sixty (60) days notice shall be given only after the parties have:
 - a. attempted to settle the dispute between themselves, and

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- b. either engaged in arbitration and received an arbitrator's decision, or received a final court decision after all appeals.
- H. The purposes of this Paragraph II of the Order are: (1) to ensure that the Acquirer will have the intention and ability to produce and sell Koate, Private Label Albumin Product, and Private Label IVIG Product independently of Respondent Grifols; (2) to ensure continued sales and distribution of Koate until such time as the Acquirer has the ability to produce a Factor VIII Product at its own facilities; (3) to ensure that the Acquirer has the ability to sell and distribute Private Label Albumin Product and Private Label IVIG Product until such time as the Acquirer has the ability to produce an Albumin Product and an IVIG Product at its own facilities; and (4) to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

III.**IT IS FURTHER ORDERED** that:

- A. Except in the course of performing its obligations under the Divestiture Agreement or as expressly allowed pursuant to this Order, Respondent Grifols and Respondent Talecris shall not
 - 1. Interfere with any suppliers, distributors, resellers, or customers of the Persons who will acquire or have acquired the Divested Business;
 - 2. Interfere with any contracts that will be divested, have been divested, will be assigned or extended to the Acquirer, or have been assigned or extended to the Acquirer pursuant to this Order; or
 - 3. Interfere in any other way with the Persons who will acquire or have acquired the Divested

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Business pursuant to this Order or with the businesses that will be divested or have been divested pursuant to this Order.

Provided however, that unless otherwise prohibited by the Order as part of contract assignments, nothing in this Paragraph III.A. shall prevent Respondent Grifols from competing for contracts or for the trade of suppliers, distributors, resellers, or customers.

- B. During the time period before the Effective Date and before the Designated Employees are hired pursuant to Paragraph VII , Respondent Grifols and Respondent Talecris shall:
1. take such actions as are necessary to maintain the full economic viability, marketability and competitiveness of the Divested Business to minimize any risk of loss of competitive potential for the Divested Business, and to prevent the destruction, removal, wasting, deterioration, or impairment of the Divested Business, except for ordinary wear and tear. Respondent Grifols and Respondent Talecris shall not sell, transfer, encumber or otherwise impair the Divested Business (other than in the manner prescribed in this Order), nor take any action that lessens the full economic viability, marketability or competitiveness of the Divested Business. Respondent Talecris shall take all actions reasonably necessary to protect its Trademarks and trade dress to be transferred to Kedrion from Third Party complaints or challenges.
 2. retain all of Respondent Grifols' and Respondent Talecris' rights, title, and interest in the Divested Business;
 3. maintain the operations of the Divested Business in the regular and ordinary course of business and in accordance with past practice (including regular

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repair and maintenance of the assets, as necessary) and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Divested Business and shall use its best efforts to preserve the existing relationships with the following: suppliers, vendors, distributors, customers, governmental agencies, employees, and others having business relations with the Divested Business.

4. maintain a work force as large as, and with equivalent or better training and expertise to, what has been associated with the Divested Business as of the Acquisition Date.
 5. provide Designated Employees with reasonable financial incentives to continue in their positions and to Develop, and manufacture the Divested Products consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Divested Products pending divestiture. Such incentives shall include a continuation of all employee benefits offered by Respondent Grifols and Respondent Talecris until the Effective Date has occurred, including regularly scheduled raises, bonuses, vesting of pension benefits (as permitted by law), and additional incentives as may be necessary to prevent any diminution of the competitiveness of the Divested Business.
- C. During the time period before the Melville Lease Termination Date, Respondent Grifols and Respondent Talecris shall provide Designated Melville Employees with reasonable financial incentives to continue in their positions. Such incentives shall include a continuation of all employee benefits offered by Respondent Grifols and Respondent Talecris until the Melville Lease Termination Date has occurred, including regularly scheduled raises, bonuses, vesting of pension benefits (as permitted by law), and

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additional incentives as may be necessary to prevent any diminution of the competitiveness of the Melville Facility.

- D. The purpose of this Paragraph III is to maintain the full economic viability, marketability and competitiveness of the Divested Business until the Effective Date, to minimize any risk of loss of competitive potential for the Divested Business, and to prevent the destruction, removal, wasting, deterioration, or impairment of the Divested Business, except for ordinary wear and tear.

IV.**IT IS FURTHER ORDERED** that:

- A. Except in the course of performing its obligations under the Divestiture Agreement, or as expressly allowed pursuant to this Order:
1. Respondent Grifols shall not provide, disclose or otherwise make available any Confidential Business Information, including the terms of the Divestiture Agreement, to any Person; and
 2. Respondent Grifols shall not use any Confidential Business Information, including the terms of the Divestiture Agreement, for any reason or purpose. Among other things, Respondent Grifols shall not use such Confidential Business Information:
 - a. to assist or inform Respondent Grifols employees who Develop, manufacture, solicit for sale, sell, or service Respondent Grifols products that compete with the products divested, sold, or distributed pursuant to this Order;
 - b. to interfere with any suppliers, distributors, resellers, or customers of the Persons who acquired the divested businesses;

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- c. to interfere with any contracts divested, assigned, or extended to the Acquirer pursuant to this Order; or
 - d. to interfere in any other way with the Persons who acquired the divested businesses pursuant to this Order or with the businesses divested pursuant to this Order.
- B. The requirements of this Paragraph IV do not apply to Confidential Business Information that Respondent Grifols demonstrates to the satisfaction of the Commission, in its sole discretion:
 - 1. was or becomes generally available to the public other than as a result of a disclosure by Respondent Grifols;
 - 2. is necessary to be included in mandatory regulatory filings; *provided, however*, that Respondent Grifols shall make all reasonable efforts to maintain the confidentiality of such information in the regulatory filings;
 - 3. was available, or becomes available, to Respondent Grifols on a non-confidential basis, but only if, to the knowledge of Respondent Grifols, the source of such information is not in breach of a contractual, legal, fiduciary, or other obligation to maintain the confidentiality of the information;
 - 4. is consented to by the Acquirer;
 - 5. is necessary information exchanged in the course of consummating the Acquisition;
 - 6. is disclosed in complying with this Order;
 - 7. is information the disclosure of which is necessary to allow Respondents to comply with the

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requirements and obligations of the laws of the United States and other countries;

8. is disclosed in defending legal claims, investigations or enforcement actions threatened or brought against Respondents or the Divested Business; or
9. is disclosed in obtaining legal advice.

V.**IT IS FURTHER ORDERED** that:

- A. Mr. R. Owen Richards, President of Quantic Regulatory Services, LLC, shall serve as the Monitor pursuant to the agreement executed by the Monitor and Respondent Grifols and attached as Exhibit H ("Monitor Agreement") and Confidential Exhibit H-1 (Monitor Compensation). The Monitor is appointed to assure that Respondent Grifols expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order.
- B. The Monitor Agreement shall require that, no later than one (1) day after the Acquisition Date, Respondent Grifols transfers to the Monitor all rights, powers, and authorities necessary to permit the Monitor to perform his duties and responsibilities, pursuant to this Order and the Asset Maintenance Order, and consistent with the purposes of this Order.
- C. No later than one (1) day after the Acquisition Date, Respondent Grifols shall, pursuant to the Monitor Agreement, transfer to the Monitor all rights, powers, and authorities necessary to permit the Monitor to perform his duties and responsibilities, pursuant to and consistent with, the purposes of the Decision and Order.

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- D. Respondent Grifols shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
1. The Monitor shall have the power and authority to monitor Respondent Grifols' compliance with the terms of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission including, but not limited to:
 - a. Assuring that Respondent Grifols expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order; and
 - b. Monitoring any agreements between Respondent Grifols and the Acquirer.
 2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.
 3. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondent Grifols' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, Related To Respondent Grifols' compliance with its obligations under the Order. Respondent Grifols shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondent Grifols' compliance with the Order.
 4. The Monitor shall serve, without bond or other security, at the expense of Respondent Grifols on such reasonable and customary terms and

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conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondent Grifols, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities. The Monitor shall account for all expenses incurred, including fees for services rendered, subject to the approval of the Commission.

5. Respondent Grifols shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, malfeasance, willful or wanton acts, or bad faith by the Monitor.
 6. The Monitor Agreement shall provide that within one (1) month from the date the Monitor is appointed pursuant to this paragraph, and every sixty (60) days thereafter, the Monitor shall report in writing to the Commission concerning performance by Respondent Grifols of its obligations under the Order.
 7. Respondent Grifols may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Monitor and each of the Monitor's consultants,

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accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement relating to Commission materials and information received in connection with the performance of the Monitor's duties.

- F. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor:
 - 1. The Commission shall select the substitute Monitor, subject to the consent of Respondent Grifols, which consent shall not be unreasonably withheld. If Respondent Grifols has not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent Grifols of the identity of any proposed Monitor, Respondent Grifols shall be deemed to have consented to the selection of the proposed Monitor.
 - 2. Not later than ten (10) days after appointment of the substitute Monitor, Respondent Grifols shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondent Grifols' compliance with the relevant terms of the Order in a manner consistent with the purposes of the Order.
- G. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- H. A Monitor appointed pursuant to this Order may be the same person appointed as the Divestiture Trustee pursuant to the relevant provisions of this Order.

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VI.**IT IS FURTHER ORDERED** that:

- A. If Respondent Grifols has not fully complied with the obligations as required by Paragraph II of this Order, the Commission may appoint a Divestiture Trustee to divest the Melville Facility and the Grifols Plasma Centers (if not divested), enter into a Plasma Sales Contract, Product Manufacturing Agreements, and any other agreements, assignments, and licenses, in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent Grifols shall consent to the appointment of a Divestiture Trustee in such action to effectuate the divestitures and other obligations as described in Paragraphs II, III, and IV. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph VI shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent Grifols to comply with this Order.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent Grifols, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondent Grifols has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent Grifols of the identity of any proposed Divestiture Trustee, Respondent Grifols shall be deemed to have

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consented to the selection of the proposed Divestiture Trustee.

- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent Grifols shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effectuate the divestitures required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph VI, Respondent Grifols shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
 - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to divest the Melville Facility and the Grifols Plasma Centers, enter into a Plasma Sales Contract, Product Manufacturing Agreements, and all other agreements, licenses and assignments as described in Paragraph II of this Order.
 - 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to divest the Melville Facility and the Grifols Plasma Centers, enter into a Plasma Sales Contract, Product Manufacturing Agreements, and all other agreements, licenses and assignments as described in Paragraph II of this Order, absolutely and in good faith, at no minimum price, to one or more acquirers that receive the prior approval of the Commission and in a manner that receives the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be

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achieved within a reasonable time, the divestiture period or periods may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be divested by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent Grifols shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent Grifols shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent Grifols shall extend the time for divestiture under this Paragraph VI in an amount equal to the delay, as determined by the Commission.
4. The Divestiture Trustee shall use best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent Grifols' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an acquirer as required by this Order.

Provided, however, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity for assets and businesses to be divested pursuant to Paragraph II and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by

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Respondent Grifols from among those approved by the Commission;

Provided further, however, that Respondent Grifols shall select such entity within five (5) days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent Grifols, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent Grifols, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondent Grifols, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
6. Respondent Grifols shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether

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or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, malfeasance, willful or wanton acts, or bad faith by the Divestiture Trustee.

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.
 8. The Divestiture Trustee shall act in a fiduciary capacity for the benefit of the Commission.
 9. The Divestiture Trustee shall report in writing to Respondent Grifols and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
 10. Respondent Grifols may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
 11. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement relating to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph VI.

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- F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the obligations under Paragraph II of this Order.
- G. The Divestiture Trustee(s) appointed pursuant to Paragraph VI of this Order may be the same Person appointed as the Monitor pursuant to Paragraph V of this Order.

VII.**IT IS FURTHER ORDERED** that:

- A. Beginning no later than: (a) the Acquisition Date and continuing until ninety (90) days after the Effective Date for Designated Employees, and (b) ninety (90) days before the Melville Lease Termination Date for Designated Melville Employees, Respondent Grifols shall, in a manner consistent with local labor laws:
 - 1. facilitate employment interviews between each Designated Employee or Designated Melville Employee, as applicable, and the Acquirer, including providing the names and contact information for such employees and allowing such employees reasonable opportunity to interview with the Acquirer and shall not discourage such employee from participating in such interviews;
 - 2. not interfere in employment negotiations between each Designated Employee or Designated Melville Employee, as applicable, and the Acquirer;
 - 3. with respect to each Designated Employee or Designated Melville Employee, as applicable, who receives an offer of employment from the Acquirer:

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- a. not prevent, prohibit, or restrict, or threaten to prevent, prohibit, or restrict the Designated Employee or Designated Melville Employee, as applicable, from being employed by the Acquirer, and shall not offer any incentive to the Designated Employee or Designated Melville Employee, as applicable, to decline employment with the Acquirer.
- b. cooperate with the Acquirer in effecting transfer of the Designated Employee or Designated Melville Employee, as applicable, to the employ of the Acquirer, if the Designated Employee or Designated Melville Employee, as applicable, accepts an offer of employment from the Acquirer.
- c. eliminate any contractual provisions, non-compete, or other restrictions entered into or imposed by Respondent Grifols that would otherwise prevent or discourage the Designated Employee or Designated Melville Employee, as applicable, from being employed by the Acquirer.
- d. eliminate any confidentiality restrictions that would prevent the Designated Employee or Designated Melville Employee, as applicable, who accepts employment with the Acquirer from using or transferring to the Acquirer any information Relating To the production and sales of Koate, the Private Label Albumin Product, or the Private Label IVIG Product.
- e. unless alternative arrangements are agreed upon with the Acquirer, retain the obligation to pay the benefits of any Designated Employee or Designated Melville Employee, as applicable, who accepts employment with the Acquirer including, but not limited to, all

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accrued bonuses, vested pensions, and other accrued benefits.

- B. Respondent Grifols shall not, for a period of two (2) years following the Effective Date for Designated Employees, or the Melville Lease Termination Date for Designated Melville Employees, respectively, directly or indirectly, solicit, induce, or attempt to solicit or induce any Designated Employee or Designated Melville Employee, as applicable, who is employed by the Acquirer to terminate his or her employment relationship with the Acquirer;

Provided, however, Respondent Grifols may place general advertisements for employees including, but not limited to, in newspapers, trade publications, websites, or other media not targeted specifically at the Acquirer's employees;

Provided further, however, Respondent Grifols may hire Designated Employees or Designated Melville Employee who apply for employment with Respondent Grifols as long as such employees were not solicited by Respondent Grifols in violation of this Paragraph.

VIII.

IT IS FURTHER ORDERED that for a period of ten (10) years from the date this Order becomes final, Respondent Grifols shall not, without providing advance written notification to the Commission in the manner described in this Paragraph VIII, directly or indirectly, acquire:

- A. any stock, share capital, equity, or other interest in any Person, corporate or non-corporate, that produces, designs, manufactures, or sells Factor VIII Product, Albumin Product, or IVIG Product in or into the United States; or

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- B. any assets used at any time after the acquisition, or during the six (6) month period prior to the acquisition, in the design, manufacture, production, or sale of Factor VIII Product, Albumin Product, or IVIG Product in or into the United States.

Said notification shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended (herein referred to as "the Notification"), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such notification, notification shall be filed with the Secretary of the Commission, notification need not be made to the United States Department of Justice, and notification is required only of Respondent Grifols and not of any other party to the transaction. Respondent Grifols shall provide the Notification to the Commission at least thirty days prior to consummating the transaction (hereinafter referred to as the "first waiting period"). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondent Grifols shall not consummate the transaction until thirty days after submitting such additional information or documentary material. Early termination of the waiting periods in this paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition.

Provided, however, that prior notification shall not be required by this paragraph for a transaction for which Notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

Provided further, however, that prior notification shall not be required by this Paragraph VIII for any acquisition after which Respondent Grifols would hold no more than one percent of the outstanding securities or other equity interest in any Person described in this Paragraph VIII.

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IX.**IT IS FURTHER ORDERED** that:

- A. Within thirty (30) days after the date this Order becomes final, and every thirty (30) days thereafter until Respondent Grifols has fully complied with Paragraph II.A. of this Order, Respondent Grifols shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent Grifols shall submit at the same time a copy of its report concerning compliance with this Order to the Monitor or Divestiture Trustee, if any Divestiture Trustee has been appointed pursuant to this Order. Respondent Grifols shall include in its report, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant Paragraphs of the Order, including a description of all substantive contacts or negotiations related to the divestiture of the relevant assets and the identity of all parties contacted. Respondent Grifols shall include in its report copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning completing the obligations.
- B. Beginning twelve (12) months after the date this Order becomes final, and annually thereafter on the anniversary of the date this Order becomes final, for the next nine (9) years, Respondent Grifols shall submit to the Commission a verified written report setting forth in detail the manner and form in which it has complied, is complying, and will comply with this Order. Respondent Grifols shall include in its compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with the Order and copies of all written communications to and from all persons Relating To this Order. Additionally,

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Respondent Grifols shall include in its compliance report whether or not it made any notifiable acquisitions pursuant to Paragraph VIII. Respondent Grifols shall include a description of such acquisitions including, but not limited to, the identity of the Person or assets acquired, the location of the Person or assets, and a detailed description of the assets or Person and its Factor VIII Product, Albumin Product, or IVIG Product sales or manufacturing.

X.

IT IS FURTHER ORDERED that Respondent Grifols shall notify the Commission at least thirty (30) days prior to any proposed:

- A. dissolution of the Respondent Grifols;
- B. acquisition of, merger with, or consolidation by Respondent Grifols; or
- C. other change in the Respondent Grifols, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

XI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to Respondent Grifols, Respondent Grifols shall, without restraint or interference, permit any duly authorized representative(s) of the Commission:

- A. access, during business office hours of Respondent Grifols and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondent Grifols Relating To

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compliance with this Order, which copying services shall be provided by Respondent Grifols at its expense; and

- B. to interview officers, directors, or employees of Respondent Grifols, who may have counsel present, regarding such matters.

XII.

IT IS FURTHER ORDERED that this Order shall terminate ten (10) years after the date on which this Order becomes final.

By the Commission.

CONFIDENTIAL EXHIBIT A

DESIGNATED AMOUNT OF PRODUCTS

[Redacted From the Public Record Version
But Incorporated By Reference]

Decision and Order

CONFIDENTIAL EXHIBIT B

**DESIGNATED PLASMA CENTER AND
SALES & MARKETING EMPLOYEES**

[Redacted From the Public Record Version
But Incorporated By Reference]

CONFIDENTIAL EXHIBIT B-1

DESIGNATED MELVILLE EMPLOYEES

[Redacted From the Public Record Version
But Incorporated By Reference]

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CONFIDENTIAL EXHIBIT C

DIVESTITURE AGREEMENT

[Redacted From the Public Record Version
But Incorporated By Reference]

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EXHIBIT D

GRIFOLS PLASMA CENTERS

PLASMA COLLECTION CENTERS

Talecris
5301 Moffett Road, Suite 230
Mobile, Alabama 36618

Talecris
250 YWCA Way
Winston-Salem, North Carolina 27101

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CONFIDENTIAL EXHIBIT E
TALECRIS ALBUMIN CUSTOMER CONTRACTS

[Redacted From the Public Record Version
But Incorporated By Reference]

CONFIDENTIAL EXHIBIT E-1

**DESIGNATED AMOUNT OF
TALECRIS ALBUMIN**

[Redacted From the Public Record Version
But Incorporated By Reference]

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CONFIDENTIAL EXHIBIT F

TALECRIS IVIG CUSTOMER CONTRACTS

[Redacted From the Public Record Version
But Incorporated By Reference]

CONFIDENTIAL EXHIBIT F-1

**DESIGNATED AMOUNT OF
TALECRIS IVIG PRODUCT**

[Redacted From the Public Record Version
But Incorporated By Reference]

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CONFIDENTIAL EXHIBIT G

KOATE CUSTOMER CONTRACTS

[Redacted From the Public Record Version
But Incorporated By Reference]

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EXHIBIT H
MONITOR AGREEMENT**MONITOR AGREEMENT**

MONITOR AGREEMENT (the "Agreement"), dated as of April 22, 2011, between Grifols, Inc. ("Grifols"), Talecris Biotherapeutics Holdings Corp. ("Talecris"), and R. Owen Richards, President of Quantic Regulatory Services, LLC, 5N Regent Street, Suite 502, Livingston, N.J. 07039 (the "Monitor").

PRELIMINARY STATEMENTS

On April 18, 2011, Grifols and Kedrion S.p.A. ("Kedrion") entered into Divestiture Agreements, which Agreements are attached hereto as Confidential Exhibit A.

Grifols and Talecris will enter into an Agreement Containing Consent Orders ("Consent Agreement") with the Staff of the United States Federal Trade Commission (the "Commission"). The Consent Agreement is subject to approval by the Commission. If the Commission determines to accept for public comment the executed Consent Agreement containing the proposed Decision and Order (collectively, the "Order"), attached hereto as Exhibit B, it is anticipated that the Commission will issue the Order to Maintain Assets, attached hereto as Exhibit C. The Order requires Grifols to divest to Kedrion the Melville Facility, the Grifols Plasma Centers, and Grifols Plasma, enter into the Contract Manufacturing Agreement, the Product Agreement, the Koate Option, License and Sale Agreement, assign, or extend to Kedrion the rights, benefits and obligations under, the Koate Customer Contracts, assign, or extend to Kedrion the rights, benefits and obligations under, the Talecris Albumin Customer Contracts, assign, or extend to Kedrion the rights, benefits and obligations under, the Talecris IVIG Customer Contracts; allows Grifols to enter into a Melville Facility Lease Agreement with Kedrion under which, for a period of no more than four (4) years from the Acquisition Date, Grifols will lease back the Melville Facility from Kedrion; and provides for the appointment of a monitor to ensure that Grifols complies with its obligations under the Order. The Order to Maintain Assets requires Grifols and Talecris to maintain and preserve, pending divestiture, the assets that are subject to the Order.

WHEREAS, the Commission may appoint R. Owen Richards, President of Quantic Regulatory Services, LLC, as the monitor pursuant to the Order to monitor Grifols' and Talecris' compliance with the terms of the Order and the Order to Maintain Assets, and R. Owen Richards has consented to such appointment;

WHEREAS, the Order further provides that Grifols shall execute a Monitor Agreement, subject to the prior approval of the Commission, conferring all the rights, powers and authority necessary to permit the Monitor to carry out such duties and responsibilities pursuant to the Order;

WHEREAS, this Monitor Agreement, although executed by the Monitor, Grifols, and Talecris, is not effective for any purpose, including but not limited to imposing rights and

Decision and Order

responsibilities on Grifols, Talecris, or the Monitor under the Order, until it has been approved by the Commission;

WHEREAS, upon such approval by the Commission, the Monitor, Grifols, and Talecris intend to be legally bound by this Monitor Agreement; and

NOW, THEREFORE, the parties agree as follows:

DEFINITIONS

A. "Grifols" means Grifols, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Grifols, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

B. "Talecris" means Talecris Biotherapeutics Holdings Corp., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Talecris, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

C. All other capitalized words or phrases appearing in this Agreement that are not otherwise defined herein are deemed to have the defined meanings assigned to them in the Order.

ARTICLE I

1.1 Powers of the Monitor. The Monitor shall have the rights, duties, powers and authority conferred upon the Monitor by the Order, attached as Exhibit B, and by the Order to Maintain Assets, attached as Exhibit C, that are necessary for the Monitor to monitor Grifols' and Talecris' compliance with the requirements of the Order and the Order to Maintain Assets. Grifols and Talecris hereby transfer to the Monitor all rights, powers, and authorities necessary to permit the Monitor to perform his duties and responsibilities pursuant to and consistent with the purposes of the Order and the Order to Maintain Assets. Any descriptions thereof contained in this Agreement in no way modify the Monitor's powers and authority or Grifols' and Talecris' obligations under the Order and the Order to Maintain Assets.

1.2 Monitor's Duties. The Monitor shall monitor Grifols' and Talecris' compliance with the Order. The Monitor's duties shall include monitoring Grifols' and Talecris' compliance with the terms of the Order and the Order to Maintain Assets including monitoring:

- a. preserving the assets to be divested pending the divestiture;
- b. divesting the Melville Facility;
- c. divesting the Grifols Plasma Centers;

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- d. divesting the Grifols Plasma;
- e. entering into and complying with the Contract Manufacturing Agreement;
- f. entering into and complying with the Product Agreement;
- g. entering into and complying with the Koate Option, License and Sale Agreement;
- h. assigning, or extending to Kedrion the rights, benefits and obligations under, the Koate Customer Contracts;
- i. assigning, or extending to Kedrion the rights, benefits and obligations under, the Talecris Albumin Customer Contracts;
- j. assigning, or extending to Kedrion the rights, benefits and obligations under, the Talecris IVIG Customer Contracts;
- k. carrying out all other duties of the Monitor specified in the Order and the Order to Maintain Assets.

The Monitor shall act in a fiduciary capacity for the benefit of the Commission only; it is understood and agreed that no such fiduciary relationship exists between the Monitor and Grifols or Talecris.

1.3 Duration of Monitor's Authority. The Monitor shall have all powers and duties described above and consistent with the Order and the Order to Maintain Assets until Grifols has completed the divestitures required by the Order and has completed the supply obligations under the Contract Manufacturing Agreement; provided, however, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Order.

1.4 Confidential and Proprietary Information. The Monitor shall enter into a confidentiality agreement, attached hereto as Confidential Exhibit D.

1.5 Access to records, documents and facilities. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Grifols' and Talecris' personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Grifols' and Talecris' compliance with its obligations under the Order and the Order to Maintain Assets. Grifols and Talecris shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Grifols' and Talecris' compliance with the Order and the Order to Maintain Assets.

1.6 Grifols' and Talecris' Duties. Grifols agrees that:

- a. no later than one (1) day after the Acquisition Date, Grifols and Talecris will transfer to the Monitor all rights, powers, and authorities necessary to permit the Monitor to perform his duties and responsibilities, pursuant to the Order and the Order to Maintain Assets consistent with the purposes of the Order.
- b. Grifols and Talecris will provide the Monitor with information that the Monitor reasonably requests to carry out his duties and responsibilities under the Order.

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c. Grifols and Talecris will designate a senior individual as a primary contact for the Monitor.

d. Grifols and Talecris will provide the Monitor with electronic or hard copies, as may be appropriate, of all reports submitted to the Commission pursuant to the Order and the Order to Maintain Assets that are relevant to the Monitor's duties, simultaneous with the submission of such reports to the Commission.

e. Grifols and Talecris will comply with the Monitor's reasonable requests for onsite visits and audits of Grifols' and Talecris' facilities.

f. Grifols and Talecris will comply with the Monitor's reasonable requests for follow-up discussions or supplementary information concerning any reports provided to or requested by the Monitor pursuant to the Order or the Order to Maintain Assets, and will provide the Monitor with access to and copies of other data, records or other information that the Monitor reasonably believes are necessary to the proper discharge of his responsibilities under the Order or the Order to Maintain Assets.

g. Grifols and Talecris consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:

1. The Monitor shall have the power and authority to monitor Respondent Grifols' and Talecris' compliance with the terms of the Order and the Order to Maintain Assets, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission including, but not limited to:

a. Monitoring Grifols' and Talecris' compliance with all of their obligations and performance of all of their responsibilities as required by the Order and the Order to Maintain Assets; and

b. Monitoring any agreements between Respondent Grifols and the Acquirer.

2. Within one (1) month from the date the Monitor is appointed and every sixty (60) days thereafter, the Monitor shall report in writing to the Commission concerning performance by Grifols and Talecris of their obligations under the Order and the Order to Maintain Assets.

3. The Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants shall sign a confidentiality agreement; PROVIDED, HOWEVER, such agreement shall not restrict the Monitor from providing any information to the Commission.

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1.7 **Effective Date.** This Monitor Agreement shall become effective only upon Commission approval of the Monitor.

ARTICLE II

2.1 **Retention and payment of Counsel, Consultants, and other Assistants.** The Monitor shall have the authority to employ, at the cost and expense of Grifols and Talecris, such attorneys, consultants, accountants, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities as allowed pursuant to the Order and the Order to Maintain Assets provided that such individuals enter into a confidentiality agreement that requires the same standard of care and obligations of confidentiality to which the Monitor must adhere. Before hiring any legal counsel, the Monitor shall confirm with counsel that there is no conflict of interest if that counsel represents the Monitor.

2.2 **Compensation of the Monitor.** Grifols and Talecris will pay the Monitor within thirty (30) days of receipt of an invoice in accordance with the hourly fee schedule attached hereto as Confidential Exhibit E for all time spent in the performance of the Monitor's duties including all monitoring activities related to the Order and the Order to Maintain Assets (including any and all such activities performed prior to the date of this Agreement), all work in connection with the negotiation and preparation of this Monitor Agreement, and all reasonable and necessary travel time.

- a. In addition, Grifols and Talecris will pay within such thirty (30) days (i) all out-of-pocket expenses incurred by the Monitor in the performance of the Monitor's duties, including, without limitation, any auto, train or air travel in the performance of the Monitor's duties, international telephone calls, and (ii) all fees and disbursements reasonably incurred by such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties.
- b. The Monitor shall have full and direct responsibility for compliance with all applicable laws, regulations and requirements pertaining to income and social security taxes, unemployment insurance, worker's compensation, disability insurance, and the like.

ARTICLE III

3.1 **Monitor's liabilities and indemnification.** Grifols and Talecris hereby agree to indemnify the Monitor and his employees, consultants, accountants, attorneys and other representatives and assistants (collectively the "Indemnified Parties") and hold the Indemnified Parties harmless in accordance with and to the extent required by the Order and the Order to Maintain Assets. Without in any way limiting the generality of the foregoing, Grifols and Talecris shall indemnify the Indemnified Parties and hold the

Decision and Order

Indemnified Parties harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including, without limitation, all reasonable fees of counsel (of Monitor's choosing) and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim or inquiry, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor. The Monitor's maximum liability to Grifols or Talecris relating to services rendered pursuant to this Agreement (regardless of the form of the action, whether in contract, statutory law, tort, or otherwise) shall be limited to the total sum of the fees paid to the Monitor by Grifols and Talecris, respectively, except to the extent that any losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton actions, or bad faith by the Monitor. IN NO CIRCUMSTANCES WHATSOEVER SHALL MONITOR BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES.

Grifols and Talecris agree that their obligations to indemnify the Monitor extend to any agreement or relationship between the Monitor and Kedrion and relates to the Monitor's responsibilities under the Monitor Agreement and/or the Order or the Order to Maintain Assets.

3.2 Monitor's removal. If the Monitor materially breaches his responsibilities under the Order, the Commission may terminate this Agreement and appoint a substitute Monitor.

3.3 Approval by the Commission. This Agreement shall have no force or effect until approved by the Commission.

3.4 Termination. This Agreement shall terminate the earlier of: (a) the date set forth in the Order; (b) Grifols' and Talecris' receipt of written notice from the Commission that the Commission has determined that the Monitor has ceased to act or failed to act diligently, or is unwilling or unable to continue to serve as Monitor; or (c) with at least thirty (30) days advance notice to be provided by the Monitor to Grifols, Talecris and the Commission, upon resignation of the Monitor. The Monitor may resign at any time during the term of this Agreement for any reason by providing such 30 days written notice to Grifols, Talecris and the Commission and Monitor shall have no liability as a result of his resignation. If this Agreement is terminated for any reason, the confidentiality obligations set forth in this Agreement will remain in force.

3.5 Conflicts of Interest. If the Monitor becomes aware during the term of this Agreement that he has or may have a conflict of interest that may affect or could have the appearance of affecting performance by the Monitor of any of his duties under this Agreement, the Monitor shall promptly inform Grifols, Talecris and the Commission of any such conflict.

3.6 Independent Contractor. It is understood that the Monitor will be serving under this Monitor Agreement as an independent contractor and that the relationship of employer and employee shall not exist between Monitor and Grifols or Talecris. The Monitor will

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not be entitled to participate in any employee benefit plans or accrue any employee benefits as a result of providing services under this Agreement.

3.7 Choice of Law. This Monitor Agreement shall be subject to the substantive law of the State of New York (regardless of any other jurisdiction's choice of law principles). This Monitor Agreement is for the sole benefit of the parties hereto and their permitted assigns and the Commission, and nothing herein express or implied shall give or be construed to give any other person any legal or equitable rights hereunder. This Monitor Agreement contains the entire agreement between the parties hereto with respect to the matters described herein and replaces any and all prior agreements or understandings, whether written or oral.

3.8 Notices. Any notices or other communication required to be given hereunder shall be deemed to have been properly given if sent by mail or reputable overnight courier, to the applicable party at its address below (or to such other address as to which such party shall hereafter notify the other party):

If to the Monitor:

R. Owen Richards, President
Quantic Regulatory Services, LLC
5N Regent Street, Suite 502
Livingston, N.J. 07039
Fax: 973.535.1734

If to Grifols:

Grifols, Inc.
2410 Lillyvale Avenue
Los Angeles, CA 90032-3514
Fax: 323.441.7151
Attention: David Ian Bell, General Counsel

With copies to:

Proskauer Rose LLP
1001 Pennsylvania Avenue, N.W.
Suite 400 South
Washington, D.C. 20004-2533
Fax: 202.416.6899
Attention: Alicia J. Batts and
Rhett R. Krulla

and

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Osborne Clarke S.L.P.
 Avenida Diagonal, 477
 Planta 20
 08036 Barcelona
 Spain
 Fax: +34.93.410.2513
 Attention: Tomás Dagá
 Raimon Grifols

If to Talecris:

Talecris Biotherapeutics Holdings Corp.
 4101 Research Commons
 79 T.W. Alexander Drive
 Research Triangle Park
 North Carolina 27709
 Fax: 1-919-287-2807
 Attention: John F. Gaither, Jr.

With a copy to:

Arnold & Porter LLP
 555 Twelfth Street, N.W.
 Washington, D.C. 20004-1206
 Fax: 202.942.5999
 Attention: Deborah L. Feinstein

If to the Commission:

Federal Trade Commission
 600 Pennsylvania Avenue, N.W.
 Washington, D.C. 20580
 Attention: Eric D. Rohlck

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed
 as of the date first above written.

R. OWEN RICHARDS, PRESIDENT
QUANTIC REGULATORY SERVICES, LLC
MONITOR:

R. Owen Richards
 President

Decision and Order

Osborne Clarke S.L.P.
Avenida Diagonal, 477
Planta 20
08036 Barcelona
Spain
Fax: +34.93.410.2513
Attention: Tomás Dagá
Raimon Grifols

If to Talecris:

Talecris Biotherapeutics Holdings Corp.
4101 Research Commons
79 T.W. Alexander Drive
Research Triangle Park
North Carolina 27709
Fax: _____
Attention: _____

With a copy to:

Arnold & Porter LLP
555 Twelfth Street, N.W.
Washington, D.C. 20004-1206
Fax: 202.942.5999
Attention: Deborah L. Feinstein

If to the Commission:

Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
Attention: Eric D. Rohlek

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed
as of the date first above written.

R. OWEN RICHARDS, PRESIDENT
QUANTIC REGULATORY SERVICES, LLC
MONITOR:


R. Owen Richards
President

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GRIFOLS:

BY: 

NAME: David Bell

Vice President, Corporate Operations

TITLE: General Counsel

TALECRIS:

BY: _____

NAME: _____

TITLE: _____

Decision and Order

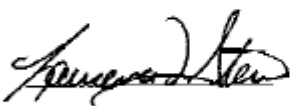
GRIFOLS:

BY: _____

NAME: _____

TITLE: _____

TALECRIS:

BY: NAME: Lawrence D. SternTITLE: Chairman and Chief Executive Officer

Decision and Order

CONFIDENTIAL EXHIBIT A

DIVESTITURE AGREEMENT

[Redacted From the Public Record Version
But Incorporated By Reference]

EXHIBIT B

**AGREEMENT CONTAINING CONSENT ORDER AND
DECISION AND ORDER**

EXHIBIT C

ORDER TO MAINTAIN ASSETS

CONFIDENTIAL EXHIBIT D

CONFIDENTIALITY AGREEMENT

[Redacted From the Public Record Version
But Incorporated By Reference]

CONFIDENTIAL EXHIBIT H-1

**EXHIBIT E TO MONITOR AGREEMENT
(COMPENSATION)**

[Redacted From the Public Record Version
But Incorporated By Reference]

Order to Maintain Assets

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission ("Commission") having initiated an investigation of the proposed acquisition of Talecris Biotherapeutics Corp. ("Respondent Talecris") by Grifols, S.A. ("Respondent Grifols") and Respondents having been furnished thereafter with a copy of the draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent Grifols and Respondent Talecris with violations of 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; and

Respondent Grifols and Respondent Talecris, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent Grifols or Respondent Talecris that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having determined to accept the executed Consent Agreement and to place such Consent Agreement containing the Decision and Order on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

1. Respondent Grifols is a corporation organized, existing and doing business under and by virtue of the laws of

Order to Maintain Assets

Spain with its office and principal place of business located at Avinguda de la Generalitat, 152, Parque empresarial Can Sant Joan, 08174 Sant Cugat del Valles, Barcelona, Spain, and with its office and principal place of business in the United States located at 2410 Lillyvale Avenue, Los Angeles, CA 90032.

2. Respondent Talecris is a corporation organized, existing and doing business under and by virtue of the laws of Delaware, with its office and principal place of business located at 4101 Research Commons, 79 T.W. Alexander Drive, Research Triangle Park, North Carolina 27709.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. "Grifols" means Grifols, S.A., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Grifols, S.A. (including Talecris, after the Acquisition Date), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. "Talecris" means Talecris Biotherapeutics Holdings Corp., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Talecris Biotherapeutics Holdings Corp.,

Order to Maintain Assets

and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

- C. "Commission" means the Federal Trade Commission.
- D. "Decision and Order" means the:
 - 1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final Decision and Order by the Commission; and
 - 2. Final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission.
- E. "Orders" means the Decision and Order and this Order to Maintain Assets.

II.**IT IS FURTHER ORDERED** that:

- A. From the date on which Respondent Grifols and Respondent Talecris sign the Consent Agreement and until the Effective Date, Respondent Grifols and Respondent Talecris shall take such actions as are necessary to maintain the full economic viability, marketability and competitiveness of each of their assets included within the Divested Business to minimize any risk of loss of competitive potential for the Divested Business, and to prevent the destruction, removal, wasting, deterioration, or impairment of the Divested Business, except for ordinary wear and tear. Respondent Grifols and Respondent Talecris shall not sell, transfer, encumber or otherwise impair any of their assets included within the Divested Business (other than in the manner prescribed in the Decision and Order) nor take any action that lessens the full economic viability, marketability or competitiveness

Order to Maintain Assets

of any of their assets included within the Divested Business.

- B. Respondent Grifols and Respondent Talecris shall retain all rights, title, and interest in each of their assets included within the Divested Business.
- C. Respondent Grifols and Respondent Talecris shall maintain the operations of each of their assets included within the Divested Business in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets, as necessary) and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Divested Business, and shall use their best efforts to preserve the existing relationships with the following: suppliers, vendors, distributors, customers, governmental agencies, employees, and others having business relations with the Divested Business. Respondent Grifols and Respondent Talecris, for each of their assets included within the Divested Business, shall be responsible for, among other things:
 - 1. Providing sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities;
 - 2. Continuing, at least at their scheduled pace, any additional expenditures authorized prior to the date the Consent Agreement was signed by Respondent Grifols and Respondent Talecris including, but not limited to, all research, development, manufacture, distribution, marketing and sales expenditures;
 - 3. Providing such resources as may be necessary to respond to competition and/or to prevent any diminution in sales of the Divested Business prior to the Effective Date;

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4. Providing such resources as may be necessary to maintain the competitive strength and positioning of the Divested Business;
 5. Making available for use by the Divested Business funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to such business;
 6. Providing the Divested Business with such funds as are necessary to maintain the full economic viability, marketability and competitiveness of the Divested Business; and
 7. Providing such support services to the Divested business as of the date the Consent Agreement was signed by Respondent Grifols and Respondent Talecris.
- D. Respondent Grifols and Respondent Talecris shall maintain a work force at the equivalent or larger size, and with equivalent or better training and expertise, to what has been associated with each of their assets included within the Divested Business as of the date the Consent Agreement was signed by Respondents.
1. Respondent Grifols shall provide all of the Designated Employees with reasonable financial incentives to continue in their positions consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of Respondents Grifols' assets within the Divested Business pending divestiture. Such incentives shall include a continuation of all employee benefits offered by Respondent Grifols until the Effective Date has occurred, including regularly scheduled raises, bonuses, vesting of pension benefits (as permitted by law), and additional incentives as may be necessary to

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prevent any diminution of the Divested Business' competitiveness.

2. Respondent Talecris shall provide all of the Designated Melville Employees with reasonable financial incentives to continue in their positions consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of Talecris' assets within the Divested Business pending divestiture. Such incentives shall include a continuation of all employee benefits offered by Respondent Talecris until the Effective Date has occurred, including regularly scheduled raises, bonuses, vesting of pension benefits (as permitted by law), and additional incentives as may be necessary to prevent any diminution of the Divested Business' competitiveness.

- E. Respondent Grifols and Respondent Talecris shall not interfere with the hiring or employing of the Designated Employees or the Designated Melville Employees, respectively, as described in Paragraph VII of the proposed Decision and Order, and shall remove any impediments within the control of Respondent Grifols or Respondent Talecris that may deter these employees from accepting employment with the Acquirer including, but not limited to, any noncompete provisions of employment or other contracts with Respondent Grifols or Respondent Talecris that would affect the ability or incentive of those individuals to be employed by the Acquirer. In addition, Respondent Grifols and Respondent Talecris shall not make any counteroffer to a Designated Employee or a Designated Melville Employee, respectively, who receives a written offer of employment from the Acquirer.

Provided, however, subject to the conditions of continued employment prescribed in this Order to Maintain Assets, this Paragraph II.E. shall not prohibit

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Respondent Grifols or Respondent Talecris from continuing to employ any Designated Employee or Designated Melville Employee, respectively, under the terms of such employee's employment with Respondent Grifols or Respondent Talecris prior to the date of the written offer of employment from the Acquirer to such employee.

- F. Unless specifically authorized by the Acquirer, Respondent Grifols and Respondent Talecris shall not use, directly or indirectly, any Confidential Business Information other than as necessary to:
1. comply with the requirements of the Orders;
 2. comply with applicable law;
 3. consummate the Acquisition;
 4. defend legal claims, investigations or enforcement actions threatened or brought against Respondents or the Divested Business; and
 5. obtain legal advice.
- G. Respondent Grifols and Respondent Talecris shall not disclose or convey any such Confidential Business Information, directly or indirectly, to any person except the Acquirer or other persons specifically authorized by the Acquirer to receive such information, other than as necessary to:
1. comply with the requirements of the Orders;
 2. comply with applicable law;
 3. defend legal claims, investigations or enforcement actions threatened or brought against Respondents or the Divested Business; and
 4. obtain legal advice.

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- H. Respondent Grifols and Respondent Talecris shall institute procedures and requirements to ensure that:
1. Employees of Respondent Grifols or Respondent Talecris with access to Confidential Business Information do not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information in contravention of this Order to Maintain Assets; and
 2. Employees of Respondent Grifols and Respondent Talecris do not solicit, access or use any Confidential Business Information that they are prohibited under this Order to Maintain Assets from receiving for any reason or purpose.
- I. Respondent Grifols shall require any agents and employees of Grifols who have access to Confidential Business Information to enter into agreements, within ten (10) days after the date this Order to Maintain Assets becomes final, not to disclose any Confidential Business Information to Respondent Grifols or to any third party except as otherwise permitted by this Order to Maintain Assets. Copies of such agreements shall be retained by Respondent Grifols and provided to the Commission.
- J. Respondent Talecris shall require any agents and employees of Talecris who have access to Confidential Business Information to enter into agreements, within ten (10) days after the date this Order to Maintain Assets becomes final, not to disclose any Confidential Business Information Relating To the Divested Business to Respondent Talecris or to any third party except as otherwise permitted by this Order to Maintain Assets. Copies of such agreements shall be retained by Respondent Talecris and provided to the Commission.

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- K. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Divested Business until the Effective Date, to minimize any risk of loss of competitive potential for the Divested Business, and to prevent the destruction, removal, wasting, deterioration, or impairment of the Divested Business, except for ordinary wear and tear.

III.**IT IS FURTHER ORDERED** that:

- A. At any time after Respondent Grifols and Respondent Talecris sign the Consent Agreement in this matter, the Commission may appoint a Monitor to assure that Respondent Grifols and Respondent Talecris expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order.
- B. The Commission shall select the Monitor, subject to the consent of Respondent Grifols and Respondent Talecris, which consent shall not be unreasonably withheld. If Respondent Grifols or Respondent Talecris has not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent Grifols and Respondent Talecris of the identity of any proposed Monitor, Respondent Grifols and Respondent Talecris shall be deemed to have consented to the selection of the proposed Monitor.
- C. Not later than ten (10) days after appointment of the Monitor, Respondent Grifols and Respondent Talecris shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondent Grifols' and Respondent Talecris' compliance with the relevant

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terms of the Orders in a manner consistent with the purposes of the Orders.

- D. Respondent Grifols and Respondent Talecris shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
1. The Monitor shall have the power and authority to monitor Respondent Grifols' and Respondent Talecris' compliance with the terms of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission including, but not limited to:
 - a. Assuring that Respondent Grifols and Respondent Talecris expeditiously comply with all of their obligations and perform all of their responsibilities as required by the Orders; and
 - b. Monitoring any agreements between Respondent Grifols and the Acquirer.
 2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.
 3. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondent Grifols' and Respondent Talecris' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request Related To Respondent Grifols' and Respondent Talecris' compliance with their obligations under the Orders. Respondent Grifols and Respondent Talecris shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to

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monitor Respondent Grifols' or Respondent Talecris' compliance with the Orders.

4. The Monitor shall serve, without bond or other security, at the expense of Respondent Grifols and Respondent Talecris on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondent Grifols and Respondent Talecris, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities. The Monitor shall account for all expenses incurred, including fees for services rendered, subject to the approval of the Commission.
5. Respondent Grifols and Respondent Talecris shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, malfeasance, willful or wanton acts, or bad faith by the Monitor.
6. The Monitor Agreement shall provide that within one (1) month from the date the Monitor is appointed pursuant to this paragraph, and every sixty (60) days thereafter, the Monitor shall report in writing to the Commission concerning performance by Respondent Grifols and Respondent Talecris of its obligations under the Orders.

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7. Respondent Grifols and Respondent Talecris may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement relating to Commission materials and information received in connection with the performance of the Monitor's duties.
- F. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor:
1. The Commission shall select the substitute Monitor, subject to the consent of Respondent Grifols and Respondent Talecris, which consent shall not be unreasonably withheld. If Respondent Grifols and Respondent Talecris have not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent Grifols and Respondent Talecris of the identity of any proposed Monitor, Respondent Grifols and Respondent Talecris shall be deemed to have consented to the selection of the proposed Monitor.
 2. Not later than ten (10) days after appointment of the substitute Monitor, Respondent Grifols and Respondent Talecris shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondent Grifols' and Respondent

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Talecris' compliance with the relevant terms of the Orders in a manner consistent with the purposes of the Orders.

- G. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- H. A Monitor appointed pursuant to this Order may be the same person appointed as the Monitor pursuant to the Decision and Order and the Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

IV.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets becomes final, and every sixty (60) days thereafter until Respondent Grifols and Respondent Talecris have fully complied with their obligations under Paragraphs II, III, IV, VI, and VII of the related Decision and Order in this matter, Respondent Grifols and Respondent Talecris shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order to Maintain Assets and the related Decision and Order; *provided, however*, that, after the Decision and Order in this matter becomes final, the reports due under this Order to Maintain Assets shall be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondent Grifols pursuant to Paragraph IX.A. of the Decision and Order.

V.

IT IS FURTHER ORDERED that Respondent Grifols shall notify the Commission at least thirty (30) days prior to any proposed:

- A. dissolution of the Respondent Grifols;

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- B. acquisition, merger or consolidation of Respondent Grifols; or
- C. other change in the Respondent Grifols, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order to Maintain Assets.

VI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order to Maintain Assets, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to Respondent Grifols, Respondent Grifols, shall, without restraint or interference, permit any duly authorized representative(s) of the Commission:

- A. access, during business office hours of Respondent Grifols and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondent Grifols related to compliance with this Order to Maintain Assets, which copying services shall be provided by Respondent Grifols at its expense; and
- B. to interview officers, directors, or employees of Respondent Grifols, who may have counsel present, regarding such matters.

VII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate on the earlier of:

- A. Three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the

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provisions of Commission Rule 2.34, 16 C.F.R. § 2.34;
or

- B. The latter of:
1. the day after the Effective Date;
 2. the day the related Decision and Order becomes final; or
- C. The day after the Commission otherwise directs that this Order to Maintain Assets is terminated.

By the Commission, Commissioner Kovacic recused.

ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS 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

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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

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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.

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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.

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.

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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

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behavior. *First*, 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

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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

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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.

Concurring Statement

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.

**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

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/0810255/091110csl-cerberusunsealedcmplt.pdf>.

³ *Id.* ¶¶ 37-44.

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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

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.

Concurring Statement

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.

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).

Complaint

IN THE MATTER OF
SETTLEMENTONE CREDIT CORPORATION
AND
SACKETT NATIONAL HOLDINGS, INC.

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5(A) OF THE FEDERAL TRADE COMMISSION ACT, SECS. 604
AND 607(A) OF THE FAIR CREDIT REPORTING ACT, AND THE
GRAMM-LEACH-BLILEY SAFEGUARDS RULE

Docket No. C-4330; File No. 082 3208
Filed, August 17, 2011 — Decision, August 17, 2011

This consent order addresses allegations that SettlementOne Credit Corporation and its parent corporation Sackett National Holdings, Inc. (“Respondents”) failed to provide reasonable and appropriate security for consumers’ personal information. According to the complaint, Respondents obtained sensitive consumer information, much of which is not publicly available, from the three nationwide consumer reporting agencies, Equifax, Experian, and TransUnion. Respondents then used this information to create “trimerge reports,” which it sold to mortgage brokers and others to determine consumers’ eligibility for credit. The complaint alleges that Respondents, among other things, failed to develop comprehensive written information security policies; to implement reasonable steps to maintain an effective system of monitoring access to consumer reports by end users; and take appropriate action to correct existing vulnerabilities or threats to personal information in light of known risks. As a result, hackers were able to exploit vulnerabilities and access hundreds of consumer reports. The order requires Respondents to establish and maintain a comprehensive information security program reasonably designed to protect consumer information. The order further requires Respondents to maintain procedures to ensure that its consumer reports are given only to those persons or entities that will use it for a permissible purpose under the Fair Credit Reporting Act. The order further requires Respondents to obtain an independent, third-party assessment of its security procedures on a biennial basis for the next 20 years.

Participants

For the *Commission*: *Anthony Rodriguez and Katherine White.*

For the *Respondents*: *Patrice A. Ficklin, Relman, Dane & Colfax, PLLC.*