

smelter, within six (6) months after the date on which the Order becomes final, to an acquirer and in a manner that receives the prior approval of the Commission.

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

By direction of the Commission.

Donald S. Clark,
Secretary.

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FEDERAL TRADE COMMISSION

[File No. 9910095]

SNIA S.p.A; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.
ACTION: Proposed consent agreement.

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

DATES: Comments must be received on or before July 19, 1999.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

FOR FURTHER INFORMATION CONTACT: Christina Perez or Michael Barnett, FTC/S-2308, 601 Pennsylvania Avenue, N.W., Washington, D.C. 20580, (202) 326-2048 or (202) 326-2541.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46, and Section 2.34 of the Commission's Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the

allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for May 14th, 1999), on the World Wide Web, at "http://www.ftc.gov/os/actions97.htm." A paper copy can be obtained from the FTC Public Reference Room, Room H-130, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580, either in person or by calling (202) 326-3627.

Public comment is invited. Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Two paper copies of each comment should be filed, and should be accompanied, if possible, by a 3½ inch diskette containing an electronic copy of the comment. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an agreement containing a proposed Consent Order ("Order") from SNIA S.p.A. ("SNIA"), which is designed to remedy the anticompetitive effects of SNIA's acquisition of all of the outstanding voting securities of COBE Cardiovascular, Inc. ("COBE"), as well as certain cardiopulmonary and other cardiovascular assets and liabilities from other subsidiaries of Gambro AB ("Gambro"). Both SNIA and Gambro manufacture and sell a wide variety of cardiovascular products, including heart-lung machines. The proposed Order remedies the acquisition's anticompetitive effects by requiring SNIA to divest COBE's heart-lung machine business.

The proposed Order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will review the proposed Order and the comments received and will decide whether it should withdraw from the proposed Order or make final the proposed Order.

Pursuant to an Asset and Stock Purchase Agreement signed on November 23, 1998, SNIA, through its Sorin Biomedica, Inc. subsidiary ("Sorin"), has agreed to purchase 100% of the outstanding voting securities of COBE, as well as certain other assets and liabilities from other subsidiaries of

Gambro, for approximately \$260 million. The proposed Complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, in the U.S. market for heart-lung machines.

Heart-lung machines are life-sustaining medical devices that are essential for any surgery that requires the heart to be stopped, such as surgeries to implant coronary artery bypass grafts, repair or replace heart valves, repair cerebral aneurysms, or transplant livers and hearts. A heart-lung machine is the equipment portion of an extracorporeal bypass system, which replaces the function of the heart and lungs during surgery by circulating and providing oxygen to the patient's blood throughout the procedure. In addition to a heart-lung machine, a complete extracorporeal bypass system is comprised of various single-use products, called disposables, that come into direct contact with the patient's blood, and therefore cannot be reused for safety reasons. Approximately 450-550 new units are sold worldwide each year, amounting to \$50 million in sales.

The U.S. market for heart-lung machines is highly concentrated and the proposed acquisition would substantially increase concentration in this market. The acquisition would result in a Herfindahl-Hirschman Index ("HHI") of 4,638 points, which is an increase of 1,554 points over the preacquisition level. SNIA and COBE are two of only four suppliers of heart-lung machines in the United States, with the fourth competitor being significantly smaller than the other three. By eliminating the competition between SNIA and COBE in this highly concentrated market, the proposed acquisition would enhance the likelihood of coordinated interaction between or among the remaining firms in the market, thus increasing the likelihood that consumers in the United States would be forced to pay higher prices for heart-lung machines.

It is unlikely that this lost competition would have been replaced by new entrants into the relevant market due to the substantial barriers to entry into the U.S. market for heart-lung machines. A new entrant into this market would need to undertake the difficult, expensive and time-consuming process of researching and developing a new product, obtaining approval from the U.S. Food and Drug Administration, establishing a nationwide service and sales network and gaining customer acceptance. This is a very difficult

process for new entrants because manufacturers are reluctant to establish a nationwide service and sales network until they have gained customer acceptance and have an established customer base, and customers are reluctant to purchase from a supplier unless it has an established service and sales network. As a result, a new entrant often finds itself in a "Catch 22" problem. For these reasons, new entry into the market would not be timely, likely or sufficient to deter or counteract the anticompetitive effects resulting from the acquisition.

The proposed Order remedies the anticompetitive effects in the heart-lung machine market by requiring SNIA to divest COBE's heart-lung machine business to Baxter Healthcare Corporation, a large manufacturer of medical products, including disposables for heart-lung machines, within ten (10) days after the Commission accepts the Agreement Containing Consent Order for public comment, or to another Commission-approved buyer within one hundred eighty (180) days after the Agreement Containing Consent Order is accepted for public comment. In the event that SNIA fails to divest the heart-lung machine assets, or the acquirer fails to obtain FDA approval and the ability to manufacture and sell heart-lung machines, the Commission may appoint a trustee to divest the COBE heart-lung machine business to a new acquirer. The divestiture trustee will have the authority and power to divest the heart-lung machine assets in a manner that satisfies the requirements of the Order.

The proposed Order requires SNIA to provide assistance to the acquirer so that it can compete effectively in the heart-lung machine business. First, SNIA must contract manufacture a supply of heart-lung machines for a limited time period while the acquirer obtains its own FDA approval and obtains the commercial capability to manufacture and sell heart-lung machines in the United States. Second, SNIA must provide technical assistance and advice to help the acquirer in its efforts to begin manufacturing and

selling heart-lung machines. The proposed Order enables the acquirer to hire former COBE employees associated with the research, development, manufacture, marketing, or sales of heart-lung machines. Finally, the Order requires SNIA to cooperate with the acquirer in any patent dispute in which a third party attempts to challenge any of the patents divested pursuant to the Order and in which the ability of the acquirer to become an effective competitor in the heart-lung machine market could be affected.

In order to facilitate the smooth transfer of assets and ensure that the acquirer will get the assistance necessary to independently manufacture the products, the proposed Order provides for the appointment of an interim trustee. The interim trustee will serve until the acquirer has received all necessary FDA approvals and obtains the commercial capability to manufacture and sell heart-lung machines. The Order also requires SNIA to provide to the Commission a report of compliance with the divestiture provisions of the Order within thirty (30) days following the date the Order becomes final, and every ninety (90) days thereafter until SNIA has completed the divestiture. The Order also requires SNIA to notify the Commission at least thirty (30) days prior to any change in SNIA that may affect compliance obligations arising out of the Order.

The purpose of this analysis is to facilitate public comment on the proposed Order and the divestiture to Baxter Healthcare Corporation, and it is not intended to constitute an official interpretation of the agreement and proposed Order or to modify their terms in any way.

By direction of the Commission.

Donald S. Clark,
Secretary.

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**GENERAL SERVICES
ADMINISTRATION**

**Interagency Committee for Medical
Records (ICMR); Automation of
Medical Standard Form 93**

AGENCY: General Services Administration.

ACTION: Guideline on automating medical standard forms.

BACKGROUND: The Interagency Committee on Medical Records (ICMR) are aware of numerous activities using computer-generated medical forms, many of which are not mirror images of the genuine paper Standard Form. With GSA's approval the ICMR eliminated the requirement that every electronic version of a medical Standard/Optional form be reviewed and granted an exception. The committee proposes to set data standards and require that activities developing computer-generated versions adhere to the required data elements but not necessarily to the image. The ICMR plans to review medical Standard/Optional forms which are commonly used and/or commonly computer-generated. We will identify those data elements which are required, those (if any) which are optional, and the required format (if necessary). Activities may not add data elements that would change the meaning of the form. This would require written approval from the ICMR. Using the process by which overprints are approved for paper Standard/Optional forms, activities may add other data elements to those required by the committee. With this decision, activities at the local or headquarters level should be able to develop electronic versions which meet the committee's requirements.

SUMMARY: With GSA's approval, the Interagency Committee on Medical Records (ICMR) eliminated the requirement that every electronic version of a medical Standard/Optional form be reviewed and granted an exception. The following data elements must appear on the electronic version of the following form:

ELECTRONIC ELEMENTS FOR SF 93

Item	Placement *
Text:	
Title: Report of Medical History	Top of form.
Note: This information is for official and medically-confidential use only and will not be released to unauthorized persons.	Top of form.
Form ID: Standard Form 93 (Rev. 6-96)	Bottom right corner of form.