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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

COUNTY OF SAN MATEO, **Plaintiff,** **v.** **CSL LIMITED; CSL BEHRING LLC; CSL PLASMA; BAXTER INTERNATIONAL INC.; and PLASMA PROTEIN THERAPEUTICS ASSOCIATION,** **Defendants.**	**Case No. 10-CV-5686-SBA** **AMENDED COMPLAINT** **DEMAND FOR JURY TRIAL**

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Plaintiff COUNTY OF SAN MATEO ("County", "San Mateo Medical Center", "SMMC" or "Plaintiff") brings this action for damages and injunctive relief under California antitrust law against Defendants CSL Limited, CSL Behring LLC, CSL Plasma (collectively "CSL"), Baxter International Inc. ("Baxter") and Plasma Protein Therapeutics Association ("PPTA") (collectively "Defendants"), and demands a jury trial.

I. NATURE OF THE CASE

1. The County purchased the human blood plasma derived protein therapies immune globulin (a.k.a. "Ig", "IVIG", "IGIV", and "SCIG", referred to herein as "Ig") and albumin (collectively with Ig, "Plasma-Derivative Protein Therapies") to treat dozens of life threatening conditions in their patients. For many conditions, including primary immune deficiencies and certain autoimmune disorders, there is no replacement for Ig therapy; and albumin is considered far and away the best product for expanding blood volume in surgery and trauma settings and for priming heart valves during heart surgery.

2. The County alleges that Defendants conspired, combined, and/or contracted to restrict output of, and to fix, raise, maintain, or stabilize the prices of, Plasma-Derivative Protein Therapies that they sold to the County from at least as early as July 1, 2003 through the present, in violation of Antitrust and Unfair Competition Laws. As a result, Plaintiff paid supracompetitive prices for Plasma-Derivative Protein Therapies, suffered from artificial shortages thereof, and otherwise suffered injury of the types that the Antitrust and Unfair Competition Laws are designed to prevent.

3. As described in detail herein, Defendants CSL and Baxter, through a concerted series of acquisitions and mergers, came to dominate and control the raw collection, development, manufacture (horizontally and vertically), and sale of Plasma-Derivative Protein Therapies. Defendants CSL and Baxter then cynically conspired to utilize their collective dominance, as well as the trade group they controlled (Defendant PPTA), to artificially shrink the supply, and raise the price, of life-saving Plasma-Derivative Protein Therapies, all the while denying the existence of artificial shortages that they had conspired to create. This led to a well-publicized and serious shortage Ig from fall 2007 through 2008. On top of plant closings, the

FDA recalled at least 24 globulin products in 1997 because of transmission fears relating to Creutzfeldt-Jacob disease. The FDA estimated that supply fell short of demand by 20% in 2007 and 30% in 2008.

4. Ironically, Defendants' conspiracy grew out of a federal government-led effort in the late 1990's to address shortages of Plasma-Derivative Protein Therapies caused by growing demand, product recalls, and safety-related plant closures.

5. As their name suggests, Plasma-Derivative Protein Therapies are manufactured from blood plasma collected from human blood plasma donors and sellers. Accordingly, there is a finite supply of raw materials for manufacturers, and a stringent set of regulatory protocols that must be followed at all stages of the manufacturing process. Thus, when several Plasma-Derivative Protein Therapy plants were closed down in the late 1990's, federal officials moved to ensure that raw blood plasma materials destined for the closed plants would not be left unused and the nation's supply of Plasma-Derivative Protein Therapies thereby unnecessarily shrunk.

6. In early 1999, in response to this series of supply-chain events, the Immune Deficiency Foundation launched the IVIG Safety Net Program, which was designed to ensure the medical prioritization of IVIG supply for primary immune deficiency patients. The program was intended to provide patients with sufficiently serious conditions an emergency supply of IVIG at a reasonable price.

7. In purported pursuit of these goals, and to ensure that other future unanticipated events did not unnecessarily result in Plasma-Derivative Protein Therapy shortages, a meeting was held in June 1999, at which the vice-president of the International Plasma Products Industry Association ("IPPIA"), several consulting firms, and government representatives were in attendance. Discussions in this meeting, however, drifted towards exploration of ways to increase inventory and supply transparency, generally, in the industry.

8. Defendants CSL and Baxter soon recognized that such information sharing could be used to artificially increase the prices charged for their products, and thus their profits, by allowing them to guard against not only shortages in the market (the government's concern), but also over-supply. Thus, over the next few years, Defendants aggressively developed a data

monitoring system that would enable them to track each supplier's current distribution and inventory levels, purportedly with the goal of preventing shortages, but actually with the goal of artificially raising, maintaining, fixing, and/or otherwise inflating the price of Plasma-Derivative Protein Therapies. Indeed, CSL's Chief Economist presciently noted at the time the system was being developed that "economics can help [us] understand how to loosen the shackles of competition." *See Fed. Trade Comm'n Complaint v. CSL Ltd.*, No. 09-cv-1000 at ¶ 43 (D.D.C. Nov. 11, 2009).

9. By the early 2000s, as a result of government interventions, including implementation of stricter safety guidelines that resulted in temporarily closed plants coming back on line, Plasma-Derivative Protein Therapies production increased, the supply of Plasma-Derivative Protein Therapies became abundant, and manufacturers, including Defendants Baxter and CSL, suffered severe drops in profitability.

10. In reaction, Defendants initiated a concerted conspiracy to "reduce" or "reign in" the supply of Plasma Protein-Derivative Therapies and maintain, increase, inflate, and/or fix the prices charged therefor, using as one of their tools the data monitoring system that had been created a couple of years before to prevent supply shortages.

11. Defendants' conspiratorial conduct in pursuit of these goals fell into five basic categories: (1) acquisition of competing manufacturers, followed by significant closures of acquired plants and blood plasma collection facilities; (2) using various means to signal to each other when supplies to the market of Ig and/or albumin should be restricted in order to maintain or raise the price of the products; (3) expansion and refinement of the data monitoring system set-up under the aegis of government intervention in the 90's, to enhance their ability to monitor each other's current inventory and supply levels, and thus effectively police the conspiracy and determine whether signals to reduce supply should be sent; (4) falsely denying the existence of supply shortages, over-reporting industry supply figures, and misleadingly attributing patient difficulties in obtaining Ig and/or albumin to Medicare reimbursement rates, in order to disguise the mechanisms and effects of the conspiracy and ward off government intervention; and (5) using PPTA meetings, private meetings and gatherings in bars and restaurants following such

meetings and other business meetings to conduct anticompetitive discussions regarding supply and pricing.

12. At various points during the conspiracy, executives at smaller firms supplying Plasma-Derivative Protein Therapies voiced concerns that CSL and Baxter were improperly exchanging anti-competitive information going to supply and pricing; however, these concerns were ignored by Defendants and government regulators.

13. However, in 2009, Defendants' ability to hide their conspiracy from the attention of government regulators and Plasma Protein-Derivative Therapy purchasers began to erode when CSL Limited moved to acquire Talecris Biotherapeutics Holdings Corporation ("Talecris"). By 2006, Talecris was the only other company with the Plasma Protein-Derivative Therapy manufacturing capacity even potentially capable of undermining Defendants' conspiracy. Obviously emboldened that their conspiracy had evaded antitrust scrutiny for most of the decade, CSL's ostensible competitor Baxter, but actual co-conspirator, publically supported CSL's move to acquire this potential threat to the effectiveness of the conspiracy.

14. The move attracted the attention of Federal Trade Commission ("FTC"). On November 11, 2009, the FTC filed an administrative complaint to block CSL Limited's attempted acquisition of Talecris, on the basis that the deal would substantially reduce competition in the United States for Plasma-Derivative Protein Therapies. *See Fed. Trade Comm'n Complaint v. CSL Ltd.*, No. 09-cv-1000 at ¶ 41 (D.D.C. Nov. 11, 2009).

15. In the redacted complaint and accompanying press release, the FTC strongly indicated that, in the course of its investigation, it had uncovered substantial evidence suggesting the existence of price fixing, manipulation of market supply of Plasma Protein-Derivative Therapies and other types of anticompetitive conspiratorial conduct by CSL and others.

16. In an FTC press release, entitled "FTC Authorizes Suit to Stop CSL's Proposed $3.1 Billion Acquisition of Talecris Biotherapeutics" dated May 27, 2009 ("FTC Press Release"), which accompanied the suit's filing, the Director of the FTC's Bureau of Competition observed "[s]ubstantial consolidation has already occurred in the plasma protein industry, and these highly concentrated markets are already exhibiting troubling signs of coordinated behavior." Further,

the "Complaint Counsel's Motion to Place Complaint on the Public Record" dated May 29, 2009 regarding *In the Matter of CSL Limited* ("FTC Motion") stated that if CSL was allowed to go forward with the proposed acquisition, CSL and others "would face no remaining significant obstacle in their ***efforts to coordinate and tighten supply conditions*** for the relevant products" (emphasis added).

17. In fact, the FTC Motion explained that the FTC, in investigating the potential anti-competitive effects of CSL's proposed acquisition of Talecris, an investigation that was not focused on price-fixing, uncovered evidence in CSL's files that "suggests a strong possibility of ongoing coordinated interaction between firms in the plasma industry." The FTC went on to describe language discovered in CSL's documents as "similar to language that in other instances has been found to be evidence supporting an illegal price fixing conspiracy," which could, in the FTC's opinion, expose CSL and others to "possible treble damages actions."

18. The FTC's complaint itself describes "troubling signs of coordinated behavior," including, in particular, signaling by CSL and others to ensure that manufacturers restrained output and growth, resulting in higher prices.

19. For example, the FTC noted that CSL and others used specific key words to: (1) signal against any increase of production, when to do so would result in a drop of prices; (2) encourage compliance with the agreements to limit supply by reminding each other that, during a period when supply increased, prices and profitability for producers of Plasma-Derivative Protein Therapies had dropped substantially; and (3) signal when small incremental increases in supply were appropriate to keep pace with increases in demand, without negatively affecting pricing or market share.

20. Soon after the FTC filed its complaint, CSL Limited abandoned the proposed acquisition.

21. This decision, however, did not prevent Defendants' conspiracy from causing injury to the County. Beginning at least as early as July 1, 2003 and continuing through the present, Defendants' conspiracy has caused supplies of Plasma-Derivative Protein Therapies to artificially shrink and prices of their products to artificially rise, both substantially. For

Defendants, this resulted in substantially increased profits. However, for the County of San Mateo, this resulted in the payment of supracompetitive prices for these products, which caused substantial financial injury.

22. Plaintiff brings this action, on behalf of itself, for purchases of Plasma-Derivative Protein Therapies indirectly from Defendants CSL or Baxter from July 1, 2003 through the present, seeking recovery from the Defendants for the financial harm that the conspiracy has inflicted on Plaintiff and seeks appropriate injunctive relief.

II. JURISDICTION AND VENUE

23. This Court has Jurisdiction over this action pursuant to 28 U.S.C. Section § 1332 because there is complete diversity between the parties and the amount in controversy exceeds $75,000.

24. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b), (c) and (d) because during the relevant time period, Defendants transacted business, were found, and/or had agents in this District, a substantial portion of the affected interstate trade and commerce discussed below has been carried out in this District, and a substantial part of the offenses complained of giving rise to the claim occurred in this District.

25. The Court has personal jurisdiction over each Defendant, because each Defendant (i) transacted business throughout the United States, including in this District; (ii) sold Plasma-Derivative Protein Therapies throughout the United States, including in this District; (iii) had substantial contacts with the United States, including this District; (iv) committed overt acts in furtherance of their illegal scheme and price-fixing conspiracy in the United States. In addition, the conspiracy was directed at, and had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

III. PARTIES

A. Plaintiff

26. **Plaintiff San Mateo County**, by and through its San Mateo Medical Center division ("Plaintiff" or "County" or "San Mateo Medical Center" or "SMMC"), administers a county system of health care providing high-quality inpatient services, outpatient services, and

long-term care, and employs more than 1,263 people, including physicians, nurses, researchers and pharmacist technicians. SMMC provides health care services through an acute care hospital, skilled nursing facility, and 11 clinics located across San Mateo County, California. The mission of San Mateo Medical Center is to serve the health care needs of all residents of San Mateo County, with an emphasis on education and prevention, and without regard for a patient's ability to pay. SMMC's service-based values state, "The purpose and focus of all we do is to serve our patients, our community and each other."

27. SMMC operates an acute care hospital, two long-term care/skilled nursing facilities, an impatient psychiatric unit, and various clinics which serve more than 40,000 patients per year, including those that require Plasma Protein-Derivative Therapies and for whom SMMC purchases Plasma Protein-Derivative Therapies. Its outpatient care clinics offer specialty, primary and pediatric care services in twelve different areas and serve patients that require Plasma Protein-Derivative Therapies and for whom SMMC purchases Plasma Protein-Derivative Therapies. SMMC also offers various public health services including provision of medical care for indigent County residents, health promotion programs, patient education programs and clinics, long-term care services, a center for family violence intervention, a pharmacy and laboratory. Provision of these public health services requires SMMC to purchase Plasma Protein-Derivative Therapies.

28. Based on the internal investigation SMMC has conducted to date, SMMC has spent millions of dollars for purchase of Plasma Protein-Derivative Therapies indirectly from Defendants CSL and Baxter during the relevant time period. As a result, the conspiracy alleged herein has caused substantial financial injury to the County including paying supracompetitive prices for Plasma Protein-Derivative Therapies, lack of access to lower priced Plasma Protein-Derivative Therapies, and lack of access to discounts and fair competitive pricing for Plasma Protein-Derivative Therapies to which it was otherwise entitled. This has added to the significant challenges that the County has struggled with in seeking to meet the healthcare needs of its most vulnerable residents.

B. Defendants

29. Defendant CSL Limited is a group of companies focused on a number of medical therapy products, with operations in the United States, Australia, Germany, and Switzerland. Its business operations began nearly a century ago developing commercialized vaccines and plasma therapies. CSL Limited is incorporated and domiciled in Australia, with its principal place of business located at 45 Poplar Road, Parkville, Victoria, 3052, Australia. CSL Limited is the second-largest supplier of Plasma-Derivative Protein Therapies in the world. It produces and sells biotherapies used for the treatment of primary and secondary immune deficiency diseases, coagulation disorders, and inherited respiratory disease. CSL Limited is a vertically integrated company: it owns and operates one of the world's largest plasma (the raw material out of which Plasma Protein-Derivative Therapies is manufactured) collection networks, CSL Plasma, with collection facilities and laboratories in Boca Raton, Florida and Marburg, Germany; and it owns and operates Plasma Protein-Derivative Therapies manufacturing sites through its wholly owned subsidiaries in Marburg, Germany and Bern, Switzerland. CSL Limited's worldwide sales for its 2008 fiscal year were about $2.5 billion. Ig sales accounted for 34% of CSL's total sales that year, and albumin, another one of its products (described below), accounted for 10% of its total sales.

30. Defendant CSL Behring LLC is a wholly owned U.S. subsidiary of CSL Limited with its principal place of business at 1020 First Avenue, King of Prussia, Pennsylvania 19406-0901. According to its website, CSL Behring is the second largest producer of plasma products in the United States. CSL Behring's products are used for the treatment of a range of disorders including hemophilia, von Willebrand disease, primary immune deficiencies, hereditary angioedema, inherited respiratory diseases and genetic emphysema. CSL Behring also produces products used in cardiac surgery, organ transplantation, burn treatment, and the prevention of hemolytic diseases in newborn infants. CSL Behring operates a manufacturing facility in Kankakee, Illinois. Behring's sales revenue totalled approximately $1.8 billion for its 2008 fiscal year.

31. Defendant CSL Plasma is a wholly owned U.S. subsidiary of CSL Behring with its principle place of business at 5201 Congress Avenue, Suite C220, Boca Raton, Florida 33487. CSL Plasma, previously known as ZLB Plasma, is one of the world's largest collectors of human plasma for the manufacture of Plasma-Derivative Protein Therapies. CSL Plasma operates more than 65 collection facilities in the U.S. and Germany. It has the largest plasma testing facility in the industry located in Knoxville, Tennessee and a logistics center located in Indianapolis, Indiana. Its German operations include a testing facility in Gottingen, Germany and a logistics center in Marburg, Germany.

32. Defendant Baxter International Inc. is a global, diversified healthcare company with more than 49,000 employees incorporated in Delaware with its principal place of business at One Baxter Parkway, Deerfield, Illinois 60015. Baxter is the largest producer of Plasma-Derivative Protein Therapies in the world, and is the largest producer of plasma products in the United States. Baxter offers its products in over 100 countries. Baxter is divided into three business major segments: BioScience; Medication Delivery; and Renal. The BioScience business manufactures and sells, among other products, biopharmaceuticals, biosurgery, vaccines, transfusions, recombinant and plasma-based proteins to treat hemophilia and other bleeding disorders, and plasma-based therapies to treat immune deficiencies, alpha l-antritrypsin deficiency, burns and shock, and other chronic and acute conditions. Medication Delivery focuses on intravenous products, anesthetics, nutrition antibiotics and chemotherapy, whereas Renal focuses on renal disease. Baxter maintains 15 manufacturing facilities in the United States and its territories, as well as facilities in 23 other countries. Its BioScience segment has 11 manufacturing sites domestically and abroad, including sites in Hayward, Thousand Oaks, and Los Angeles, California and in Beltsville, Maryland. In 2008, Baxter's net sales exceeded $12.3 billion, deriving about 20% of its sales from plasma products. In 2009, net sales totaled $12.6 billion, a 2% increase.

33. Defendant Plasma Protein Therapeutics Association (PPTA) is an international trade association founded in 1992, originally as the International Plasma Products Industry Association (IPPIA). Its European counterpart, the European Association of the Plasma Products

Industry (EAPPI), was founded in 1994. Formed by the union of the IPPIA and EAPPI in 2000, the PPTA is comprised of the global leading collectors of source plasma and manufacturers of Plasma-Derivative Protein Therapies. The PPTA is headquartered at 147 Old Solomons Island Road, Suite 100, Annapolis, Maryland 21401. The PPTA consists of global and regional boards of directors, elected from their member companies, which represent the geographic interests of its members. It does not include purchasers or patients of Plasma-Derivative Protein Therapies or any entities or groups that advocate for those groups' interests. The PPTA participated in and facilitated the conspiracy during the relevant time period (defined below).

C. Co-Conspirators

34. Various other individuals, firms and corporations, not named as Defendants herein, may have participated as co-conspirators with Defendants and performed acts and made statements in furtherance of the conspiracy. Plaintiff reserves the right to subsequently name some or all of these persons as defendants.

35. Whenever reference is made in this Complaint to any act, deed or transaction of any corporation, the allegation means that the corporation engaged in the act, deed or transaction by or through its officers, directors, agents, employees or representatives while they were actively engaged in the management, direction, control or transaction of the corporation's business or affairs.

IV. INTERSTATE TRADE AND COMMERCE

36. The activities of Defendants and their co-conspirators, as described in this Complaint, were within the flow of and substantially affected interstate commerce.

37. During the relevant period, Defendants CSL and Baxter sold substantial quantities of Plasma-Derivative Protein Therapies in a continuous and uninterrupted flow of interstate commerce, including through and into this District. Defendant PPTA facilitated and furthered the conspiracy.

38. The conspiracy in which the Defendants and their co-conspirators participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

V. BACKGROUND

A. Plasma Protein-Derivative Therapies

39. As the term "plasma-derivative protein therapies" suggests, these pharmaceuticals are manufactured, or *derived from*, proteins from human blood plasma. The source blood plasma needs to be collected at collection centers from paid and non-paid donors. Accordingly, the manufacturing process for Plasma Protein-Derivative Therapies is multi-stepped, time-consuming, and highly regulated. For both Baxter and CSL, the seven to twelve-month manufacturing process is now a vertically integrated process, which each controls from collection to distribution.

40. Plasma-Derivative Protein Therapies are essential treatments for a number of serious and life-threatening illnesses, including immune deficiency diseases, coagulation disorders, bleeding disorders, and respiratory diseases, for which there is no practical substitute. For at least 150 other illnesses, treatment with the Plasma-Derivative Protein Therapy Ig, while still technically "off-label," has been increasing in popularity. Accordingly, the market for Ig has seen an average 8% in growth annually in recent years.

41. As discussed herein, this has created a very strong and increased demand for Plasma-Derivative Protein Therapy, of which a very substantial portion is inelastic: i.e., regardless of the price, purchasers of Plasma-Derivative Protein Therapies – especially hospitals and other health care facilities – will purchase the pharmaceuticals if needed to treat patients with conditions that cannot be treated in any other method. The necessity for the products and the constricted supply left the County with no alternative except to pay drastically higher prices for Ig – especially for emergency orders.

42. This has allowed Defendants to drastically increase prices for Plasma-Derivative Protein Therapies, without experiencing any drop off in demand, causing their profits to soar.

43. The first step in the manufacturing process is plasma collection. Plasma is collected at specialized dedicated facilities at which people are attached to a machine which takes from them whole blood, extracts the blood plasma from the blood, and then pumps the remaining

blood constituents back into the person. This blood plasma is the raw material out of which Plasma Protein-Derivative Therapies are manufactured.

44. Formerly, plasma collection facilities existed throughout the United States and were operated by independent companies that sold the collected plasma to Defendants CSL and Baxter and other manufacturers of Plasma Protein-Derivative Therapies. However, as part of Defendants' efforts to control the supply of Plasma Protein-Derivative Therapies, and thus prices for these products, Defendants CSL and Baxter have purchased the formerly independent plasma collection companies, allowing them to control the supply in the market of the raw material out of which Plasma Protein-Derivative Therapies are created. This ultimately allowed CSL and Baxter to control the total quantity of Plasma Protein-Derivative Therapies that can be created out of that plasma. In 1999, over 75% of collection centers were independently operated and owned. By 2005, less than 10% of centers remained independent.

45. In addition to owning the vast majority of plants, Baxter also took advantage of its vertically integrated process by converting the blood processing equipment of its acquisitions to its own. One such acquisition, that of Apple Therapeutics, brought Baxter 41 additional plasma collection centers. Shortly after acquisition, Baxter announced plans to sell 38 out of the 41 newly-acquired collection centers. Baxter subsequently faced legal action by Haemonetics, Alpha's equipment provider and Baxter's only industry competitor for blood processing machinery, for not honoring existing minimum purchase agreements.

46. By United States Food and Drug Administration ("FDA") regulation, only blood plasma collected in the United States can be used to manufacture Plasma Protein-Derivative Therapies sold in the United States. This has allowed Defendants CSL's and Baxter's actions to control the supply of Plasma Protein-Derivative Therapies to be effective by controlling the supply of blood plasma. As no potential competitor is allowed to import blood plasma into the United States for use in the manufacturing Plasma Protein-Derivative Therapies, Defendants were able to effectively starve any potential competitors of raw materials by buying up independent plasma collection companies and closing down many of the facilities thereby acquired.

47. After the plasma is collected, it is processed through a time-consuming process called "fractionation." This involves precipitation of certain desired proteins from the plasma by manipulation of solution pH, temperature, and other methods. While the focus of Defendants' conspiracy was on the Plasma Protein-Derivative Therapies, Ig and albumin, this process fractionation also produces the plasma protein derived therapies alpha-1 and Rho-D.

48. Following fractionation, the products that will ultimately become Plasma Protein-Derivative Therapies are then run through a purification process, quality control, and lot release. Every step of this process is subject to strict regulatory control and supervision As discussed herein, these regulations make entrance into the market by another potential competing manufacturer very difficult.

1. Ig

49. Immune globulin or "Ig" refers to a class of proteins found primarily in blood that have an important role in providing immunity and treating a broad range of medical conditions. These globular proteins are also known as "antibodies." Antibodies bind to antigens (a bacterium, virus or other pathogen) in the blood and cue them for destruction.

50. Ig can be administered intravenously ("IVIG" or "IGIV"), subcutaneously ("SCIG"), or the intramuscularly ("IMIV"). Ig has over 20 FDA-approved indications, and as many as 150 off-label uses. Ig therapies are antibody-rich and have long been used in the treatment of primary immune deficiencies (to provide antibodies a patient is unable to make) and certain autoimmune disorders where it acts as an immune modulator. In addition, the off-label uses of Ig – *i.e.,* uses that are not described in the product's labeling and differ from those tested in clinical studies and approved by the FDA or other countries' regulatory agencies – include treatment of muscular dystrophy, graft-versus-host disease in transplant patients, prevention of antiphospholipid syndrome in miscarriages, and human immunodeficiency syndrome progression after delivery. For several of these conditions, including Guillain-Barre syndrome, Dermatomyositis, myasthenia gravis, Lambert-Eaton syndrome, and acute disseminated encephalomyelitis, treatment with Ig therapy can constitute the preferred standard of care and/or treatment of last resort. The medical significance of Ig also includes reducing the reoccurrence

rate of acute infections and symptoms in patients with immunodeficiency diseases. Ig, however, is a highly regulated commodity-like product, with no meaningful difference existing between Ig manufactured by one or another company.

51. SMMC uses Ig for, *inter alia*, first line treatment for diseases such as primary immunodeficiency diseases, and chronic inflammatory demyelinating polyneuropathy, a neurological condition. No reasonable substitute for treatment with Ig therapy is available for these conditions, and, because the County has a legal mandate to provide medical care to its indigent residents, the County must purchase Ig therapy to treat patients presenting with these conditions regardless of the price.

52. Ig represents the largest Plasma-Derivative Protein Therapy by value. The use of plasma treatment products helped grow the $5 billion market in 2000 to a nearly $10 billion industry in 2007. The global market was estimated to be $15 billion in 2009. According to a 2002 National Patient Survey, four out of five patients diagnosed with primary immunodeficiency disease had been treated with Ig. Two-thirds of the same group of respondents were contemporaneously being treated with Ig. Ig represents nearly half of the sales in the plasma market by revenue. It has grown from $400 million in 2000 to over $4 billion in 2008. Of the immune-deficient patients in the US, about half are currently treated with Ig therapies.

53. CSL's profits for the 2003-2004 fiscal year increased 150% over the preceding fiscal year. In the period 2002-2009, CSL's profits soared at an average annual rate of 40%. Its sales revenue from Ig sales increased from $260 million to $1.7 billion over the same span. Baxter's Ig sales totaled $1.5 billion in 2009.

54. Industry and Defendants reported the 2003-2004 Ig price to be about $40/gram. Over the following two years 2005-2006, the same sources reported the Ig price to average about $50/gram. Over the subsequent two years 2007-2008, the price of Ig topped $70/gram. During the relevant period Baxter's profits increased on average over 7% per annum. CSL's profits increased on average over 55% per annum during this period.

55. As the use of plasma therapies has increased for off-label uses, many patients do not gain access to Ig treatment for a number of reasons, primarily related to socio-economic reasons, including lack of insurance coverage and lack of access to primary care. The annual cost for such treatments can exceed $90,000 per patient in some cases.

56. It is estimated that approximately 70% of Ig sold in the United States is purchased by hospitals; 13% by physician offices; and 17% by home care companies and specialty pharmacies.

57. The County and other purchasers of Ig do so through what are effectively spot markets organized by independent distributors and/or through group purchasing organizations of which the purchaser is a member. Prior to 2007, the County did not have contractual allocations with a group purchasing organization and instead was subject to spot purchasing of Ig from distributors.

58. In 2007, in the face of market volatility caused by shortages in supply, the County switched to purchasing annual allocations of Ig from contractual distributors to obtain Ig. Medical providers such as the County, physicians, and hospitals purchase Ig through distributors and group purchasing organizations that buy from manufacturers. Manufacturers establish relationships with these contracted distributors. Distributors purchase Ig from manufacturers and then independently resell Ig to medical providers, or work in conjunction with GPOs to provide Ig to members of a GPO. GPOs are intended to provide their members with access to lower-cost products by negotiating prices for Ig from manufacturers. GPOs do not purchase drugs themselves; rather, they enter into group purchasing contracts with manufacturers on behalf of the GPO members. The contracts stipulate the terms under which GPO members can purchase plasma products. GPO members then purchase products from distributors or manufacturers according to terms specified in the contract. Distributors do not determine GPO contract prices; they only provide available drugs to GPO members on contracted-for terms.

59. In the case of purchases made through GPOs, the County and other purchasers are not guaranteed contracted prices, but rather are, depending on availability, supposed to have Ig available for purchase at prices lower than available on the secondary or *pure* spot market.

However, in the absence or seeming absence of available Ig, the County often did not have access to the lower priced Ig. Instead, the County was forced to pay a higher price for any available product in the spot market – especially in the case of emergencies. Even when the County made purchasing contracts through GPOs, its allocation was contracted for, but its prices were not. The County would often only have access to the more or most expensive product brands.

60. In 2002, the County was able to obtain the product for $45/gram on average. In 2003, supply increased and prices dropped to approximately $38/gram for the County. However, during the 2004-2007 period, as a result of Defendants' conduct, the County was paying on average $70/gram for Ig therapies. Defendants and others falsely explained this pricing as the product of a supply shortage. In 2008-2009, the County paid prices at $75/gram and above for these same products. When seeking emergency supplies of Ig, the County was limited to a single distributor that generally offered one available product option at one price. The spot prices that the County paid were consistently at least ten dollars higher per gram than the previously described industry figures.

2. Albumin

61. Albumin is the most abundant protein in human plasma. It is synthesized by the liver and performs multiple functions, including the transport of many small molecules in the blood and the binding of toxins and heavy metals, preventing the damage that these toxins otherwise might cause. Thus, Albumin is often used in surgical and trauma settings and typically is sold to hospital groups. Albumin is commonly used to expand blood volume and to prime heart values during surgery.

62. Albumin is a commodity-like product for which there are no good or reasonably interchangeable substitutes. Physicians and hospitals regard albumin as far superior from a clinical standpoint to any potential alternatives, such as hetastarch and saline products.

63. San Mateo Medical Center uses albumin for first line treatment for blood volume expansion and for heart valve priming during surgery.

64. The County's purchases of Albumin reflects unusual pricing trending throughout the relevant period similar to that of Ig discussed above. From 2002 through 2004, the price of

Albumin per gram was steadily available to the County at a rate of $2/gram. When the industry supply increased, prices dropped in 2005 to $1.3/gram. However, starting in late 2005 onward, prices steadily increased without relief. In 2006, the County bought Albumin at prices on an average of $1.75/gram. This pattern of price increases continued through 2007, rising above $2/gram. By late 2008, prices soared north of $3 per gram through the end of the year. Defendants' manipulation forced some spot purchases by the County in early- and late-2009 for as much as $3.6/gram. These inflated prices continue to dictate the market price.

B. Relevant Geography

65. Like all pharmaceutical products, each Plasma-Derivative Protein Therapy must be approved for sale in the United States by the FDA. To obtain approval, the products must be produced from plasma collected in the United States at collection centers approved by the FDA. The products also must be manufactured at plants approved by the FDA.

66. Performing the requisite clinical trials and undergoing the FDA approval process for plasma and Plasma-Derivative Protein Therapies takes well over two years. Accordingly, Plasma-Derivative Protein Therapies produced outside of the United States are not viable: competitive alternatives do not exist for United States customers, who cannot buy products produced abroad even in the event of a price increase for products available in the United States.

C. Market and Industry Factors Conducive To Creation Of Anticompetitive Conspiracy

67. The structure and characteristics of the Plasma-Derivative Protein Therapies markets and industry have encouraged and facilitated Defendants' conspiracy.

1. Commodity-Like Products

68. A commodity-like product is one that is considered to be matured in its development life cycle and standardized, allowing for a high degree of substitutability in the market. When products offered by different suppliers are viewed as interchangeable, commoditized products by purchasers, it is easier for suppliers to agree on and to monitor set prices for the product.

69. Moreover, producers of commoditized products face substantial price pressure; price being the principle basis on which such producers can compete. This, in turn, creates a substantial incentive for producers to fix prices, rather than engage in price competition, which would reduce profits for all.

70. Plasma-Derivative Protein Therapies are homogeneous, commodity products within a given product category (e.g., Albumin or Ig), and one Defendant's Plasma-Derivative Protein Therapies easily can be substituted for corresponding products made by the other Defendant. Indeed, Talecris noted in a 2008 SEC filing that "[a]mong albumin products, competition is generally based on price, given that the products tend to be homogeneous" (emphasis added).

71. Because Plasma-Derivative Protein Therapies are commodity-like products, purchasers make purchase decisions based predominantly, if not entirely, on price.

72. The Plasma-Derivative Protein Therapies are bought and sold in a spot market, a market in which a commodity is bought or sold for immediate delivery or delivery in the very near future.

73. During the relevant period, Plaintiff purchased Ig and albumin on a regular basis through the spot market. Plaintiff was forced to accept whatever price it was quoted in order to receive the Plasma-Derivative Protein Therapies it required for its patients. Plaintiff was often told that the only available Ig and albumin was the more expensive brands, most often one of Defendants' products.

2. Lack of Substitutes

74. The FDA classifies Plasma-Derivative Protein Therapies as sole-source biological products that are not interchangeable with one another or any other product. There are no acceptable generic or substitute product for the therapies. The lack of available substitutes for a product also helps facilitate an effective price-fixing conspiracy. Without substitutes, producers of the product can raise prices without losing significant sales to closely competing products.

75. For hospitals, physicians, and others that use Plasma-Derivative Protein Therapies, there simply are no suitable substitutes for these products, at any price. They must

purchase Plasma-Derivative Protein Therapies regardless of the price; nothing else will do. Indeed, as Patrick Robert of the Marketing Research Bureau Inc. has noted, "therapeutic plasma proteins [which includes Plasma-Derivative Protein Therapies] remain essential life-saving drugs for which there is still no competitive drug" (emphasis added).

3. Industry Concentration

76. Due to the highly advanced and expensive manufacturing process and high profile public health interests, there is a higher degree of industry concentration facilitating coordination amongst industry participants.

77. The combined U.S. market share of CSL and Baxter as a percentage of the overall plasma derivative protein industry is estimated at about 60 percent. Baxter maintains a 36 percent share, while CSL Behring holds a 24 percent share of the market. The next largest manufacturers, Talecris, Grifols USA ("Grifols"), and Octapharma USA, Inc. ("Octapharma"), collectively control about 35 percent of the U.S. market share. Talecris, which was targeted for takeover by Defendant CSL, notably possesses a 23 percent share of the overall domestic market for such products.

78. Defendants' combined market share of the Ig market is even higher. In 2008, Defendants' sales volumes combined to total 62.9 percent market share of the domestic Ig market. Baxter had 35.4 percent and CSL had 27.5 percent of the domestic market. The next three largest manufacturers, Talecris, Grifols, and Octapharma possessed 20 percent, 9 percent, and 7.2 percent of the market, respectively.

79. Defendants' combined market share of the Albumin market is even higher still. According to 2008 domestic market sales volume information for Albumin, Defendants CSL and Baxter collectively possessed approximately 73 percent of the market. CSL and Baxter possessed 36.61 percent and 36.44 percent of the markets respectively. The remaining top suppliers, Talecris, Grifols and Octapharma possess market share percentages of 8.83, 13.06, and 5.07, respectively.

80. The FTC and U.S. Department of Justice use what is known as the Herfindahl-Hirschman Index ("HHI"), a statistical measure of the sum of squares of the market shares of the

50 largest firms in an industry. The HHI measures firm size relative to market size and the degree of concentration. An HHI value below 100 indicates a very competitive market whereas, any value over 1,800 is an indication of high concentration. According to the HHI, to determine market concentration, the domestic Ig market has a calculated value of 2,579 in 2008. The HHI value for the Albumin market in 2008 was 2,942 - even more concentrated than the domestic Ig market.

81. The fewer competitors that exist in an industry, the more likely it is for collusion to occur, because with fewer competitors, it is easier to arrive at a consensus and to monitor each other's price and supply decisions. In a duopoly, such as that which effectively exists between CSL and Baxter as to Plasma-Derivative Protein Therapies, collusion is even easier. The major market players do not have to worry about the small competitors because, even if the small competitors are not part of the agreement to restrict output, they do not have enough capacity to significantly blunt price increases caused by the large competitors' conspiracy to limit supply.

82. Throughout the relevant period, Defendants collectively possessed market power to raise prices above competitive levels in the Plasma-Derivative Protein Therapies markets in the United States without losing appreciable market share to non-conspirators.

4. Barriers to Entry

83. Barriers to entry are obstacles that prevent new market entrants from competing in the market. The presence of significant entry barriers to potential competitors that could otherwise cause the incumbents to reduce their prices helps facilitate coordination among co-conspirators.

84. The market for Plasma-Derivative Protein Therapies is characterized by high entry barriers. No firm has entered the market in recent history, and prospective entrants have little chance of making a meaningful market impact in the foreseeable future. As of 2007, only five firms had approval by the FDA to supply Ig to the U.S. market: Baxter, ZLB Behring, Talecris, Grifols, and Octapharma.

85. According to CSL's own observations, there are "immense barriers to entering the market" for Plasma-Derivative Protein Therapies. CSL, in fact, identifies "significant barriers to

entry" as one of the six "key characteristics of the Ig market," and notes that there is "[n]o realistic prospect for an increase in the number of firms." Talecris similarly noted that "significant regulatory, IP, and capital barriers to entry mitigate the threat of new competitors as well as capacity increases for several years."

86. Each step of the manufacturing process for Plasma-Derivative Protein Therapies involves substantial production time-intervals, complex processes, inspection processes, up-front costs, onerous and lengthy regulatory approvals by federal and state agencies, and specialized technical expertise.

87. In 1997, the FDA increased the corrective measures imposed on fractionators in order to comply with Good Manufacturing Practices. The fractionation process of plasma to derive the many different derivative protein components is a complex industry application requiring expenditures on plant equipment and research and development. Equally as costly and challenging is the need for developing improved methodologies for increasing the protein yield.

88. Entry into the Plasma-Derivative Protein Therapies markets also requires a significant amount of intellectual property, including trade secrets relating to increasing the protein yield, purification of products and pathogen safety, quality control testing, and substantial product research and development.

89. Regulatory hurdles by the FDA further pose significant barriers to entry and extend the time it would take a new entrant to enter the US market, let alone gain market share.

90. In addition, the construction and maintenance of production facilities, including regular improvements necessitated by evolving standards of manufacturing practices, require extensive capital expenditures and may involve long lead times to obtain the necessary governmental approval.

91. Any new market entrant in the United States also would need to secure an adequate supply of domestic plasma, because only plasma collected in the United States is certified for use in products sold domestically. Because there currently are only a very limited number of independent plasma suppliers, most of whose plasma collection and center development capacity is already contracted to existing manufacturers, if not owned by them, any

new competitor likely would have to develop its own domestic-based plasma collection centers and related infrastructure.

5. Demand Inelasticity

92. Price elasticity of demand is the measure of responsiveness in the quantity demanded for a product as a result of change in price of the same product. Inelastic demand is a market characteristic that facilitates anticompetitive behavior, allowing suppliers to raise prices without triggering product substitution and diminished revenue. Thus, inelastic demand is another indicator that a price-fixing conspiracy would be successful.

93. The demand for Plasma-Derivative Protein Therapies is highly inelastic. Plasma-Derivative Protein Therapies are considered medical necessities that must be purchased by hospitals, physicians, and others at whatever the cost. Moreover, there are no close substitutes for these products.

6. Opportunity for Conspiratorial Communications

94. Defendants CSL and Baxter are global members of trade associations, such as the PPTA and the IDF, and regularly maintained communications, attended meetings together and meet privately before or after these association meetings.

95. As previously noted, the PPTA bills itself as "the primary advocate for the world's leading source plasma collectors and producers of plasma-based and recombinant biological therapeutics;" Baxter and CSL are members of the PPTA; and no purchasers or patient advocacy groups count themselves as members of the PPTA.

96. The annual association meeting, known as the Plasma Protein Forum, is held annually in June in the Washington, D.C. metropolitan area, and high-level executives from Defendants, such as Messrs. Turner and Guiheen, routinely attend. The PPTA also holds regular conferences such as the PPTA Business Forum, which took place in New Orleans, Louisiana on October 25, 2009.

97. Defendants also gather regularly for the stated purpose of discussing relevant regulation, which provides Defendants with an opportunity to share information.

98. As discussed elsewhere herein, in 2008 executives from CSL and Baxter gathered monthly with the IDF for the stated purpose of developing legislation to restore access to Ig supply to hospitals, homecare, and other sites.

99. Such meetings provide the opportunity for participants in anti-competitive conspiracies such as this one to meet, to have improper discussions under the guise of legitimate business contacts, and perform acts necessary for the operation and furtherance of the conspiracy.

100. Defendants also used private analysts as go-betweens to swap competitive information about their stock of plasma-protein supplies. Analysts regularly called Defendants to ascertain supply levels because supply correlates to price in the plasma-protein derivative market. After having spoken with one Defendant, analysts would call the other Defendant, and relay supply information.

101. Moreover, Defendants use the same market research firm, the Marketing Research Bureau, to estimate future demand for Plasma-Derivative Protein Therapies and to monitor pricing trends.

VI. DEFENDANTS' CONSPIRACY

A. Groundwork For Conspiracy Laid In Late 1990s And Early 2000s

1. Late 1990s: Decreased Supply, Growing Demand, And Government Intervention

102. During the late 1990s, a series of supply shortage events caused by at least 24 FDA-ordered product recalls, a decline in donated plasma, and temporary plant closures resulted in extensive decreases in domestic and global supply of Plasma-Derivative Protein Therapies.

103. In 1997, in the wake of a series of recalls of albumin produced by Centeon, the FDA mandated the temporary closure of the plant then owned by Centeon at Kankakee, Illinois (a plant which CSL Limited now owns). FDA recalls on plasma products were prompted by elevated standards for refined plasma products and the prevalent fear of contaminating diseases. In 1999, the Alpha Therapeutic Corporation plant in Los Angeles, California (a plant which Baxter now owns) was temporarily shut down. The shortages that resulted from these disruptions, particularly with respect to Ig, caused higher prices in the United States, spurring

producers to increase plasma collections, as well as output of Plasma-Derivative Protein Therapies.

104. These plant closures and supply shortages garnered the national spotlight in 1997 and 1998. During this period, the need for tighter and more extensive regulatory control grew as the industry faced new challenges and threats to the safety of the blood and plasma supply, including the growing awareness of the risk of variant Creutzfeldt-Jakob Disease. Congress held hearings on the safety of plasma-derivative protein therapy products, and the television program "60 Minutes" produced a segment discussing Ig supply shortages.

105. This spotlight led to heightened regulation of the collection and manufacturing of Plasma-Derivative Protein Therapies, including a mandate by the FDA that the industry implement various "good manufacturing procedures."

106. Additionally, the FDA required that the industry monitor the distribution levels of Plasma-Derivative Protein Therapies. Pursuant to 21 C.F.R. § 600.81, the FDA required suppliers to provide the Center for Biologics Evaluation and Research ("CBER"), a division of the FDA, with *bi-annual* data regarding the distribution levels for all Plasma-Derivative Protein Therapies.

107. IPPIA, a trade association that represented industry manufacturers, unilaterally volunteered to submit *monthly* data to the FDA/CBER regarding distribution *and* inventory of Plasma- Derivative Protein Therapies for each of its members. The IPPIA further promised to make aggregated data available to the public at large; competitor-specific data would be made available to the Center for Biologics Evaluation and Research. The data volunteered by the IPPIA went beyond that required by the FDA, and assisted Defendants in implementing and monitoring their conspiracy.

2. <u>June 1999 Meeting Regarding Industry Supply Monitoring</u>

108. The Blood Products Advisory Committee, an FDA/CBER committee responsible for the regulatory oversight of the U.S. blood supply, held a meeting in June 1999 at its headquarters in Rockville, Maryland attended by FDA officials, industry representatives, and patient representatives.

109. Plasma manufacturers were represented at this meeting by Dennis Jackman, the Vice-President of the IPPIA. Mr. Jackman also served as executive director of the Plasma Protein Therapeutics Association. Mr. Jackman currently serves as a Senior Vice-President at CSL Behring. During his time as the Vice-President of the IPPIA and executive director of the PPTA, Mr. Jackman had access to distribution and inventory data for the entire industry, some of which he presented at the meeting.

110. At the meeting, the FDA presented individual company sales data and monthly distribution data for 1998. While distribution figures for individual companies were not revealed, anyone with knowledge of each company's market share could easily determine such company's distribution totals.

111. During the meeting, Mr. Jackman stated that future supply would be "heavily impacted" by the industry's "investment in plant capacity and new processes." *Id.* 215:8-10. Mr. Jackman further affirmed the industry's purported goal of meeting demand. "Individual companies and members of our association . . . are going to seek to meet demand." Blood Products Advisory Comm. Mtg., Tr. 217:21-22 (Jun. 16, 1999). However, Jackman cautioned participants, the industry had to be very careful how they worked to meet demand in light of antitrust laws. Despite the legal obstacles, he stressed, "we are trying to collaborate in any way we can and cooperate by providing our monthly data." *Id.* at 215:5-6.

112. Mr. Jackman, however, communicated the industry's intent in "collaborating" and sharing sensitive data regarding output and inventories. This output signaling would become Defendants' eventual strategy for restricting total market supply while increasing price in the marketplace.

113. Industry participants, including Defendants CSL and Baxter, also held discussions regarding future demand for Plasma-Derivative Protein Therapies. From this meeting it became clear that the demand for Plasma-Derivative Protein Therapies, particularly Ig, had grown and would continue to grow.

114. Representatives from the research firm Marketing Research Bureau, Inc. also attended the meeting to discuss demand trends. The Marketing Research Bureau is an

independent organization that monitors a range of industries including the blood plasma market and the plasma-derivatives market and it provides Defendants and other manufacturers with industry-related reports to distribution, price, and demand for plasma derivative products. The Market Research Bureau provides the industry – including Defendants – with annual reports detailing the demand for blood plasma derivative products and pricing information across both domestic and global markets.

115. The Marketing Research Bureau noted in its analysis that market demand for Ig had observed "fairly steady growth" in the last 17 years. The market for Ig in 1998 was 15.5 million grams, and the Marketing Research Bureau had projected that the market in 2000 would be 18 million grams – a 16 percent increase. The Bureau emphasized in its report that future demand would be increasing.

116. CSL, Baxter and the industry's other suppliers were well aware of the growing demand for Plasma-Derivative Protein Therapies. According to remarks from a distributor representative at the meeting, industry executives from the plasma fractionation market estimated annual demand at 21 to 25 million grams for 1998, estimates well above those of other attendees.

117. Another research group, Georgetown Economic Services, made presentations at the industry meeting. The IPPIA initially contracted Georgetown Economic Services to analyze distribution and inventory data provided by the plasma manufacturers. Georgetown Economic Services continues to provide this service for the PPTA, the successor organization to the IPPIA.

118. Georgetown Economic Services reported its plan to assemble information to predict demand for plasma-derivative products over the next year, three years, and five years. To paint a picture of future demand, they intended to gather distribution data from the manufacturers, wholesalers, group purchasing organizations, and home health care providers. Next, they planned to interview private and government scientists to assess future demand related to scientific breakthroughs and potential off-label uses.

119. These industry trade meetings provided the foundation for accomplishing key goals of Defendants' future conspiracy: Defendants' trade association began its inventory and supply data monitoring effort; the Marketing Research Bureau and Georgetown Economic

Services announced plans to monitor future demand for the industry collectively; and Dennis Jackman was made privy to inventory and supply data for the major plasma manufacturers in the industry.

3. Years 2000 - 2003: Increasing Supply and Declining Profits

120. Between 2000 and 2003, formerly closed production facilities, CSL Behring's Kankakee facility and Baxter's Los Angeles facility, had begun to operate again. These extra production sources contributed to an abundant supply of Plasma-Derivative Protein Therapies in the market. The excess supply in the market led to significantly lower market pricing, causing a one-third reduction in operating margins for Baxter, CSL, and other suppliers. Also, because fixed costs represent a major component of cost for plasma protein production, suppliers accordingly experienced a significant drop in profits.

121. The lower price and additional supply transformed the industry. On October 16, 2003 in an annual address, CSL Limited Chairman noted that its plasma business "had a difficult year primarily due to what he alleged was "an oversupplied US market." The competitive market conditions and lack of profit convinced the producers within the industry to reduce both collection and manufacturing of therapies. This overall decrease in operations also led to vertical integration within the industry.

122. During this period of excess supply, Defendants' trade association, the PPTA, refined its data monitoring system and began exploring the repercussions and legal parameters of the antitrust laws.

123. In April 2001, Former PPTA's President, Jan Bult presented supply monitoring issues in the industry. Bult noted that because the plasma manufacturing industry was concentrated, it had to be especially careful of running afoul of the antitrust laws. He explained that the association had a difficult approach in balancing what would be considered collusive behavior versus a legitimate "sharing of knowledge." He asserted that the industry was "not allowed to facilitate information exchange among members which are focusing on the future situation. Of course, we are free to talk about what has happened and what is the retrospective

data, but about future issues it's very difficult." *See* Advisory Comm. on Blood Safety and Availability, (Apr. 20, 2001) available at http://www.hhs.gov/ophs/bloodsafety/advisory committee/pastmeetings/transcripts/20010420.htm(last accessed August 23, 2010).

124. The practice of the PPTA was and is to publicly provide aggregate trailing monthly figures totaling production through its website. The FDA receives each individual supplier's production numbers by regulatory requirement. The PPTA has reiterated how careful the industry participants had to be when discussing supply data: "You can think you can be very creative and find ways to have public announcements and organize meetings and do it that way. It doesn't work. It doesn't work because there are statements that say these disclosures could be viewed as a means of signaling competitors so they can make plans based upon the activities of the other manufacturers. And we cannot do that." *Id.*

125. Mr. Bult especially noted the borderline legality the PPTA organized to gather and monitor supply and output information from industry participants. He admitted, *"Well, we had a discussion today about inventories. I just want to make you aware that we are at the edge [of] what we can do from a legal point of view." Id*. (emphasis added).

4. Development of a Industry Supply Monitoring System

126. During the Fall of 2002, the PPTA launched a new data monitoring system that would allow manufacturers to monitor total industry output – the system would ultimately become a key means by which Defendants monitored and policed the conspiracy.

127. According to its President, Jan Bult, the PPTA would track data for seven groups of products that include different formulations of Albumin, recombinant Factor VIII, high purity Factor VIII, and immunoglobulins. The PPTA announced the creation of a "light system," which would warn industry participants when inventory levels of Plasma-Derivative Protein Therapies reached certain levels. Working closely with economists, the PPTA identified ideal inventory to distribution "ratios" for the industry. Inventories were labeled "red" when approximately two weeks or less of inventory was available; "yellow" when two to five weeks of inventory was available; and "green" when greater than five weeks of inventory was available. Desired

inventory levels were based on the ratio of the existing inventory on the first day of the month to the average distribution of a particular protein therapy over the previous 12 months.

128. According to Vice President of the PPTA's North American division, Ms. Birkofer, "these ratios were developed in very close consultation with economists and experts in the field of data collection and analyses."

129. In a highly concentrated industry such as the Plasma-Derivative Protein Therapies industry, a monthly warning system that reports current inventory levels is potentially a very effective mechanism for monitoring competitor supply and output levels. This potential to coordinate effectively is enhanced by the availability of bi-weekly data in the Plasma-Derivative Proteins industry that tracks a wide range of products. However, when the system was first implemented, the PPTA did not represent all Plasma-Derivative Protein Therapies manufacturers; two manufacturers were not members, which limited somewhat the potential effectiveness of the "light system" as a mechanism for facilitating a conspiracy to limit supply and increase prices. However, the independence of those manufacturers soon disappeared.

5. Industry Consolidation

130. Due to barriers of entry and regulation, there have always been a limited number of approved manufacturers of plasma products for sale in the U.S. market. However, this number has substantially shrunk over time. In the 1990s, there were at least 13 domestic producers of Plasma-Derivative Protein Therapy products. In 2003, that number was reduced to nine. Since 2005, there have been only five: CSL Behring, Baxter, Talecris, Grifols, and Octapharma. According to a study by the Department of Health and Human Services (HHS) in 2006, the three leading manufacturers of Ig (CSL Behring, Baxter, and Talecris) controlled 85 percent of the market share.

131. Effectively, the U.S. market is controlled by the three largest producers: CSL Behring, Baxter and Talecris. Grifols and Octapharma are much smaller, with market shares less than 10 percent, and a limited ability to expand their presence in the United States. All five producers are part of the Global PPTA membership body.

132. The result of this highly concentrated industry structure is that the contract, combination and conspiracy alleged herein does not require the participation of the smaller firms to be effective. In particular, the two smallest firms, Grifols and Octapharma, are not in a position to effectively compete or to blunt any price increase by the larger firms, because the smaller firms have limited production capacity. While they could lower prices, they could not capture enough volume to make the cartel price unprofitable. Talecris' growing expansion presented a threat to the market dominance of CSL and Baxter. This led to an attempt by CSL to first acquire Talecris for $3.1 billion in 2008. This merger/acquisition was supported by Baxter.

133. Several smaller plasma collection firms merged or were acquired over this period of time as well. The large, integrated suppliers, most notably Defendants Baxter and CSL, have acquired numerous independent plasma collectors and facilities, and continue to do so. Soon after acquiring these facilities, Defendants shut down many of them in order to reduce supply.

134. In July 2000, CSL acquired the Swiss Red Cross fractionator, ZLB, and acquired 47 plasma collection centers and laboratory facilities operated by Nabi in 2001. CSL also acquired Aventis Behring's plasma products business in 2004, combining it with ZLB Bioplasma to create ZLB Behring, today known as CSL Behring. CSL subsequently closed 35 plasma collection centers in the United States, reduced plasma collections by 1 million liters, and reduced plant output by 1.1 million liters.

135. On February 1, 2001, Baxter announced the acquisition of Sera-Tec Biologicals LP for the stated purpose of ensuring "[l]ong-term access to a consistent, stable supply of source plasma." Sera-Tec was a major independent supplier of source plasma. The company owned and operated 80 plasmapheresis centers in 28 states and a large central testing center. The acquisition allowed Baxter to control over 110 collection centers worldwide.

136. In late 2002, Baxter acquired 42 plasma collection centers and a laboratory from Alpha Therapeutic Corporation (Mitsubishi Pharma). In early 2003, Baxter shut down 13 collection centers. Baxter subsequently closed a total of 26 of its own plasma collection centers and 38 collection centers that it acquired from Alpha Therapeutic, as well as a plasma manufacturing plant in Rochester, Michigan.

137. As one investment firm with knowledge of the industry has noted, "[a]bout 80% of the [plasma collection] centers are now owned by plasma-products companies such as Baxter International, CSL Limited, Grifols, and Talecris Biotherapeutics. This represents a complete reversal in ownership since 2000, when 80% of the centers were independent enterprises." *See* Turner Investment Partners, "Will plasma products' prospects remain sunny?" (Feb. 6, 2008) *available at http://www.turnerinvestments.com/index.cfm/fuseaction/commentary.detail/ID/2500/CSID/387/* (last accessed May 28, 2010).

138. In 2005, the American Red Cross, a major plasma supplier, exited the plasma products industry. From the 1980s through the 1990s, the Red Cross controlled upwards of half of all blood collected in the United States. Baxter purchased the American Red Cross's remaining supply of plasma.

139. Presently, the plasma products industry has lower inventory than it did even six years ago. The remaining suppliers, most notably among them Defendants Baxter and CSL, are larger and more vertically integrated than ever before.

140. All five of the remaining plasma manufacturers are global members of the PPTA. As members, they submit monthly distribution and inventory data to the PPTA, as well as attend regular meetings.

B. Defendants Utilized Various Means To Restrict Supply And Fix Prices Of Plasma Protein-Derivative Therapies

141. Defendants' conspiracy to restrict supply and increase prices for Plasma-Derivative Protein Therapies began at least as early as July 1, 2003 and has continued through the present. Through the consolidation of firms and the coordination of the Plasma-Derivative Protein Therapies industry, supply has been held to artificially low levels in the face of increasing demand, causing prices to increase. GPOs, distributors, hospitals, physicians, and patients have experienced unpredictable supply shortages along with increased prices.

142. The PPTA has played an important role in facilitating information exchange between CSL and Baxter, explaining the economics of the industry, and both gathering and presenting data to monitor Defendants' compliance with supply restrictions. The association has

used the pretext of avoiding public health emergencies in times of supply shortages to justify monitoring, collecting and distributing competitor output information.

143. Once Defendants restricted the supply of Plasma-Derivative Protein Therapies, the PPTA helped maintain the conspiracy by coordinating an effort to prevent a government declaration of a public health emergency due to supply shortages.

144. The co-conspirators implemented their illegal agreement by coordinating and restricting output and by sharing inventory and production information with one other. While the source production data of each conspirator was supposedly confidential in nature, the obvious differences in the scale and magnitude of supply and production values readily identified the source of such information by industry participants. This was particularly so once CSL and Baxter collectively controlled an overwhelming majority of the market. Indeed, during and after the period of excess capacity earlier in the decade, Defendants recognized that controlling capacity was critical to preventing price competition and increasing profits.

145. Integral to the conspiratorial collusion was the Defendants' focus on coordinating the limitation of supply of Plasma-Derivative Protein Therapies in the marketplace, as the firms were acutely aware that restrained output was profitable only if they cooperated. CSL referred to this as the *"OPEC problem,"* explaining that "[w]henever capacity is greater than profit maximizing output levels, *there is a danger that a firm will 'break ranks' and chase market share, with the result that prices will fall." See Fed. Trade Comm'n Complaint v. CSL Ltd.*, No. 09-cv-1000 at ¶ 41 (D.D.C. Nov. 11, 2009) (emphasis added). Baxter similarly has recognized that as long as competitors are not "*irrational*" and do not "*trash price and take share*," they can increase supply steadily in line with market demand to keep prices high. *Id.* (emphasis added).

146. The conspiratorial actions taken by Defendants in pursuit of these goals is categorized into a number of methods: (1) acquisition of competing manufacturers, followed by significant closures of acquired plants and blood plasma collection facilities; (2) using various means to signal to each other when supplies to the market of Ig and/or albumin should be restricted in order to maintain, or raise the price of the products; (3) expansion and refinement of the data monitoring system set-up under the aegis of government intervention in the 90's, to

enhance their ability to monitor each other's current inventory and supply levels, and thus effectively police the conspiracy and determine whether signals to reduce supply should be sent; (4) falsely denying the existence of supply shortages, over-reporting industry supply figures, and misleadingly attributing patient difficulties in obtaining Ig and/or albumin to Medicare reimbursement rates, in order to disguise the mechanisms and effects of the conspiracy and ward off government intervention; and (5) using PPTA meetings, private meetings in bars and restaurants following such meetings and other business meetings to conduct anticompetitive discussions regarding supply and pricing.

1. Defendants Acquired Competitors And Closed Former Competitors' Plants To Reduce Supply Of Plasma Protein-Derivative Therapies

147. Since as early as 2003, CSL and Baxter began conspiring to control the supply of plasma products. Given the small number of firms and the market dominance of the two largest suppliers, CSL and Baxter determined that market conditions were susceptible to manipulation. CSL recognized doing so as one of their "critical success factor[s]" in maintaining the artificially high supply/demand equilibrium and the high prices.

148. After previous shortages disappeared, CSL and Baxter focused on preventing any oversupply of IVIG and plasma. As a key part of this strategy, CSL and Baxter initiated the purchase of plasma donation and manufacturing facilities and promptly closed a substantial number of those acquired with the apparent purpose of limiting supply.

149. Dennis Jackman left his position as an executive director of the PPTA in 2003 to take a post as a Senior Vice-President at CSL Behring. In this new position, Jackson could implement the strategy, first laid out in 1999, of restricting supply and increasing prices by acquiring and closing plasma collection centers and fractionation facilities.

150. In July 2003, Baxter announced plans to restructure its business, including closing or consolidating facilities, simplifying infrastructure and eliminating a number of positions to improve its plasma economics by reducing the amount of plasma collected and fractionated, and optimizing its supply. Baxter reported that it planned to reduce its total annual plasma production from 4.6 million liters to 4.0 million liters, a total reduction of approximately 13%.

At that same time, Baxter announced that it planned to close 26 plasma collection centers as well as its Rochester, Michigan fractionation facility. This was an early foundational maneuver in Defendants' coordinated efforts to reduce supply.

151. In December 2003, CSL Limited announced that it had acquired rival Aventis Behring. Initially, CSL described the acquisition as an opportunity for CSL to achieve synergies of operation. In January 2004, after the deal cleared key regulatory hurdles, CSL's managing director, Dr. Brian McNamee, stated that he believed full integration of the two companies could take 18 months, but predicted that benefits of the merger would be seen within a year. Within the CSL Group, ZLB Behring's President Peter Turner, also added that the combined Ig production capabilities of both companies would bring about "enhanced economic returns" due to among other factors, lower cost plasma sourcing.

152. The acquisition of Aventis Behring was finalized on April 1, 2004. Included in the deal was acquisition of manufacturing facilities in Kankakee, Illinois, Marburg, Germany, and Vienna, Austria. The Kankakee facility manufactured almost twice as much Plasma-Derivative Protein Therapies, by volume, as the other two sites combined. Immediately after the deal's finalization, CSL announced that it would reduce plasma input at its Kankakee facility by half and that the Kankakee facility would cease production of three plasma products. CSL thusly signaled to Baxter that it would join Baxter's efforts to reduce supply.

153. CSL has, in fact, admitted in federal court that the its purpose in acquiring Aventis Behring and reducing production at the Kankakee facility was to reduce the global supply of Plasma-Derivative Protein Therapies; this is contrary to CSL's statements before the deal closed. These admissions occurred in a suit unrelated to this action. *Gloria Fletcher, et al. v. ZLB Behring,* No. 05-cv-2695 (N.D. Ill. Jul. 12, 2007).

154. After its acquisition of Aventis Behring, CSL set its sights on further consolidation of the industry and the effects that it believed "[o]ne further round of consolidation" would produce:

> If the number of significant market participants were reduced from 5 to 4, and the new entity were to reduce capacity by 25% (not atypical), then:

1. The new entity would be more profitable than would be the aggregate of the separated firms (depending on the merger combinations). That is, the merged entity could appropriate some of the gains.

2. Market prices would rise soon after the capacity rationalization.

3. The market would become less risky because the number of firms that profit by raising output would be reduced from 3 to 1 (or from 3 to 2).

4. [CSL] would benefit as a participant in the merger, or as a bystander.

155. CSL further concluded that it was "less likely that a further [CSL] or Baxter acquisition (affecting the US market) would get FTC approval." *See Fed. Trade Comm'n Complaint v. CSL Ltd.*, No. 09-cv-1000 at ¶ 11 (D.D.C. Nov. 11, 2009).

156. CSL also destroyed its own plasma inventories in order to reduce the supply in the market of the materials, with the apparent goal of artificially inflating plasma product pricing. On at least on one occasion, CSL destroyed plasma paste at its Kankakee manufacturing facility. Plasma paste is derived from plasma during manufacturing. The paste is the intermediate form of product before plasma can be manufactured into Ig or albumin. Thus, by destroying supply, CSL limited the availability of Plasma-Derivative Protein Therapies.

157. The reduction in output by both manufacturers demonstrated the effectiveness of output signaling in a duopoly where two firms dominate the market. Then on April 22, 2004, Baxter announced that it intended to further reduce plasma production by another 13% (or 400,000 liters); and in 2005, Baxter closed some of the blood collection facilities it had acquired when it purchased the American Red Cross's plasma supply.

158. Defendants initially tried to downplay shortages resulting from their supply restrictions. In the summer of 2004, CSL informed one of its salespeople that it did not foresee a shortage of Ig or albumin. Less than two months later, and shortly after a similar announcement from Baxter, CSL announced a shortage of Ig and albumin. CSL gave its own employees no advance warning of the shortage.

159. CSL and Baxter collusively and intentionally created these shortages, and provided pretextual explanations for the shortages they had worked to create. The Plasma-Derivative Protein industry reported a variety of excuses to both customers and the media for the shortages of IVIG and albumin. The excuses ranged from increased allocation of blood to areas of war to the explanation that IVIG and albumin cannot both be extracted from the same unit of blood.

2. Defendants Pressured Smaller Competitors Not To Appreciably Increase Capacity

160. CSL and Baxter have explored means of punishing firms, most notably Talecris, that have attempted to buck the prevailing restrained industry approach by increasing output.

161. Baxter and CSL closely monitor industry participants' output information, collecting and cataloguing an extraordinary wealth of timely competitive information, to ensure that all suppliers are engaging in desired "rational" and "disciplined" behavior. According to the FTC, CSL and Baxter have explored means of punishing firms, based on this data, that have dared to "'break ranks' and chase market share." *See Fed. Trade Comm'n Complaint v. CSL Ltd.*, No. 09-cv-1000 at ¶ 5 (D.D.C. Nov. 11, 2009).

162. The FTC noted that Talecris is "the one firm that has consistently and significantly expanded output in the United States." Statements from Defendants' files corroborate this, noting that Talecris "has significantly and consistently increased production and U.S. supply year after year—more than any other manufacturer," and that it planned to continue to do so in the coming years. *Id*.

163. According to its SEC filing, Talecris "intend[ed] to serve the overall market growth with incremental increases in production capacity" in 2008 and 2009. Before agreeing to CSL's planned acquisition, Talecris planned to be responsible for 45% of the industry's future output expansion over the next two years – a business strategy CSL labeled "irrational."

164. Talecris' intended expansion and increase of market supply would be adverse to the strategies employed by Baxter and CSL. The company's announced business strategy thus was at odds with Defendants' conspiracy to restrict supply, which elicited punishment by CSL and Baxter.

165. The Cerberus-Plasma Holdings LLC (Talecris' majority shareholder) executives described CSL as "truly scared that Talecris might actually succeed with its planned center expansion" and the consequent increase in output. The effect would be a significant drop in the market price. Cerberus executives further remarked that CSL executives were "worried ... that [Talecris'] expansion will have a negative effect on the market as a whole."

166. Without the aggressively expanding Talecris, Baxter and CSL, the only two remaining significant producers of Protein-Derivative Plasma Therapies could more successfully and completely control industry production and output. CSL's Chief Economist remarked, an "[i]ncrease in industry concentration should make price stability and/or price increases easier to sustain" because "competition erodes rents."

167. Consequently, in a further attempt to reduce industry production capacity and maintain high prices and margins, CSL Limited attempted to acquire Talecris. CSL's concern over the potential effects of Talecris' increased production and the price-reducing effect that Talecris' planned expansion would have in the market compelled CSL to offer a significant price premium in 2008 – about $800 million more than it was willing to pay in 2007.

168. In response to the potential merger, Baxter responded in a manner that was out of character for a competitor whose largest competitor was contemplating a large acquisition that would increase the competitor's market share and power. Baxter supported the move, publicly expressing its view that CSL's proposed acquisition of Talecris would be "a positive stabilizing move within the industry." The FTC subsequently filed suit to block the attempted acquisition. (The FTC action is further discussed below.)

169. The next two largest competitors in the industry, Grifols and Octopharma, possess too small a market share to have any significant market impact. Talecris executives discussed the smaller competitors' potential threat – or lack thereof – in high-level, internal communications: "[S]o really the question is whether grf [Grifols] and octa[pharma] would trash the market. And they're not big enough to strongly shock supply. . . ."

170. The continued consolidation and rigid oligopoly market structure has further reinforced and enhanced Defendants' agreement to restrict supply and raise prices to artificially high levels. The potentially non-conspiring participants in the industry have so little market power that they recognized that they are better off avoiding competition, restricting supply, and raising prices in response to the biggest market movers. Defendants' unlawful output signaling has aided and reinforced this recognition on behalf of all industry participants.

3. Baxter And CSL Signal Each Other To Reduce Or Stabilize Supply Of Plasma Protein-Derivative Therapies

171. In addition to the illegal information sharing and the direct conspiratorial communications described herein, Defendants CSL and Baxter signaled each other using public statements to keep supply under control. These announcements served several purposes, including providing a pretext for the implementation of the agreements reached during private conspiratorial meetings.

172. While a fair amount of competitive information is widely available from industry sources, the trade association, and the competitors themselves, CSL and Baxter also closely monitor each other's activities with respect to plasma collection, manufacturing, and output. This has facilitated Defendants' ability to monitor and maintain the conspiracy and to ensure that agreements reached were actually executed.

173. One method of enforcing the conspiracy was for CSL executives to track publicly filed financial documents. CSL told its employees at town-hall meetings that they kept track of the competitors' information, in part by monitoring 10-K filings.

174. CSL and Baxter further took advantage of such information availability by engaging in signaling, i.e., the intentional sharing of their intentions and output goals for purposes of ensuring that each restrained output, curbed growth, and maintained high prices, as secretly agreed upon.

175. Defendants have used specific language and key words, as a general practice, to: (1) communicate to each other that increasing the production of Plasma-Derivative Protein Therapies could hurt the firms' ability to reap significant profits that they all gained during an extended period when demand exceeded supply; (2) remind each other of how supply surpluses drop prices and profitability; and (3) encourage one another to increase only incrementally in response to increases in demand, and not increase supply in a manner that would bring down prices.

176. Throughout the conspiracy, Baxter and CSL routinely signaled each other to reduce plasma fractionization capacity, and, in response, both firms then reduced capacity by the same amount.

177. For example, during an investor call on November 18, 2004, Baxter's CFO at the time and then President of International Operations, John Greisch, stated:

> We've reduced our throughput capacity by about 30 percent. We have shut the number of plasma collection centers and significantly reduced the cost in this business.
>
> In addition, there's quite a bit of industry consolidation going on in the plasma business. Many of you are aware CSL has acquired the Aventis plasma business, *and has similarly reduced their capacity by a similar amount, approximately 1 million liters*. And Bayer, which is the third major player in this business, has its business up for sale. So the economics in this business which deteriorated significantly in approximately 2002 and early '03 as a result of significant excess supply, which drove reduced pricing, has begun to improve. We are seeing improved pricing, particularly in the U.S. IGIV of the [sic] market, which is our largest single market and our largest single product line. And as the industry consolidation continues, we're confident the economics of this business will improve. (emphasis added.)

178. Although Baxter had the capability to increase its output of Plasma-Derivative Protein Therapies, along with its sales volume and market share, it signaled its competitors that it would not increase its supply. During an investor call on April 21, 2005, Mr. Greisch stated that

Baxter could increase fractionization, stating: "To your question about whether we have capacity for more volume, the answer is yes." Yet Baxter then overtly signaled that Baxter did not intend to take advantage of that capacity, stating, "we brought our production levels down to a specific level to optimize the profitability of this business; and we have no intention, right now, of bringing that production capacity up."

179. In the same November call, Mr. Greisch further signaled Baxter's continued allegiance to the terms of the conspiracy, explaining that the company's strategy "has changed fundamentally to more of a straight focus on improving profitability, maximizing the cash flow out of this business and not chase growth going forward." Additionally, he explained, that "this is not going to be a high-growth business for the Company over the next several years, but it should be the source of improved profitability and cash flow."

180. On a June 2006 investor call, Mr. Greisch noted that Baxter, as well as CSL, had reduced production in an attempt to increase profitability:

> The Plasma business, as I mentioned, this really was a business that took some significant profit hits in '01 and '02. It was an industry that ended up with some significant excess supply dynamics in that period. In the middle of '03 we bit the bullet and significantly restructured our business. We took about a third of our production capacity and at the same time the industry was going through some pretty significant consolidation with CSL, which is a large Australian competitor in the business. . . . from a micro-perspective, *Baxter reduced our commitment to this business by taking out about a third of our production capacity, and industry wide, about 20% of the industry capacity came out on the back of our actions and CSLs* [sic]. (emphasis added.)

181. CSL also announced publicly a similar strategy that avoided growth in favor of increased profitability. During an investor call on August 21, 2007, the CEO of CSL Ltd., Brian McNamee, explained:

> If I just want to step back and say, "What drives our Plasma business?" I think it's important that -- we get a lot of questioning about volume. *And certainly volume growth is a factor but it's actually a relatively small factor in our thinking. I just wanted to highlight that.* I think that maintaining the quality of our business, having efficient cost base is fundamental. So having a really -- an outstanding plasma collection capability, having efficient high quality manufacturing units is really first and foremost. (emphasis added.)

182. In a September 11, 2006 industry conference hosted by Bear Stearns, Rob Davis, the current CFO of Baxter, made and explained the case for capacity reductions in order to improve prices, emphasizing that this strategy was only possible due to the consolidation that had occurred:

> The market has . . . consolidated going from approximately 12 players down to really three major players, and five players of significance overall. As well as both within the industry and within Baxter, you've seen a significant reduction in the amounts of plasma collections. *For instance within Baxter we actually took out half of our plasma collection capacity through a restructuring we had in both 2003 and 2004* as well as in the overall level of fractionation that is in the market. Given this reduction in supply we now have seen the market come back into equilibrium between supply and demand which has allowed the pricing to stabilize and given the long leadtimes it takes to bring new fractionization capacity on line which is roughly three to five years puts us in a very good position to see stable growth in this business going forward over the next three to five years. (emphasis added.)

183. CSL acted accordingly with this strategy regarding the opportunities presented by a more consolidated industry and committed to limiting its supply increases to the single digits. Mr. McNamee signaled this commitment during investor call on August 22, 2006:

> *What we see now is, I think, the industry now heading to a much more predictable phase of stability because we have a much more consolidated industry*, and it's truly global. Particularly Baxter and ourselves, we're truly global as the major players. Talecris is a very significant U.S.-centric player, and we have the two niche players of Grifols and Octopharma [sic] also fundamentally attempting to be global as niche players. And we think that the combination of consolidation, global players, with vertical integration of the supply chain, particularly three majors of Baxter, ourselves, and Grifols have significant supply chain issues. We think that that vertical integration gives a degree of – high degree of planning in the supply chain that the sector previously didn't have. So we are certainly forecasting a continued steady growth in IVIG usage across the globe. We think, as we've always said, around the 6 to 7% is a reasonable underlying growth pattern for the tradable market in immunoglobulin. The U.S. might be a little higher sometimes, Europe might be a little low, but we think the blended long term sectors is an approximately that, and assuming there are no significant surprises we think that we're entering a period of stable growth (emphasis added).

184. Less than a month later, Baxter responded by signaling its commitment to refrain from significantly increasing supply. On October 19, 2006 Baxter CEO Bob Parkinson stated:

> We continue to see anywhere between what I could characterize as price stability to pricing buoyancy. . . . We don't really see anything in what I will call the supply demand equilibrium in the marketplace that has changed or in our view is likely to change going forward. . . . the stability continues to be very good and so there will be some pricing latitude there going forward.

185. Later, he succinctly stated, "[t]here certainly aren't any major initiatives to dramatically expand plasma collection."

186. On September 10, 2007, Mr. Davis admitted that Baxter's minimal annual growth had been limited to "the mid to high-single digits" just like the growth observed with CSL.

187. During an investor call on January 28, 2008 Mr. Parkinson stated that, "it would seem that people [competitors] are doing what they need to do to ensure that the global demand can be met collectively by the industry." Baxter's CEO has publicly emphasized on several occasions Baxter's commitment to not attempt to significantly increase its market share.

188. During another investor call on May 1, 2008, Mr. Davis expounded on this thought and signaled Baxter's competitors that it did not make sense for any competitor to lower price and to try to gain market share. He made it clear that, if everyone kept prices up collectively, they could all expect continued high profits. Indeed, Mr. Davis essentially acknowledged that Baxter and its competitors were signaling one another not to compete for "short-term gain" at the expense of long term collective profitability:

> No, no one has really [been] signaling a dramatically different view on demand from one another. We might be all off a percent or two from each other, but no one is saying a significantly different signal. . . . Why any of us would, for a very short-term gain, do anything to change that, I just don't see why we would. *It wouldn't make sense and from everything we read and all the signals we get, there is nothing that says anyone would do that. I think people are very consistent in the messages they deliver, which are pretty consistent with what we have told you today.* (emphasis added.)

189. Moreover, during an investor call on January 22, 2009, Mr. Davis expressed the company's deliberate intentions to taper annual growth to single digit percentage points despite increasing demand for Plasma-Derivative Protein Therapies, *"we're going to see or promote total market perspective, growth, and volume of the highest single digits and growth in price of low to mid-single digits longer term."*

190. In August 2008, CSL Behring's President publicly dismissed the issue of supply shortages, promulgating the theory that it was based on faulty perception rather than reality.

> [The supply] may be a little flat at the minute. I don't know the reason for that because *clearly each company is producing its own volumes of product*, but essentially there is a lot of product still being distributed. And if we look at the difference, say, 1999 and today, supply has grown from something like 15-16 million grams to 27 million grams in the U.S. today (emphasis added).

191. Instead, Mr. Turner blamed perceived shortage supplies on "profiteers in the distribution channel that are exploiting patients and then certainly providers and payors, as well." Turner went on to add that "[CSL's] contracts are written to prevent [price gouging]."

192. However, CSL Behring's President, Peter Turner, had publicly signaled that the company would not dramatically increase its production of Plasma-Derivative Protein Therapies, despite the existence of widespread supply shortages and the specter of a public health emergency. Mr. Turner stated: "In terms of 2005-2006, we will have a similar supply to the last 12 months plus we hope to have a new product, which is a subcutaneous immune globulin infusion." Although Mr. Turner acknowledged some supply shortages, stating, "I accept that supply may be tight, certainly tighter than it's been in recent years," he confirmed that CSL Behring's manufacturing levels would remain relatively stable, stating that "if you look at the status quo, *we will continue to supply the equivalent volume that we've been supplying to the U.S. market*." *See Key Issues Dialogue: The Partnership Between the Modell Foundation and ZLB Behring*, available at http://www.cslbehring.com/s1/cs/enco/ 1154398192290/content/ 1154398189443/content.htm (last accessed August 23, 2010) (emphasis added).

193. While CSL's President acknowledged the harms of price gouging he simultaneously warned against price declines. On the topic of Ig pricing, Mr. Turner declared that pricing in 2008 was not at the levels they were "several years [before]" and that "discounting in pricing in recent years...threatens the very viability of the industry."

194. Defendants made further public statements signaling that other firms should not "cheat and add capacity" and that by limiting their manufacturing, producers could avoid

increases in supply that would prevent conspirators from enjoying "better pricing." At a May 3, 2006 conference hosted by Morgan Stanley, John Greisch, Baxter's CFO, stated in response to questions by Glenn Reicin of Morgan Stanley, that the decline in the number of competitors would help the competitors monitor each other to rationalize production and avoid doing "silly" things that could lead to increases in the supply and lower prices:

> Glenn Reicin [Morgan Stanley analyst]: Now the BioScience division in the past has always been sort of linked to the behavior of others, right? So the better pricing hits, the more tempted manufacturers are to sort of cheat and add capacity. The difference now is you have three public companies … they are all in the same situation enjoying better pricing with disciplined manufacturing ….
> John Greisch [Baxter CFO]: Sure. More predictable industry dynamics I think are definitely there today. Not only have the number of – has the number of competitors declined but as you said, Glenn, at least the two big ones, us and CSL, obviously are more visible to the investment community in terms of how the business is managed. And if Telecris [sic] ends up going publicly and even if they don't, I think the financial discipline that they've got under [Cerberus]' ownership brings a much stronger stability and I think rationalization to the industry leaders in terms of avoiding doing some of the silly things that have happened in the past.

195. Defendants have consistently demonstrated importance and utility of signaling. During an investor call with Credit Suisse Group on November 18, 2008, Mr. Davis acknowledged that "more visibility and transparency among the players" facilitated the "very stable situation in the plasma business" that Baxter did not desire to, or foresee, changing. In May 2008, Mr. Davis had acknowledged that, "based on anything we look at, whether you look at PPTA data, . . . or looking at months on hand in the chain, if we look at our data, all of the competitive intelligence we can draw, *tracking at what our competitors are signaling,* nothing tells us that this is going to get out of whack over the near term." (emphasis added.)

4. <u>The PPTA Furthered and Facilitated the Conspiracy</u>

196. The PPTA was formed as a response to historical shortages for the purported purpose of ensuring supply stability and to prevent shortages of important life-saving therapies. Because CSL and Baxter controlled a majority of the market, the PPTA's executive members and leadership body is primarily composed of officer-employees of Defendants. While

determining their approach and policy for manufacturing, the Defendants' held a crystal-clear understanding of what supply output levels would mean in terms of profitability for each company. Thus, signaling was particularly effective as all members of the PPTA had a transparent understanding of how production levels would affect pricing across the board.

197. Defendants CSL and Baxter are key members of the PPTA with personnel from both companies holding committee and officer positions with the PPTA. The PPTA claims to be "the primary advocate for the world's leading source plasma collectors and producers of plasma-based and recombinant biological therapeutics." CSL and Baxter are Global, North American, and European Members of the association.

198. High-level executives from both CSL and Baxter effectively control all major aspects of the PPTA and dominate its Board of Directors. Board Members past and present include:

- Larry Guiheen, President of Baxter BioScience (currently serves as the Board's Chairman).
- Paul Perreault, Executive Vice President, Worldwide Commercial Operations and Business Development of CSL Behring.
- Dennis Jackman, Senior Vice President of Public Affairs of CSL Behring. (Jackman chairs the PPTA's Global Management Committee.)
- Jean Marie Vlassembrouck, Vice President of Industry Affairs at Baxter (serves on the PPTA's Global Management Committee).
- Lynn Powell, Baxter's Senior Vice President, North America Commercial Operations (serves on the PPTA's North American Board of Directors).
- Peter O'Malley, Baxter's Vice President of Business Alliance (serves on the PPTA's North American Board of Directors).
- Randy Furby, Senior Vice President of CSL Behring and General Manager of CSL Plasma (serves on the PPTA's Source Board of Directors).
- Roland Martin, Senior Vice President and General Manager of CSL Behring (serves on the PPTA's European Board of Directors).
- Daniel Kenny, Vice President of Baxter BioScience Europe (serves on the PPTA's European Board of Directors).
- Peter Turner, the current President of CSL Behring and recently appointed Chief Operating Officer of CSL Limited (served as the Chairman of the PPTA's Global Board of Directors from 2003 to 2007).

- Robert Lefebvre, Vice President and General Manager of U.S. Operations at CSL Behring (previously served on the PPTA's North American Board of Directors).

199. Notably, Gordon Naylor, Executive Vice President of Plasma, Supply Chain, and Information Systems at CSL Behring, and Joe Rosen, Director of Business Development and Planning at Baxter BioLife, served on the PPTA's Source Board of Directors and Mr. Naylor served as the Board's Chairman. Mr. Naylor was recently tapped to serve as the Finance Director at CSL Limited.

200. This unusually high-level of correlation between membership in executive positions at CSL and Baxter and membership in leadership positions in the PPTA facilitated Defendants' numerous opportunities to use PPTA meetings, presentations, shared distribution data, and resources in furtherance of the conspiracy. The participation of the Defendants' high-level executives on PPTA's Board of Directors provided the manufacturer Defendants with ample opportunity to effectively conspire by coordinated manipulation of each firm's manufacturing goals, using the PPTA to facilitate the antitrust violations alleged herein.

201. The PPTA also provided CSL and Baxter a public forum for signaling that output should be restricted. For example, on August 26, 2004, PPTA President, Jan Bult, gave a presentation to the Health and Human Services Advisory Committee on Blood Safety and Availability. Mr. Bult explained the economics of the plasma-protein business: if supply continued to increase, Defendants would not realize any profit, but if Defendants continued to control supply, prices and profit margins would see concurrent increases.

202. Moreover, as part of the PPTA leadership, CSL and Baxter officials had intimate access to not only Bult's presentation, transcripts of the meeting, and meeting minutes but also the underlying data and substance of the analysis.

203. The presentation by the PPTA President warned of the economic perils the industry had faced and noted the need for change: "if we talk about long-term viability of this industry, we need to make economic adjustments. There is no other way around it." Advisory Comm. on Blood Safety and Availability Mtg., Tr. 287 (Aug. 26, 2004) available at

http://www.hhs.gov/bloodsafety/transcripts/ACBSA08262004.pdf (last accessed August 23, 2010).

204. Mr. Bult explained, however, that exchanging certain types of information was illegal and so "even when we would like to do it, we can't." Id. at 288-89. Tellingly, Mr. Bult went on to concede that the plasma-protein industry was "highly concentrated" and warned his fellow manufacturing leaders that they ought to be "extremely sensitive to Anti-trust laws."

205. Despite the warning and acknowledgment of risk, Mr. Bult nevertheless proceeded to inform PPTA members that a system was in place to give Defendants ready access to inventory levels. The system gathered data monthly and posted the results to a public website. Even though the monitoring system had been initiated as a response to acute supply shortages in the late 1990s, the PPTA and Mr. Bult continued to support the monitoring system for the purposes of furthering the conspiracy.

206. Mr. Bult went on to remark on the production response to the shortages of the 1990s. He noted that in the 2004, "The question now is do we have the right balance? In '98 we had the situation where demand exceeded supply. Is that still the case? If we have increases in supply, is this balanced with demand or are we building and filling inventories?" *Id.* at 291.

207. Mr. Bult further emphasized that "the best revenue comes from the first liter of plasma that is manufactured and the further you get into the system the more problematic it becomes." *Id.* at 292. In this way, Mr. Bult signaled that the more plasma protein that they manufactured, the less profit CSL and Baxter would realize, and thus the necessity that they limit supply.

208. Mr. Bult bluntly added, "[I]f there is any concern about immune globulins and, as I told you before, we don't see a near-term threat for immune globulins, but you can ask the question why don't you make more? Just make more so you can avoid all the problems. Well, if that is the case this is going to happen. You can make more but you can't sell it. So you put it in inventory and also you get more albumin and it is still below your cost of manufacture. That leads to a situation where this industry is going to lose a significant amount of money and, as we have seen with the changes in the marketplace, we are not in a position to do that. So, this will

not happen, especially not if you look at the revenue that we have seen over the last years that has come down significantly. All the changes that you see in the marketplace right now are a clear response to the economic pressures." *Id.* at 294.

209. Bult continued, "based on what we know today we do not see a near term short supply," and signaled to suppliers they should do nothing to increase supply: "we will see – and that is my prediction – that individual companies, in response to their economic challenges, will tighten supply." *Id*. at 289.

210. Mr. Bult ended his presentation with an ominous warning clearly intended for industry participants: "We will continue to make the point that economic adjustments are needed because look around and look at the companies that were in place in 1998 – let me just give you a couple of examples, Alpha Therapeutics Corporation no longer exists. Biopharma has decided to divest and Baxter has significantly reduced its activities. Aventis Behring or Cention is now part of CSL. So, that is the reality.... [J]ust look around you and you will see what has happened as a result of the economic challenges." *Id.* at 298 (emphasis added).

5. Defendants Met Privately And Concealed Topics of Industry Meetings

211. In furtherance of the conspiracy, Defendants met regularly in private. Upon information and belief, CSL and Baxter exchanged manufacturing plans and other information related to the supply and price of Plasma-Derivative Protein Therapies in the course of these private meetings. While Defendants' executives regularly attended PPTA meetings, their contacts with each other did not stop at the conclusion of those meetings. Outside of these formal meetings, Defendants' executives socialized in restaurants and bars for meetings beyond the watchful eyes of the PPTA's attorneys or those of independent persons and continued to discuss supply volumes and pricing.

212. In a Boston meeting involving Defendants' executives, Dennis Jackman expressed a desire for better information concerning the global supply of plasma-protein derivative products. Mr. Jackman expressed a goal to obtain more accurate data relating to optimal production levels in order to maximize profit margin. Mr. Jackman went so far as to suggest that the PPTA consult with an economist to evaluate global demand for Plasma-

Derivative Protein Therapies and collectively determine the exact amount of supply each manufacturer should produce in order to maximize profitability for each cartel member.

213. In order to conceal anti-competitive behavior, minutes from PPTA meetings, including the recent July meeting in Boston, are routinely "scrubbed" to remove references to any topic of conversation that potentially violated antitrust laws. Defendants went through these extra concerted efforts so that the conspiracy would remain hidden.

214. Likewise, Defendants met often under the guise of discussing the impact of industry regulations, using these opportunities to exchange pricing and supply of plasma products. Throughout 2008 Defendants met regularly with the IDF under the pretext of discussing regulatory policy. These meetings took place at either the IDF headquarters or at local offices of the manufacturers' lobbying firms. The officially stated purpose of these meetings was to develop legislation to improve access to IVIG supply for hospitals, providers, and homecare sites. However, these conversations would often include inappropriate dialogue about collusive determinations of supply and pricing.

215. Important Defendant executives and members of Board of the PPTA, attended the IDF meetings, including, but not limited to: Dennis Jackman, Senior Vice President of Public Affairs for CSL; Deb Williams, a lobbyist for Baxter; and Peter O'Malley, President of Baxter's Bioscience division. Defendants used the meetings, both formal and informal, to conspire and reach manufacturing and distribution agreements regarding supply and pricing of plasma.

216. Indeed, smaller, non-colluding manufacturers of Plasma-Derivative Protein Therapies have voiced concerns that CSL and Baxter overstepped the bounds of antitrust laws by exhibiting clear-cut anti-competitive behavior by openly discussing the supply and pricing of Plasma-Derivative Protein Therapies at PPTA and other industry meetings.

6. Defendants Monitored The Conspiracy Using System Established In The 1990s And Now Administered By The PPTA

217. The PPTA's monitoring system and regular collection of industry data allowed Defendants to effectively police their co-conspirators.

218. The monitoring system first implemented in the late 1990s ultimately served as an effective tool for implementing the conspiracy. However, at the time, 13 different companies competed and not all 13 firms were members of the trade association; thus, there the system did not provide a complete picture of the distribution data. However, as industry consolidation increased, these deficiencies were corrected. Since Baxter and CSL each possessed more than 25% of the market shares of both Ig and albumin (Baxter has approximately 35.4% of the Ig market and 36.44% of the albumin market; CSL possesses approximately 27.5% of the Ig market and 36.61% of the albumin market), the data collected and analyzed by the PPTA could be easily used to identify the distribution data for specific companies.

219. Thus, by 2003, and increasingly thereafter, the system became a very effective means by which Defendants could monitor each other's compliance with the terms of their collusive agreement.

7. Defendants Publicly Denied Supply Shortages, Over-reported Industry Supply, And Blamed Medicare To Disguise And Hide Operation Of Conspiracy

220. Defendants' collectively made numerous attempts to dissuade the United States Department of Health and Human Services ("HHS") from declaring a public health emergency during times of acute Plasma-Derivative Protein Therapy supply shortages. Defendants' executives, particularly Dennis Jackman, had learned from the events of the late 1990s and knew that declaration of a public health emergency would bring about an invasive government investigation of the industry. This investigation would target the very crux of the problem – the reason for supply shortages despite widely accepted reports of increased aggregate supply. Government intervention would have rendered the conspiracy ineffective and/or made the Defendant participants in the conspiracy vulnerable to civil and/or criminal liability.

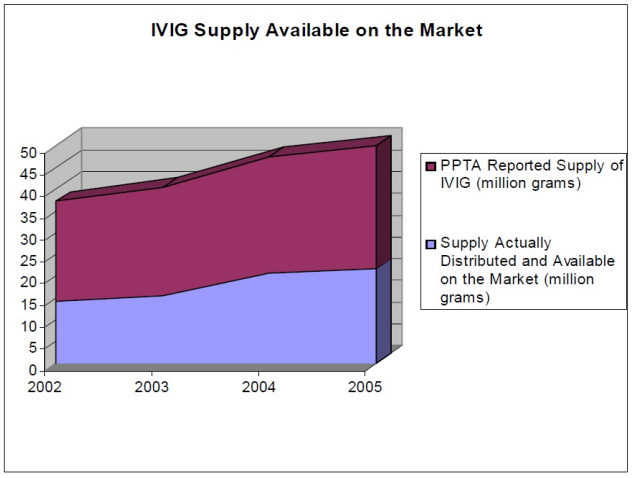
221. Thus, to avoid the declaration of a public health emergency and the accompanying government investigation, Defendants used their control of the PPTA to provide false market information. The PPTA, controlled by Defendants, publicly denied supply shortages and coordinated an over-reporting of the actual supply of Plasma-Derivative Protein Therapies available in the market. The PPTA also sought to shift the focus away from reports of

a supply shortage by publicly characterizing Medicare reimbursement rates as the sole cause for supply issues, as cost-conscious hospitals faced a more difficult time staying under-budget.

222. Despite the rampant price spikes, price information asymmetry, and the inability of purchasers to obtain sufficient life-saving medical supply, Defendants' consistently denied the existence of a supply shortage through statements made by and through the PPTA. The most notable examples of Defendants' cover-up involves the supply of Ig. Throughout 2006 and 2007, HHS investigated claims of an Ig shortage. In response to this investigation, the PPTA provided HHS with data regarding the supply of Ig available for distribution. As part of the investigation, an independent company, IMS Health, also evaluated the amount of Ig available for distribution. According to the HHS report, the PPTA reported nearly twice as much Ig available for distribution as did IMS Health.

223. Several explanations were proffered for this discrepancy in reporting: rounding error; exports and offshore demand; and the lack of inventories. There is an obvious implausibility of a rounding error accounting for a 30 million gram difference in reported data. The PPTA later verified that the submitted data did not include exported Ig. However, export data fails to reasonably account for the magnitude of the discrepancy. A much more plausible explanation is that Defendants restricted supply to manipulate prices, and then misreported this supply to HHS to avoid a public health emergency declaration that would lead to government intervention.

224. The following graph illustrates the difference in the amount of supply PPTA reported compared with what was actually available on the market, as reported by IMS Health:



225. The PPTA Defendants also shifted government and patient attention away from reported supply shortages problems by constantly scapegoating Medicare reimbursement rates as the reason for supply shortages. Defendants misleadingly blamed patients' inability to obtain sufficient amounts of Plasma-Derivative Protein Therapies on the failure of Medicare reimbursement rates to keep up with the price for these therapies, leading to lack of access to supplies. Synchronizing the effort, Julie Birkofer, Vice President of the PPTA, made a number of presentations to HHS advocating new Medicare reimbursement formulas to compute Plasma-Derivative Protein Therapy reimbursement rates.

226. Medicare reimbursements had, in fact, already increased significantly along with prices. In 2003, the administration spent $180 million on reimbursements for immune globulin. In 2004, the amount had skyrocketed to $300 million.

227. The PPTA Defendants also made representations to the IDF and other patient-advocacy groups to skew the acceptance of the reality of supply shortages. They combated the recognition by physicians and patients that a supply shortage existed by calling attention to problems related to the reimbursement rates provided by Medicare.

228. This concerted effort on the part of Defendants encouraged the IDF not to report physician survey data verifying their allegations of a supply shortage.

229. Defendants likewise went to great lengths to censor and edit advocate messages to eliminate any hint that the industry was acting collectively regarding IVIG supply shortages or that patients or GPOs were unable to obtain sufficient supplies of important life-saving plasma therapies. On at least one occasion, Defendants actually censored a patient advocate's presentation in an effort to keep advocates on message and off the topic of supply shortages.

230. By misrepresenting supply shortages and shifting attention away from supply and to Medicare reimbursement rates, Defendants were able to conceal their conspiracy and avoid the declaration of a public health emergency, which likely would have led to an intrusive government investigation that could well have revealed Defendants' conspiracy.

C. Effect Of Defendants' Conspiracy: Artificial Shortages Of Plasma Protein-Derivative Therapies And Artificially High Prices

1. Defendants' Conspiracy Created Artificial Shortages Of Plasma Protein-Derivative Therapies Causing Health Care Crisis Supply Restrictions Did Not Result From Natural Market Forces

231. As previously discussed, the restriction of supply and increase in prices did not result from natural market forces. Rather, both were caused by Defendants' conspiracy, which Defendants formed in response to the abundant supply and resulting decreased prices and lowered profits that occurred earlier in the decade.

232. Defendants' coordinated acquisition and closure of plasma collection and fractionation plants are not consistent with free and open competition, and thus are themselves evidence of coordinated activity. As acknowledged by trade industry professionals and independent research, demand for Plasma-Derivative Protein Therapies increased steadily throughout the relevant time period, and Defendants would have been irrational to restrict supply absent an illicit agreement that included assurances that other leading manufacturers would do likewise. In addition, the lack of new market entrants serves as indication that the high level of consolidation acted as competitive barriers. Otherwise, one Defendant's supply restrictions merely would have provided an opportunity for a new firm or the other existing firms to increase production and expand market share, thereby increasing sales volume and revenue.

233. On a number of occasions, statements made to the public by Defendants have admitted that supply shortages did not result from insufficient plasma donation. Although Defendants told patient advocates that shortages were caused by a lack of volunteer donors, they told their investors otherwise. During one investor call, Baxter CEO Bob Parkinson responded to a question about the cause of reduced plasma supplies by stating that he did not "believe that the number of people coming forward willing to donate plasma necessarily ha[d] any impact relative to overall supply." Furthermore, Rob Davis, VP and CFO of Baxter explained that the "bottleneck" existed not at the collection end, but rather at the manufacturing centers.

234. According to a major distributor of Plasma-Derivative Protein Therapies, distributors began to see "a tightened supply trend" around October of 2003 and throughout that year, "[s]upply was gradually, almost imperceptibly starting to tighten." This same distributor attributed difficulties in obtaining Ig to the "new market reality— fewer suppliers and rising prices." At the time in October 2003, prices for powdered or liquid Ig cost upwards of $78 per gram as reported by the New York Times.

2. Defendants' Conspiracy Caused A Public Health Crisis

235. Defendants conspired to maintain the available supply of Plasma-Derivative Protein Therapies in the market at low enough levels to keep prices high. Defendants' coordinated supply restrictions were implemented, however, during a period of growing demand for these therapies, and as a result, there was insufficient supply to meet patients' needs. Insufficient supply and excessively high spot pricing moved patients, doctors, and patient advocates to urge the government to declare a public health emergency in 2005 and again in 2006.

236. The difficulties with obtaining plasma products was due to the small number of manufacturers and specialty distributors. While much of the available product was committed to contracted entities, i.e., GPOs, allocations are not always honored and pricing was not guaranteed.

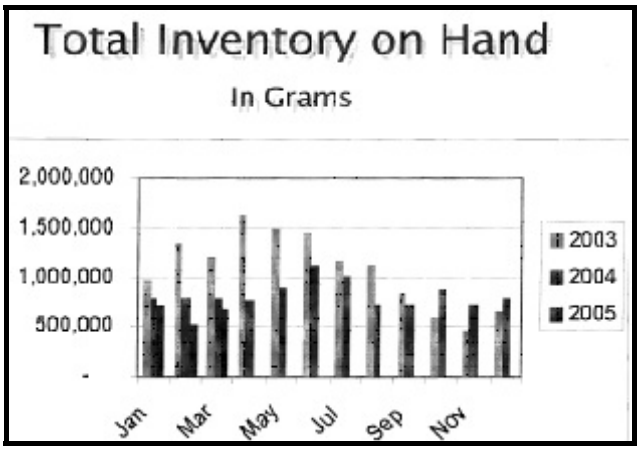
237. Hospitals, patients, physicians, and insurance companies first began reporting supply shortages of plasma-derivative protein therapies in 2005-approximately one year after Defendants completed their efforts to close plasma collection and manufacturing facilities. Prices in Fall 2005 for the product ranged from $42 to $56 per gram nationally. As previously explained, it typically takes between seven months to one year to manufacture plasma into Plasma-Derivative Protein Therapies. Thus, one would expect to see the full effects of Defendants' efforts to control supply in 2005 and 2006.

238. An IDF survey conducted in 2005 assessed the scope of Ig shortages that patients and physicians had been reporting. According to that survey, 33% of responding physicians reported significant difficulty obtaining Ig products for their patients. Physicians also reported

that 40% of their patients had suffered adverse health effects due to problems accessing sufficient Ig supply.

239. In 2005, the Advisory Committee on Blood Safety and Availability recommended that the Secretary of Health and Human Services declare a public health emergency, which would have allowed Medicare to change reimbursement rates. The *New York Times* reported on July 19, 2005 that the Medicare reimbursement policy, mandated by the 2003 overhaul, had the intended effect of preventing overuse and prescription of the drug. Yet despite this, the IDF's vice president for government affairs, Michelle B. Vogel, noted that "We've got patients all over the country who are not getting treatment."

240. According to the HHS, the shortage caused a general decline in the amount of Ig that hospitals and facilities were able to keep on hand, as illustrated in the graph below:



241. Insurance companies also felt the effects of the supply shortages (and increased prices) as well. In 2005, Kaiser Permanente informed patients that due to "an acute nationwide shortage of IVIG due to pharmaceutical manufacturing shortages" it could not cover patients' IVIG treatment.

242. HHS also received countless letters and statement from doctors, nurses and hospitals from around the country describing their difficulties and frustrations with the IVIG shortage:

> It is very frustrating trying to find an adequate supply of a safe and effective IVIG at a reasonable price. The cost has risen out of hand, while reimbursement has

> been lowered. The average price for IVIG is anywhere from $75.00 to $92.00 per gram! We are sending many patients to an acute care setting where I know they are not receiving the same quality of care. (Judy Back, RN, BSN, Innovative Infusions, Benbrook, TX)
>
> Cost of IVIG is higher by 5% than what Medicare reimburses. The infusion for patients will cost me an out of pocket loss of 35% for Medicare patients. There is a shortage and local hospitals... have refused to accept them. The prediluted products, which are below or at Medicare reimbursement levels, are not available to me due to product allocation. The costs at secondary markets are at least 25% above Medicare reimbursement levels. Although I continue to see Medicare patients I cannot take on any new patients for infusion, because of the above. (Dr. Kumaraswamy Sivakumar, Scottsdale, AZ)
>
> We cannot obtain IVIG at a price lower than or equal to Medicare's reimbursement rate. In the face of recent cutbacks, which have been devastating to physicians practices, we cannot continue to lose each time we treat a patient. Overall, the IVIG shortage, cost and reimbursement has created confusion, stress and frustrations for providers and patients. (Cherie Moore RN, OCN, CCRP, Cancer Center of Boston)
>
> The cost of IVIG has risen, while reimbursement has been dramatically lowered by Medicare. We are seriously considering denial of this vital therapy to Medicare patients. They would be referred to a hospital for outpatient treatment and subsequently be exposed to a variety of pathogens while in a compromised immune state. Many would simply not go at all. Either way, many would probably succumb to pneumonia and other illnesses requiring lengthy hospital stays and extensive treatment and possible disability. (Joan M. Nasr, RN, CA Allergy & Asthma Medical Group, Los Angeles, CA)
>
> I am writing to address the issue of the IVIG shortage, allotments and outages that are being felt across the nation. It is a travesty to tell people that it is approved for their condition, but we cannot obtain enough of the drug to take care of them. I had several patients contact me about trying to locate a supply of IVIG for their condition, because their doctor or other provider can no longer obtain enough to keep them going. This is sad, especially since some of these patients have just started having their quality of life restored to them. (James Mike Jones, R.Ph., Christus St. Michael)
>
> IVIG is on allocation, therefore, whenever a new patient needs to get the drug, I have a very difficult time finding it... This very serious issue will, in the end, be a barrier to care, considering the cost/ reimbursement of the drug. This is very serious, and the one who will suffer the most for the decisions made by others will be the sick patient who needs IVIG. (Angie Brinegar, RN BSN OCN, Coastal Cancer Center, Myrtle Beach, SC)

243. In 2006, supply shortages of Plasma-Derivative Protein Therapies led to a series of crises at the patient level. The CBER Product Shortages e-mail address received dozens of emails that year from hospitals, patients, doctors, and pharmacists unable to obtain sufficient supply.

244. According to one such patient with common variable immune deficiency, "I just received a phone call from my pharmacy telling me they do not have the product and am not sure when they will receive any. IVIG keeps me alive. Once my levels get too low, I will get very sick with pneumonia and be put in the hospital. Please restore access to IVIG so I can be healthy and not be sick in the hospital!"

245. Likewise, a mother of three children receiving IVIG for common variable immune deficiency wrote "to confirm the fact that there is indeed a shortage of IVIG" that threatened to put her children's lives in danger. "It is difficult enough to keep my kids out of the hospital with bacterial infections—let alone think what will happen if they miss their infusions due to a lack of IVIG."

246. That year, patients and doctors, along with a bipartisan coalition of 55 members of Congress, asked the Secretary of HHS to declare IVIG shortages a public health emergency. The HHS Committee on Blood Safety and Availability joined this coalition in urging the Secretary to declare a public health emergency, stating "there is a worsening crisis in the availability of and access to IGIV products that is affecting and placing patients' lives at risk." It was Defendants' artificial supply restrictions that created the crisis and forced rationing of Plasma-Derivative Protein Therapies.

247. In 2006, HHS investigated reports that patients were experiencing problems purchasing IGIV. HHS stated that "[m]anufacturers are currently allocating IGIV to their customers. Under this allocation system, most customers are expected to justify their current IGIV use to the manufacturer to maintain and/or increase their allocations. In economic terms, current IGIV supplies are being rationed." HHS also noted that "[t]he existence of a secondary market with high IGIV prices combined with a manufacturer instituted allocation system for IGIV are symptomatic of a market in which demand exceeds supply." HHS concluded that a majority of hospitals surveyed could not purchase enough IGIV to meet all of their patient needs, and calculated that the shortfall of supply relative to demand was approximately 14%.

248. The shortages penetrated every level of patient care. Participants across the industry reported supply shortages of Plasma-Derivative Protein Therapies. A representative

from a GPO noted that "the market is certainly tight" and explained that distributors were forced "to manage inventories to the gram level."

249. The supply shortages affected every geographic region in the US market to different degrees; however, according to the IDF, patients and doctors in almost every state had reported inadequate IVIG access.

250. Evidence also suggests that hospitals and pharmacies experienced trouble obtaining sufficient supplies of albumin. According to an email from the American Society of Health Pharmacies to CBER Product Shortages, pharmacies in Virginia experienced an albumin shortage in 2006. An email from the University of Michigan Blood Bank and Transfusion Center to CBER Product Shortages expresses the frustration and confusion felt throughout the industry in the face of these shortages: "[w]e have a market shortage of human albumin . . . I am told this is a national problem, but I do not see anything on the CBER shortage web page. What is going on?" Hospitals in Arizona, Illinois, Indiana, North Carolina, and Tennessee similarly reported trouble obtaining sufficient amounts of albumin due to a supply shortage.

251. The conspiracy caused extremely low supplies of Plasma-Derivative Protein Therapies that caused many patients to go without crucial life-saving therapy treatments. According to a survey of hospital pharmacies administered by the IDF in 2006, 32% of hospitals had turned away patients seeking Ig. Similarly, 57% of physicians surveyed reported that they had been unable to provide patients with adequate amounts of Ig during the first quarter of 2006. According to the same survey, 100% of the distributors asked responded that they had been unable to obtain extra Ig from manufacturers.

252. As a result of Defendants' supply restrictions, patients were forced to go without Plasma-Derivative Protein Therapies. Some patients reportedly suffered side effects from alternative treatments and infections caused by delayed treatment. In some instances, patients even reportedly died when they had to wait too long to receive treatment.

253. The difficulties faced by patients experiencing IVIG access problems is perhaps best summarized by one patient from Florida who, in a statement to the IDF, said "It's

disgusting. What do they expect us to do? Are we supposed to just get sicker and sicker until we pass away?"

254. Another patient from Missouri called the IDF, stating "I am an 81 year old Medicare PID [primary immunodeficiency disorder] patient ... I am sick all the time, and am not sure if I will be able to live long enough to get my next infusion. I had an infusion scheduled at the hospital. As I was leaving for the hospital, they called to cancel my appointment. They told me that they will not be able to infuse me."

255. These are but two representative statements out of hundreds from patients who contacted IDF to report problems obtaining Plasma-Derivative Protein Therapies.

256. The artificially high prices also limited those treating indigent patients from obtaining enough plasma therapies at reasonable rates. Consequently, Medicare patients and those receiving medical care through other government assistance programs for the indigent suffered from supply shortages of Plasma-Derivative Protein Therapies at a disproportionate rate compared to privately insured patients. According to a survey conducted by the IDF, twice as many Medicare patients as privately insured patients encountered problems obtaining Ig between 2003 and 2006.

257. Privately insured patients, however, were also impacted by the artificial supply shortages. Many were denied treatment when supplies ran out. As stated by one distressed father from Ohio after his son's appointment to receive IVIG was canceled, "my family is covered by Anthem BCBS, which I thought was good insurance. How can something like this happen?" And, according to the IDF, 50% of private insurance companies paid at, or below, the Medicaid rate for Plasma-Derivative Protein Therapies, forcing patients to pay the difference or denying coverage altogether.

258. The evidence presented herein makes it economically irrational for the manufacturer Defendants individually, absent an agreement to manipulate supply, to have reduced or steadfastly maintained their supply levels during the relevant time period even in times of severe shortage. The rational reaction to this shortage by any firm would have been to increase supply. CSL's and Baxter's mutual refusal to do so only makes economic sense in light

of Defendants' arrangement to collectively reduce or maintain supply in order protect artificially high pricing.

D. Defendants' Conspiracy Caused Prices For Plasma Protein-Derivative Therapies To Artificially Rise

259. Defendants' conspiracy succeeded, causing Plaintiff to purchase Plasma-Derivative Protein Therapies at supracompetitive prices. Beginning as early as July 1, 2003, prices for Plasma-Derivative Protein Therapies stabilized and then consistently increased.

260. According to an analyst presentation that Grifols gave on March 5, 2008, the average sales price for a gram of IVIG has increased from about $47.60 in 2005 to about $57 in 2009. The Grifols presentation stated that "IVIG, which remains the driver of the plasma derivatives market, has witnessed price increases since 2005, coinciding with increased demand related to product availability."

261. According to the same presentation, the average sales price for a gram of albumin has increased from about $1.25 in 2005 to about $2.20 in 2009. The presentation also reports that "average albumin prices have steadily increased since 2005 from U.S. $14 to around U.S. $35 per 12.5 g. vial at present."

262. A Talecris 2008 SEC filing similarly notes that "[p]rices for albumin have increased significantly since 2005 .... The average selling price in 2007 was $28.55, having grown at a CAGR [compound annual growth rate] of 35% since 2005, when the U.S. average selling price (ASP) was $15.58."

263. CSL's and Baxter's contemporaneous business reports corroborate these findings.

264. For example, CSL Limited reported in its October 2004 Annual General Meeting presentation: "IVIG -prices have been stable with upward pressure going forward; currently experiencing solid demand;" and "Albumin - prices stable after period of weakness; inventory oversupply reducing." In its October 2005 Annual General Meeting presentation, CSL Limited remarked that "U.S. IVIG pricing environment improving," and that with respect to CSL Behring, it is "managing plasma throughput to match: run down in inventory benefit; reduction

of inventory levels; [and] demand." The Chairman's Address from the same 2005 meeting stated that "CSL Behring is well positioned to develop its global business through," among other things, "an effective balance between supply and demand." And in its October 2006 Annual General Meeting presentation, CSL Limited noted both the continuing "strong global demand for plasma therapies continues," and "plasma sector stability."

265. Defendants' conspiracy has caused supracompetitive pricing resulting in significant annual increases profits for CSL and Baxter, even as most other industries have experienced drastically lowered earnings in the face of the global economic crisis.

266. CSL experienced a post-tax net profit of $502 million for the half-year ended December 31, 2008, an increase of 44% from that same period the previous year. The report also notes that "[t]he global financial crisis has had little to no impact so far on sales of CSL's portfolio of life-saving therapies and essential vaccines .... [a]nd we anticipate broadly stable market conditions to continue."

267. CSL Behring's total sales revenue increased 33% to $1.8 billion compared with the same period the previous year, "with strong contributions from both core and specialty plasma products," according to the same March 2009 CSL report.

268. Baxter's BioScience revenue climbed 12% to $1.36 billion in 2008, largely due to sales of plasma-based hemophilia and immune disorder treatments, vaccines and biosurgery products. Due to the profit its BioScience unit has generated, one news article noted that "Baxter is one of a handful of stocks that have proven somewhat resistant to the global recession."

VII. FTC INVESTIGATION

269. As discussed herein, CSL announced its proposed acquisition of rival Talecris in 2008. On March 27, 2009, the FTC authorized a lawsuit to block CSL Limited's proposed $3.1 billion acquisition of Talecris, charging that the deal would be illegal and substantially would reduce competition in the United States markets for Ig, albumin, Rho-D, and Alpha-1. The same day the FTC also sought a preliminary injunction in federal district court in the District of Columbia to stop the transaction pending completion of an administrative trial.

270. In a press release, Richard Feinstein, Director of the FTC's Bureau of Competition, stated that "[s]ubstantial consolidation has already occurred in the plasma protein industry, ***and these highly concentrated markets are already exhibiting troubling signs of coordinated behavior***" (emphasis added).

271. The FTC observed, among other things, "troubling signs of coordinated behavior," including Defendants' statements made in reports and to the press, meetings made outside of trade association meetings, signaling output levels, product rationing, and other conspiratorial actions by Defendants indicative of anti-competitive conduct.

272. The FTC alleged that, "with the elimination of Talecris-the one firm that has consistently and significantly expanded output in the United States— ***CSL and Baxter International, Inc. ("Baxter") would face no remaining significant obstacle in their efforts to coordinate and tighten supply conditions for the relevant products, to the great detriment of consumers"*** (emphasis added).

273. The FTC also reported that language contained in documents of CSL and Baxter suggests a strong possibility of ongoing coordinated interaction between firms in the plasma industry. Evidence of transparency, interdependence, and signaling among firms is particularly relevant to the allegations in this matter. The language at issue bears on these very important points, and demonstrates how firms used specific key words to:

- suggest to each other that increasing the production of lifesaving drugs could hurt the firms' ability to reap the significant profits they all achieved during an extended period where demand exceeded supply for the key products;
- remind each other of how, during a period when supply increased, prices and profitability for the firms in the market dropped significantly; and
- encourage each other to only increase supply incrementally to keep pace with demand, not increase supply to the extent the firms actually compete with each other for market share.

274. The FTC also has noted that the "quoted language" in its complaint taken from the files of Baxter and CSL "is similar to language that in other instances has been found to be evidence supporting an illegal price fixing conspiracy. *See, e.g., In re High Fructose Corn*

Syrup Antitrust Litigation, 295 F.3d 651, 662 (7th Cir. 2002) (Posner, J.) (referring to competitor as a 'friendly competitor,' mentioning an 'understanding between the companies that . . . causes [them] not to ... make irrational decisions,' and querying whether competitors 'will play by the rules (discipline)' can all be evidence of an explicit agreement to fix prices)."

275. The FTC has recognized that some of the language from the files of CSL and Baxter would cause them "embarrassment" and "could 'expose [CSL] to possible treble damages actions.'"

276. Shortly after the filing of the FTC complaint, on June 8, 2009, CSL Limited and Talecris publicly announced that they would abandon their proposed merger. On June 15, 2009, the FTC and the two firms jointly filed a motion to dismiss the FTC's complaint on that basis, and on June 22, 2009, the FTC dismissed the complaint.

VIII. ANTITRUST VIOLATIONS

277. Beginning at least as early as July 1, 2003, Defendants and their co-conspirators engaged in a continuing agreement, understanding and conspiracy in restraint of trade to restrict output to artificially raise, fix, maintain and/or stabilize the prices of Plasma-Derivative Protein Therapies in the United States.

278. Based on the foregoing, and on information and belief, in formulating and effectuating the contract, combination or conspiracy, Defendants and their coconspirators engaged in anti-competitive activities, the purpose and effect of which were to restrict output and to artificially raise, fix, maintain, and/or stabilize the price of Plasma-Derivative Protein Therapies sold in the U.S. These activities included:

a. Defendants participating in meetings, conversations and communications to discuss the supply and price of Plasma-Derivative Protein Therapies in the United States; and

b. Defendants agreeing during those meetings, conversations and communications to restrict output and to charge prices at specified levels and otherwise to fix, raise, maintain or stabilize prices of Plasma-Derivative Protein Therapies sold in the United States.

279. Defendants and their co-conspirators engaged in the activities described above for the purpose of effectuating the unlawful agreements described in the Complaint.

280. Throughout the relevant time period, Plaintiff purchased Plasma-Derivative Protein Therapies directly and indirectly from Defendants (or their subsidiaries or controlled affiliates) or their co-conspirators at supracompetitive prices.

281. Defendants also agreed to exchange information regarding output and production capacity that had the effect of restricting output and of fixing, raising, maintaining, or stabilizing the prices of Plasma-Derivative Protein Therapies.

282. Defendants' contract, combination or conspiracy constitutes an unreasonable restraint of interstate trade and commerce in violation of the Antitrust and Unfair Competition Laws.

IX. EFFECTS OF THE CONSPIRACY

283. As a result of Defendants' unlawful conduct, Plaintiff has been injured in its business and property because it has paid more for Plasma-Derivative Protein Therapies than it would have paid in a competitive market.

284. Defendants' unlawful contract, combination or conspiracy has had at least the following effects:

a. price competition in the markets for Plasma-Derivative Protein Therapies has been artificially restrained;

b. prices for Plasma-Derivative Protein Therapies sold by Defendants have been raised, fixed, maintained, and/or stabilized at supracompetitive levels; and

c. purchasers of Plasma-Derivative Protein Therapies from Defendants have been deprived of the benefit of free and open competition in the Plasma-Derivative Protein Therapies markets; and

d. Plaintiff has suffered financial injuries as a result.

/ / /

/ / /

X. FRAUDULENT CONCEALMENT

285. Plaintiff did not discover, and could not have discovered through the exercise of reasonable diligence, the existence of the conspiracy alleged herein until May 27, 2009, when the FTC's redacted complaint was filed.

286. Because Defendants' alleged conspiracy was kept secret until May 27, 2009, Plaintiff was unaware of Defendants' unlawful conduct alleged herein before that time, and it did not know before that time that they were paying supra- competitive prices for Plasma-Derivative Protein Therapies during the relevant period.

287. The affirmative acts of the Defendants alleged herein, including acts in furtherance of the conspiracy, were wrongfully concealed and carried out in a manner that precluded detection.

288. By its very nature, Defendants' conspiracy was inherently self-concealing. Plasma-Derivative Protein Therapies are not exempt from antitrust regulation, and thus, before May 27, 2009, Plaintiff reasonably considered the plasma-derivative protein therapy industry to be a well-regulated, competitive industry.

289. In addition, as detailed previously, Defendants, through their trade association, the PPTA, intentionally over-reported the supply of Plasma-Derivative Protein Therapies to the marketplace during the relevant period in order to avoid governmental and public scrutiny of their sales and marketing practices, and to conceal the existence of the shortages created by their conspiracy.

290. Under the circumstances surrounding Defendants' pricing practices, Defendants' acts of concealment were more than sufficient to preclude suspicion by a reasonable person that Defendants' pricing was conspiratorial. Accordingly, a reasonable person under the circumstances would not have been alerted to investigate the legitimacy of Defendants' Plasma-Derivative Protein Therapies prices before May 27, 2009.

291. Plaintiff could not have discovered the alleged conspiracy at an earlier date by the exercise of reasonable diligence because of the deceptive practices and techniques of secrecy

employed by Defendants and their coconspirators to avoid detection of and fraudulently conceal their conspiracy.

292. Because the alleged conspiracy was both self-concealing and affirmatively concealed by Defendants and their co-conspirators, Plaintiff had no knowledge of the alleged conspiracy, or of any facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed, until May 27, 2009, when the FTC complaint, and its corresponding factual allegations of anti-competitive conduct concerning Plasma-Derivative Protein Therapies, were first publicly disseminated.

293. None of the facts or information available to Plaintiff prior to May 27, 2009, if investigated with reasonable diligence, could or would have led to the discovery of the conspiracy alleged herein prior to that date.

294. As a result of Defendants' fraudulent concealment of their conspiracy, any statute of limitations has been tolled with respect to any claims that Plaintiff has alleged in this Complaint.

295. Defendants and their co-conspirators engaged in a successful anti-competitive conspiracy concerning Plasma-Derivative Protein Therapies, which they affirmatively concealed, at least in the following respects:

a. By communicating secretly to discuss output and prices of Plasma-Derivative Protein Therapies in the United States.

b. By agreeing among themselves not to discuss publicly, or otherwise reveal, the nature and substance of the acts and communications in furtherance of their illegal scheme;

c. By mis-reporting supply to HHS in order to conceal the dangerous shortages caused by their conspiracy;

d. By falsely denying the existence of supply shortages for Plasma-Derivative Protein Therapies; and

e. By "scrubbing" the minutes of the trade association meetings to remove references to anti-competitive discussions.

296. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting Plaintiff's claims have been tolled.

XII. VIOLATIONS ALLEGED

FIRST CLAIM FOR RELIEF

(VIOLATION OF CALIFORNIA ANTITRUST LAW)

315. Plaintiff incorporates and re-alleges, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Complaint.

316. Defendants created, operated, aided, or abetted a trust, combine, or monopoly of Plasma-Derivative Protein Therapies by fixing, controlling, or maintaining prices in violation of the state antitrust statutes listed below.

332. As set forth herein, Defendants created, operated, aided, or abetted a trust, combine, or monopoly of Plasma-Derivative Protein Therapies by fixing, controlling, or maintaining prices in violation of the California Cartwright Act, Cal. Bus. & Prof. Code §§ 16700 *et seq*. Defendants' unlawful conduct had the following effects: (1) the Plasma-Derivative Protein Therapies price competition and output were restrained, suppressed, and eliminated throughout California; (2) the price of Plasma-Derivative Protein Therapies was raised, fixed, maintained, and stabilized at artificially high levels throughout California; (3) Plaintiff was deprived of free and open competition; (4) Plaintiff relied on Defendants' false representation that the price of Plasma-Derivative Protein Therapies was a product of a free and fair market; and (5) Plaintiff paid supracompetitive, artificially inflated prices for Plasma-Derivative Protein Therapies.

333. Defendants conspired to fix the prices for the Plasma-Derivative Protein Therapies. Defendants agreed not to divulge the existence of the conspiracy, conducted meetings and conversations in secret, confined the plan to a small group of high-level officials, and avoided the creation of documents. United by their common interests, Defendants colluded to substantially limit, lessen, and exclude competition. Defendants reduced the production of Plasma-Derivative Protein Therapies, which prevented and restrained trade and commerce.

With the ability to preclude free and unrestricted competition, Defendants increased the price of Plasma-Derivative Protein Therapies.

334. Plaintiff suffered an ascertainable loss of money or property from the supracompetitive, artificially inflated prices.

335. Defendants' conduct is a substantial factor of the Plaintiff loss. The loss was a direct and proximate result of Defendants' willful price-fixing conspiracy. Plaintiff purchased Plasma-Derivative Protein Therapies at supracompetitive, artificially inflated prices because Defendants fixed prices after Defendants precluded free and unrestricted competition.

336. Defendants created, operated, aided, or abetted a trust with the purpose of fixing, controlling, or maintaining prices of Plasma-Derivative Protein Therapies, in violation of the California Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, *et seq*., and Plaintiff seeks damages and injunctive relief pursuant to Cal. Bus. & Prof. Code § 16750.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays as follows:

A. That the Court determine that the contract, combination or conspiracy, and the acts done in furtherance thereof by Defendants and their co-conspirators be adjudged to have violated California's Antitrust Laws.

B. That judgment be entered for Plaintiff against Defendants for damages sustained by Plaintiff and/or restitution as allowed by law.

C. That Plaintiff recover pre-judgment and post-judgment interest as permitted by law.

E. That Plaintiff recover their costs of the suit, including attorneys' fees, as provided by law.

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F. That Defendants be enjoined from continuing their participation in the alleged conspiracy.

G. For such other and further relief as is just and proper under the circumstances.

DATED: June 28, 2013

COTCHETT, PITRE & McCARTHY, LLP

By: */s/ Steven N. Williams*
Steven N. Williams

Attorney for Plaintiff County of San Mateo

JURY DEMAND

Plaintiff demands a jury trial on all issues so triable.

DATED: June 28, 2013

COTCHETT, PITRE & McCARTHY, LLP

By: */s/ Steven N. Williams*
Steven N. Williams

Attorney for Plaintiff County of San Mateo