# UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION

In the Matter of	) )
FRESENIUS AG	)
a corporation; and	) File No. 961-0053
FRESENIUS USA, INC.	) )
a corporation.	) )

#### AGREEMENT CONTAINING CONSENT ORDER

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Fresenius AG of National Medical Care, Inc. from W.R. Grace & Co., and it now appearing that Fresenius AG and Fresenius USA, Inc. (hereinafter sometimes referred to as "proposed respondents") are willing to enter into an agreement containing an order to divest certain assets, and to cease and desist from making certain acquisitions without providing advance written notification to the Commission, and providing for other relief:

- IT IS HEREBY AGREED by and between proposed respondents, by their duly authorized officers and attorneys, and counsel for the Commission that:
- 1. Proposed respondent Fresenius AG is a corporation organized, existing and doing business under and by virtue of the laws of Germany with its office and principal place of business located at Borkenberg 14, 61440 Oberursel/Ts, Bad Homburg, Germany.
- 2. Proposed respondent Fresenius USA, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of Massachusetts with its principal place of business located at 2637 Shadelands Drive, Walnut Creek, California 94598.
- 3. Proposed respondents admit all the jurisdictional facts set forth in the draft of complaint here attached.

- 4. Proposed respondents waive:
  - a. any further procedural steps;
  - b. the requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;
  - c. all rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement; and
  - d. any claim under the Equal Access to Justice Act.
- 5. Proposed respondents shall submit, within thirty (30) days of the date this agreement is signed by proposed respondents, an initial report signed by the proposed respondents setting forth in detail the manner in which the proposed respondents will comply with Paragraph II of the order when and if entered. Such report will not become part of the public record unless and until the accompanying order is made final by the Commission and the required divestiture accomplished.
- 6. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission it, together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the proposed respondents, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.
- 7. This agreement is for settlement purposes only and does not constitute an admission by proposed respondents that the law has been violated as alleged in the draft of complaint here attached, or that the facts as alleged in the draft complaint, other than jurisdictional facts, are true.
- 8. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 2.34 of the Commission's Rules, the Commission may, without further notice to the proposed respondents, (1) issue its complaint corresponding in form and substance with the draft of complaint here attached and its decision containing the following order to

divest and to cease and desist in disposition of the proceeding and (2) make information public with respect thereto. When so entered, the order to divest shall have the same force and effect and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery by the United States Postal Service of the complaint and decision containing the agreed-to order to proposed respondents' addresses as stated in this agreement shall constitute service. Proposed respondents waive any right they may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

9. Proposed respondents have read the proposed complaint and order contemplated hereby. Proposed respondents understand that once the order has been issued, they will be required to file one or more compliance reports showing that they have fully complied with the order. Proposed respondents further understand that they may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

#### ORDER

Ι

- IT IS ORDERED that, as used in this Order, the following
  definitions shall apply:
- A. "Respondents" or "Fresenius" means Fresenius AG and Fresenius USA, Inc., their directors, officers, employees, agents and representatives, their predecessors, successors, and assigns; their subsidiaries, divisions, and groups and affiliates controlled by Fresenius, and the respective directors, officers, employees, agents, representatives, successors and assigns of each; their domestic and foreign parents, and the subsidiaries, divisions, and groups and affiliates controlled by any other domestic or foreign parent, and the respective directors, officers, employees, agents, representatives, successors and assigns of each.
- B. "NMC" means National Medical Care, Inc., its directors, officers, employees, agents and representatives, its predecessors, successors, and assigns; its subsidiaries, divisions, and groups and affiliates controlled by NMC, and the

respective directors, officers, employees, agents, representatives, successors and assigns of each; its domestic and foreign parents, including W.R. Grace & Co., and the subsidiaries, divisions, and groups and affiliates controlled by any other domestic or foreign parent, and the respective directors, officers, employees, agents, representatives, successors and assigns of each.

- C. "Commission" means the Federal Trade Commission.
- D. "NMC Acquisition" means the acquisition by Fresenius AG of NMC that is the subject of an Agreement and Plan of Reorganization entered into on or about February 4, 1996.
- E. "Hemodialysis Concentrate" means the acid portion of the dialysate solution used in hemodialysis treatment of End Stage Renal Disease to carry waste materials from the patient's blood during the treatment.
- F. "Assets and Businesses" means assets, properties, businesses, and goodwill, tangible and intangible, including, without limitation, the following:
  - 1. All plant facilities, machinery, fixtures, equipment, vehicles, transportation and storage facilities, furniture, tools, supplies, stores, spare parts, and other tangible personal property;
  - 2. All customer lists, vendor lists, catalogs, sales promotion literature, advertising materials, research materials, technical information, dedicated management information systems, information contained in management information systems, rights to software, trademarks, patents and patent rights, inventions, trade secrets, technology, know-how, ongoing research and development, specifications, designs, drawings, processes and quality control data;
  - 3. Raw material and finished product inventories and goods in process;
  - 4. All right, title and interest in and to real property, together with appurtenances, licenses, and permits;
  - 5. All right, title, and interest in and to the contracts entered into in the ordinary course of business with customers (other than contracts in which Hemodialysis Concentrate is sold as part of a package of products), suppliers, sales representatives, distributors, agents, personal property lessors, personal property lessees, licensors, licensees, consignors and consignees;
  - 6. All rights under warranties and guarantees, express or implied;

- 7. All separately maintained, as well as relevant portions of not separately maintained, books, records and files; and
  - 8. All items of prepaid expense.
- G. "Hemodialysis Business to Be Divested" means the Fresenius Lewisberry, Pennsylvania Hemodialysis Manufacturing Facility, and any additional Fresenius Hemodialysis Concentrate Assets and Businesses (as defined) as are necessary to assure the Viability and Competitiveness of the Hemodialysis Business to Be Divested in the manufacture, marketing or distribution of Hemodialysis Concentrate.
- H. "Viability and Competitiveness" means that the Hemodialysis Concentrate Business to Be Divested is capable of functioning independently and competitively in the Hemodialysis Concentrate business in substantially the same manner achieved by Fresenius prior to the divestiture.

II

# IT IS FURTHER ORDERED that:

Respondents shall, absolutely and in good faith, divest the Hemodialysis Business to Be Divested to Di-Chem, Inc. ("Di-Chem"), within 10 business days of either (i) the date this Order is made final, or (ii) the closing of the NMC Acquisition, whichever is later, pursuant to and in accordance with the May 17, 1996 agreement between Fresenius USA, Inc. and Di-Chem ("Divestiture Agreement"). If the terms of such Divestiture Agreement are changed or supplemented in any way, notice of such changes or supplementations must be provided to the Commission, and any material changes or supplementations may be made only with the prior approval of the Commission. In the event that the Divestiture Agreement is terminated through no fault of Respondents, Respondents shall divest the Hemodialysis Business to Be Divested within four (4) months of either (i) the date this Order is made final, or (ii) the closing of the NMC Acquisition, whichever is later, and Respondents shall also effect such additional arrangements so as to assure the Viability and Competitiveness of the Hemodialysis Business to Be Divested. Respondents shall divest the Hemodialysis Business to Be Divested to an acquirer that receives the prior approval of the Commission and only in a manner that receives the prior approval of the Commission.

The purpose of the divestiture is to enable the acquirer to compete in the manufacture and sale of Hemodialysis Concentrate in the United States and to remedy the lessening of competition resulting from the NMC Acquisition as alleged in the Commission's Complaint.

B. Pending divestiture of the Hemodialysis Business to Be Divested, Respondents shall take such actions as are necessary to maintain the marketability, viability and competitiveness of the Hemodialysis Business to Be Divested, including, but not limited to, taking necessary steps to ensure that the Lewisberry plant is capable of, and has been approved for, commercial production, and to prevent destruction, removal, wasting, deterioration or impairment of the Hemodialysis Business to Be Divested, other than ordinary wear and tear.

#### III

#### IT IS FURTHER ORDERED that:

If Respondents have not divested the Hemodialysis Business to Be Divested within four (4) months of either (i) the date this Order becomes final, or (ii) the closing of the NMC Acquisition, whichever is later, the Commission may appoint a trustee to divest the Hemodialysis Business to Be Divested pursuant to Paragraph II of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(1) of the Federal Trade Commission Act, 15 U.S.C. § 45(1), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a trustee in such action. Neither the appointment of a trustee nor a decision not to appoint a trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed trustee, pursuant to  $\S$  5(1) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by the Respondents to comply with this Order. The Commission shall select the trustee under this Paragraph, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The trustee shall be a person with experience and expertise in acquisitions, divestitures, and licensing. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed trustee, Respondents shall be deemed to have consented to the selection of the proposed trustee.

- B. If a trustee is appointed by the Commission or a court pursuant to Paragraph III.A of this Order, Respondents shall consent to the following terms and conditions regarding the trustee's powers, duties, authority, and responsibilities:
  - 1. Subject to the prior approval of the Commission and consistent with the provisions of Paragraph II of this Order, the trustee shall have the exclusive power and authority to divest the Hemodialysis Business to Be Divested.
  - 2. Within ten (10) days after the appointment of the trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, and in the case of a court-appointed trustee, of the court, transfers to the trustee all rights and powers necessary to permit the trustee to effect the divestiture required by this Order.
  - 3. The trustee shall have twelve (12) months from the date the trust agreement described in this Paragraph III.B is approved by the Commission to accomplish the divestiture of the Hemodialysis Business to Be Divested, which shall be subject to the prior approval of the Commission. If, however, at the end of this twelve (12) month period, the trustee has submitted a plan of divestiture or believes that divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court-appointed trustee, by the court.
  - 4. The trustee shall have full and complete access to the personnel, books, records and facilities related to the Hemodialysis Business to Be Divested and to any other relevant information as the trustee may reasonably request. Respondents shall develop such financial or other information as the trustee may reasonably request and shall cooperate with the trustee. Respondents shall take no action to interfere with or impede the trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a courtappointed trustee, by the court.
  - 5. The trustee shall use his or her best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest at no minimum price. The divestiture shall be made

in the manner and to an acquirer as set out in Paragraph II of this Order; provided however, if the trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the trustee shall divest to the acquiring entity or entities selected by Respondents from among those approved by the Commission.

- 6. The trustee shall serve without bond or other security at the cost and expense of Respondents, and on such reasonable and customary terms and conditions as the Commission or a court may set. The trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are reasonably necessary to carry out the trustee's duties and responsibilities. trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed trustee, by the court, of the account of the trustee, including fees for his or her services, all remaining monies shall be paid at the direction of the Respondents, and the trustee's power shall be terminated. The trustee's compensation shall be based at least in significant part on a commission arrangement contingent on the trustee's divesting the Hemodialysis Business to Be Divested.
- 7. Respondents shall indemnify the trustee and hold the trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the duties of the trustee, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the trustee.
- 8. If the trustee ceases to act or fails to act diligently, a substitute trustee shall be appointed in the same manner as provided in Paragraph III.A of this Order.
- 9. The Commission or, in the case of a courtappointed trustee, the court, may on its own initiative or at the request of the trustee issue such additional orders

or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

- 10. The trustee shall have no obligation or authority to operate or maintain the Hemodialysis Business to Be Divested.
- 11. The trustee shall report in writing to Respondents and the Commission every thirty (30) days concerning efforts to accomplish the divestiture.

IV

#### IT IS FURTHER ORDERED that:

A. Within twenty (20) days after the date this Order becomes final and every thirty (30) days thereafter until Respondents have fully complied with the provisions of Paragraphs II and III of this Order, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order. Respondents shall include in their compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with Paragraph II of the Order, including a description of all substantive contacts or negotiations for the divestiture and the identity of all parties contacted. Respondents shall include in their compliance reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning divestiture.

V

IT IS FURTHER ORDERED that, for a period of ten (10) years from the date this Order becomes final, Respondents shall cease and desist from acquiring, without Prior Notification to the Commission (as defined below), directly or indirectly, through subsidiaries or otherwise, any assets for manufacturing Hemodialysis Concentrate or any Hemodialysis Concentrate manufacturing facility, that have been employed in Hemodialysis Concentrate manufacturing in the United States within one (1) year of the date of an offer by Fresenius to purchase the assets, or any interest in a Hemodialysis Concentrate manufacturing facility in the United States, or any interest in any individual, firm, partnership, corporation or other legal or business entity that directly or indirectly owns or operates a Hemodialysis Concentrate manufacturing facility in the United States.

Provided, however, that this Paragraph V shall not be deemed to require Prior Notification to the Commission for (i) the construction of new facilities by Fresenius, (ii) the acquisition of new or used equipment in the ordinary course of business from a person other than the acquirer of the Hemodialysis Business to Be Divested, or any other present producer of Hemodialysis Concentrate; or (iii) the purchase or lease by Fresenius of a facility that has not been operated as a Hemodialysis Concentrate manufacturing facility at any time during the year immediately prior to the purchase or lease by Fresenius.

"Prior Notification to the Commission" required by Paragraph V shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations, as amended (hereinafter referred to as "the Notification Form"), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such notification, notification shall be filed with the Secretary of the Commission, notification need not be made to the United States Department of Justice, and notification is required only of Fresenius and not of any other party to Fresenius shall provide the Notification the transaction. Form to the Commission at least thirty (30) days prior to consummating any such transaction (hereinafter referred to as the "first waiting period"). If, within the first waiting period, representatives of the Commission make a written request for additional information, Fresenius shall not consummate the transaction until twenty (20) days after substantially complying with such request for additional information. Early termination of the waiting periods in this paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition. Notwithstanding, Fresenius shall not be required to provide Prior Notification to the Commission pursuant to this order for a transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

# VI

IT IS FURTHER ORDERED that until the obligations set forth in Paragraphs II, III and V are met, Respondents shall notify the Commission at least thirty (30) days prior to any proposed change in the corporate Respondents such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change

in the corporations that may affect compliance obligations arising out of the Order.

#### VII

- IT IS FURTHER ORDERED that Respondents, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, upon written request and on five days notice to Respondents, shall permit any duly authorized representative(s) of the Commission:
- A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of Respondents relating to any matters contained in this Order; and
- B. Without restraint or interference from Respondents, to interview Respondents' officers, directors, or employees, who may have counsel present, regarding such matters.

Signed this \_\_\_\_\_ day of May, 1996. FOR THE BUREAU OF COMPETITION FOR FRESENIUS AG AND FEDERAL TRADE COMMISSION FRESENIUS USA, INC. Udo Werle Robert S. Tovsky Chief Financial Officer Attorney Fresenius AG M. Howard Morse Assistant Director Dr. Rainer Runte Counsel Fresenius AG George S. Cary Senior Deputy Director Ben J. Lipps, Ph.D. President Fresenius USA, Inc. William J. Baer FOR O'MELVENY & MYERS

Director

Richard G. Parker
David T. Beddow
Counsel to Fresenius AG and
Fresenius USA, Inc.

# UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION

In the Matter of	<u> </u>	
FRESENIUS AG		
a corporation	n; and	
FRESENIUS USA, INC.		
a corporation	n.	

#### COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act and of the Clayton Act, and by virtue of the authority vested in it by said Acts, the Federal Trade Commission, having reason to believe that Fresenius AG, the parent company of Fresenius USA, Inc. (collectively "Fresenius"), has entered into an Agreement and Plan of Reorganization with W.R. Grace & Co. ("Grace") whereby Fresenius will acquire from Grace the businesses comprising National Medical Care, Inc. ("NMC"), and that such 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, and having reason to believe that Fresenius has entered into such agreement in restraint of trade in violation of Section 5 of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint stating its charges as follows:

# I. THE RESPONDENTS

- 1. Respondent Fresenius AG is a corporation organized, existing and doing business under and by virtue of the laws of Germany with its office and principal place of business located at Borkenberg 14, 61440 Oberursel/Ts, Bad Homburg, Germany.
- 2. Respondent Fresenius USA, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of Massachusetts with its principal place of business located at 2637 Shadelands Drive, Walnut Creek, California 94598.

3. At all times relevant herein, the Respondents (collectively "Fresenius") have been, and are now, engaged in commerce as "commerce" is defined in Section 4 of the Federal

Trade Commission Act (15 U.S.C.  $\S$  44) and Section 1 of the Clayton Act (15 U.S.C.  $\S$  12), and are corporations whose business is in or affecting commerce as defined in Section 4 of the Federal Trade Commission Act (15 U.S.C.  $\S$  44).

#### II. THE PROPOSED ACQUISITION

- 4. On or about February 24, 1996, Fresenius and Grace executed an Agreement and Plan of Reorganization in which Fresenius would acquire the assets and businesses comprising Grace's NMC subsidiary.
- 5. Fresenius and NMC are substantial direct competitors in the United States market for hemodialysis concentrate.

#### III. THE RELEVANT LINE OF COMMERCE

- 6. One relevant line of commerce within which to analyze the effects of the acquisition is the United States market for hemodialysis concentrate. Hemodialysis concentrate is a bicarbonate solution used in hemodialysis treatment of End Stage Renal Disease to carry waste materials from the patient's blood during the treatment.
- 7. Hemodialysis concentrate is a necessary product for hemodialysis treatment with no available substitute. The cost of the hemodialysis concentrate accounts for a small portion of the cost of hemodialysis treatment.
- 8. Imports of hemodialysis concentrate into the United States are rare. The potential for significant imports is constrained by the fact that most concentrate is shipped in an aqueous solution, making shipping costs very high relative to the value of the product.
- 9. Total sales of hemodialysis concentrate in the United States are approximately \$50 million.

# IV. MARKET CONCENTRATION

10. Fresenius and NMC are two of a small number of producers of hemodialysis concentrate in the United States. NMC is the leading producer. The other producers include CGH Medical, Minn-Tech Corporation, Rockwell Medical and Dana Laboratories. After the acquisition, Fresenius would have a market share of hemodialysis concentrate sales of over 50 percent in the United States.

11. The United States market for hemodialysis concentrate is highly concentrated as measured by the Herfindahl-Hirschman Index (HHI). On the basis of capacity, the proposed acquisition would increase concentration, as measured by the HHI, by over 1250 points, to over 3100. On the basis of sales, the proposed acquisition would increase concentration, as measured by the HHI, by over 950 points, to over 3000.

#### V. CONDITIONS OF ENTRY

- 12. Entry into the hemodialysis concentrate market would not be likely to deter or offset reductions in competition resulting from the acquisition.
- 13. In addition to obtaining FDA approval, a new entrant would need to obtain a relatively high volume of sales in order to have cost-competitive production, and to support the costs of product testing. The need to capture a large market share makes the success of new entry less likely, and acts as a deterrent to entry. Most of the investment in production would likely be sunk in the event that entry were unsuccessful.
- 14. The likelihood of new entry is also reduced by the fact that a significant proportion of the dialysis clinics that use hemodialysis concentrate, including NMC, also produce the concentrate, and therefore are unlikely to purchase from a new entrant. Vertically integrated firms account for approximately a third of patients receiving hemodialysis treatment.
- 15. Moreover, a new entrant into hemodialysis concentrate would need to have an effective distribution system. However, there are only a few large full-line distributors of hemodialysis products, the largest of which (Fresenius, NMC, and CGH Medical) already produce hemodialysis concentrate.

# VI. EFFECTS OF THE ACQUISITION

- 16. The acquisition of NMC by Fresenius may substantially lessen competition in the United States market for hemodialysis concentrate because, among other things:
  - a. it will eliminate substantial head-to-head competition between NMC and Fresenius;
  - b. it will increase concentration substantially in a highly concentrated market;
  - c. it will increase the likelihood of coordinated interaction among producers of hemodialysis concentrate;

- d. company documents project that the increased
  "consolidation" of suppliers will likely lead to "price
  stabilization;" and
- e. it will likely result in increased prices for hemodialysis concentrate.

#### VII. VIOLATIONS CHARGED

- 17. The acquisition agreement between Fresenius and NMC described in paragraph 4 violates Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. \$ 45.
- 18. The proposed acquisition of NMC by Fresenius would, if consummated, violate Section 7 of the Clayton Act, as amended, 15 U.S.C.  $\S$  18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C.  $\S$  45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this \_\_\_\_\_ day of \_\_\_\_\_, 1996, issues its complaint against said respondents.

By the Commission.

Seal

Donald S. Clark Secretary

Issued:

# ANALYSIS TO AID PUBLIC COMMENT ON THE PROVISIONALLY ACCEPTED CONSENT ORDER

The Federal Trade Commission ("the Commission") has accepted for public comment, from Fresenius AG and Fresenius USA, Inc., an agreement containing a consent order. This agreement has been placed on the public record for sixty days for reception of comments from interested persons.

Comments received during this period will become part of the public record. After sixty days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's order.

The Commission's investigation of this matter concerns the proposed acquisition by Fresenius of the businesses of W.R. Grace & Co. that comprise National Medical Care, Inc. ("NMC") The Commission's proposed complaint alleges that Fresenius and NMC compete with each other in hemodialysis concentrate, a chemical solution that is necessary in hemodialysis treatment of patients with End Stage Renal Disease, or chronic kidney failure.

The agreement containing consent order would, if finally accepted by the Commission, settle charges that the acquisition may substantially lessen competition in the production and sale of hemodialysis concentrate. The Commission has reason to believe that the acquisition agreement violates Section 5 of the Federal Trade Commission Act and the acquisition would have anticompetitive effects and would violate Section 7 of the

Clayton Act and Section 5 of the Federal Trade Commission Act if consummated, unless an effective remedy eliminates such anticompetitive effects.

The Commission's Complaint alleges that hemodialysis concentrate is a necessary product in hemodialysis treatment, and that the use of this product would not be significantly affected by a price increase. The Complaint further alleges that imports of hemodialysis concentrate are small and, because of high shipping costs, would not be responsive to a price increase in the United States. The market for hemodialysis concentrate in the United States is highly concentrated. In addition, the entry of other producers is unlikely. The Commission's Complaint alleges that the proposed acquisition would lessen competition by eliminating competition between Fresenius and NMC, and would make more likely coordinated interaction among the remaining producers of hemodialysis concentrate, leading to higher prices. Company planning documents, in fact, project that "increased consolidation" among concentrate producers will lead to "stabilization" of prices.

The proposed order accepted for public comment requires

Fresenius to divest its Lewisberry, Pennsylvania concentrate

manufacturing plant to Di-Chem, Inc. ("Di-Chem"), along with

other assets. The purpose of the proposed divestiture is to

create a viable and competitive producer of hemodialysis

concentrate and thereby to remedy the lessening of competition

alleged in the complaint. Di-Chem already manufactures and markets other dialysis products. In addition, Di-Chem's management has substantial experience in the hemodialysis concentrate business and in other products used in hemodialysis. Public comments regarding all aspects of the proposed divestiture to Di-Chem will be considered along with other comments on the proposed order.

Under the terms of the proposed order, Fresenius must divest the Lewisberry plant to Di-Chem within ten (10) days after the proposed Order is made final by the Commission. If the divestiture to Di-Chem is not accomplished, then Fresenius must divest the Lewisberry plant within four (4) months to an acquirer that is approved by the Commission. If Fresenius fails to accomplish the divestiture, then the Commission may appoint a trustee to divest the Lewisberry plant, along with ancillary assets or other arrangements that may be necessary to assure that the Lewisberry plant is capable of being operated independently and competitively by its acquirer. The proposed order also requires that Fresenius provide prior notice to the Commission of future acquisitions of either assets used to manufacture hemodialysis concentrate or companies that produce hemodialysis concentrate.

The purpose of this analysis is to invite public comment concerning the proposed order. This analysis is not intended to

constitute an official interpretation of the agreement and order or to modify their terms in any way.

# DISSENTING STATEMENT OF COMMISSIONER ROSCOE B. STAREK, III

#### In the Matter of

# Fresenius AG, et al., File No. 961 0053

I cannot join in the Commission's decision to accept a consent agreement for public comment in this matter. The evidence accumulated in the investigation is not sufficient to give rise to reason to believe that respondents' acquisition of National Medical Care, Inc. ("NMC") from W.R. Grace & Co. is likely to lessen competition substantially in a United States market for hemodialysis concentrate ("HD concentrate").

HD concentrate consists of various salts (sodium chloride, magnesium chloride, calcium chloride, and potassium chloride) and dextrose in purified water, with sodium bicarbonate (i.e., baking soda) added at a later stage. Because this easily formulated mixture does not enter the body and therefore is not a "drug" for purposes of Food and Drug Administration ("FDA") regulation, the FDA applies to HD concentrate the somewhat more lenient regulations applicable to medical devices. Regulatory delay thus does not significantly constrain entry by new firms or expansion by incumbents.

The investigation revealed that various producers of HD concentrate — including Fresenius itself — entered quickly and easily into the manufacture of the product, and some stated that they could inexpensively increase their capacity to make HD concentrate by as much as 60 percent within 30 days, without substantial investment or the need for additional FDA approval.¹ These indicia of cheap and simple entry and expansion may explain why the delivered price of HD concentrate has fallen continuously since the product first became available.²

Given the contrast between the time required for entry in the United States and that required in Germany, it is perhaps unsurprising that the latter nation's Bundeskartellamt concluded that Fresenius' acquisition of a competitor in HD concentrate would have anticompetitive effects. Entry into the German HD concentrate business apparently takes three to five years. In the United States, entry requires around nine months.

It is difficult to accept the proposition that "[m]ost of the investment in production would likely be sunk in the event that entry were unsuccessful" (proposed complaint, ¶ 13). The equipment used in the manufacture of HD concentrate appears to be adaptable to alternate uses, and indeed there is evidence of (continued...)

Thus, any assessment of this acquisition's potential to increase concentration in the market for HD concentrate -- and in turn make likelier an exercise of market power -- must take into account several strongly mitigating factors, including approximately 40 percent current excess capacity, the aforementioned ability of manufacturers to expand capacity speedily and at minimal cost, and the evident ability of customers (hemodialysis clinics) to integrate into the manufacture of HD concentrate in the event concentrate producers behave anticompetitively. Certain customers that speculated that the acquisition might lead to higher prices for HD concentrate appear to have been unaware of current plans for significant entry or capacity expansion by firms other than Fresenius and NMC. Moreover, other customer complaints seem to have been motivated by a fear that the vertical integration of Fresenius (a manufacturer of kidney dialysis products) and NMC (an operator of hemodialysis treatment centers, among its other businesses) could make the merged firm a stronger competitor in dialysis treatment.

It is always tempting to accept the "bird in the hand" represented by a consent agreement proffered in the early stages of an investigation, such as the one entered into (apparently without significant resistance) by Fresenius. Nevertheless, when the evidence on entry, expansion, and the absence of anticompetitive effects is as clear as in this case, the issuance of a consent order is unwarranted.

I therefore dissent.

<sup>&</sup>lt;sup>2</sup>(...continued)
firms planning to convert some HD concentrate facilities to other purposes.