# UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION

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In the Matter of
<b>BAXTER INTERNATIONAL INC.</b> , a corporation;
and
<b>WYETH</b> , a corporation.

Docket No. C-4068

## COMPLAINT

The Federal Trade Commission ("Commission"), having reason to believe that Respondent Baxter International Inc. ("Baxter"), a corporation subject to the jurisdiction of the Commission, has agreed to acquire certain assets of Respondent Wyeth, a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. §45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

### I. DEFINITIONS

- 1. "Commission" means the Federal Trade Commission.
- 2. "FDA" means the United States Food and Drug Administration.

3. "ESI" means ESI Lederle, a division of Wyeth that, among other things, researches, develops, manufactures and sells human generic injectable pharmaceuticals. ESI is organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its offices and principal place of business located at Five Giralda Farms, Madison, New Jersey 07940.

4. "Respondents" means Baxter and Wyeth individually and collectively.

5. "Metoclopramide" means any injectable pharmaceutical composition containing any formulation or dosage of the active ingredient generically known as metoclopramide or metoclopramide hydrochloride.

6. "New Injectable Iron Replacement Therapies" or "NIIRTs" means any injectable pharmaceutical composition containing any formulation or dosage of the active ingredient generically known as iron gluconate or iron sucrose.

7. "Pancuronium" means any injectable pharmaceutical composition containing any formulation or dosage of the active ingredient generically known as pancuronium or pancuronium bromide.

8. "Propofol" means any injectable pharmaceutical composition containing any formulation or dosage of the active ingredient generically known as propofol.

9. "Vecuronium" means any injectable pharmaceutical composition containing any formulation or dosage of the active ingredient generically known as vecuronium or vecuronium bromide.

# **II. RESPONDENTS**

10. Respondent Baxter is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its office and principal place of business located at One Baxter Parkway, Deerfield, Illinois 60015. Baxter, among other things, is engaged in the research, development, manufacture and/or sale of generic injectable pharmaceuticals, including: Pancuronium, Vecuronium, Metoclopramide, Propofol and NIIRTs.

11. Respondent Wyeth is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware with its office and principal place of business located at Five Giralda Farms, Madison, New Jersey 07940. Wyeth, through ESI, is engaged in the research, development, manufacture and/or sale of generic injectable pharmaceuticals, including: Pancuronium, Vecuronium, Metoclopramide, Propofol and NIIRTs.

12. Respondents are, and at all times relevant herein have been, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and are corporations whose business is in or affects commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

#### **III. THE PROPOSED ACQUISITION**

13. On June 8, 2002, Baxter and Wyeth entered into an Asset Purchase Agreement whereby Baxter agreed to acquire substantially all of the assets relating to Wyeth's human generic injectable pharmaceutical business, operated by Wyeth's ESI Lederle division (hereinafter "Acquisition").

#### **IV. THE RELEVANT MARKETS**

14. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are:

- 1. the manufacture and sale of Pancuronium;
- 2. the manufacture and sale of Vecuronium;
- 3. the manufacture and sale of Metoclopramide;
- 4. the manufacture and sale of Propofol; and
- 5. the manufacture and sale of NIIRTs.

15. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant lines of commerce.

#### V. THE STRUCTURE OF THE MARKETS

16. Baxter and ESI are the two leading U.S. suppliers of Pancuronium, a neuromuscular blocking agent. The Acquisition would create a duopoly in the market for the manufacture and sale of Pancuronium. After the acquisition, the combined company would account for 74% of annual sales of Pancuronium in the United States, and the post-acquisition Herfindahl-Hirschman Index ("HHI") would be 6,152, representing a 2,496 point increase in the HHI.

17. The market for the manufacture and sale of Vecuronium is also highly concentrated. Baxter and ESI were the two leading suppliers of Vecuronium in the United States, with a combined market share of 53%, until ESI temporarily suspended sales of Vecuronium in 2001. The postacquisition HHI would be 3,598, representing a 1,364 point increase in the HHI. Prior to the announcement of the Acquisition, ESI had planned to relaunch its Vecuronium product.

18. The market for the manufacture and sale of Metoclopramide is highly concentrated as measured by the HHI. Baxter and ESI are two of only four suppliers of Metoclopramide. Baxter and ESI, respectively, represent approximately 12% and 39% of the market. As a result of the Acquisition, Baxter would account for 51% of the market and the post-Acquisition HHI would be 3,852, an increase of 936 points above the pre-Acquisition HHI.

19. The market for the manufacture and sale of Propofol is highly concentrated. Currently, AstraZeneca Pharmaceuticals LP and Baxter market the only Propofol products in the United States. ESI is seeking FDA approval for its own Propofol product and is one of the two best-positioned firms to enter the market. Other firms that have undertaken efforts to develop Propofol have either failed in their efforts or lag well behind ESI.

20. The market for the manufacture and sale of NIIRTs is highly concentrated. Currently, Watson Pharmaceuticals, Inc. and Baxter jointly market one of only two NIIRT products approved for use in the United States. ESI has the most advanced development effort for a NIIRT and appears to be the best-positioned firm to enter the market for the manufacture and sale of NIIRTs.

### VI. ENTRY CONDITIONS

21. Entry into any of the relevant product markets described in Paragraph 14 would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Developing and obtaining approval for even the simplest generic injectable takes at least two years and significantly longer for more complex products. Additionally, patents and other intellectual property create large and potentially insurmountable barriers to entry in some of the product markets.

### **VII. EFFECTS OF THE ACQUISITION**

22. The effects of the Acquisition, if consummated, may be to lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

1. by eliminating actual, direct, and substantial competition between Baxter and Wyeth, and reducing the number of competitors, in the market for the manufacture and sale of Pancuronium, thereby (a) increasing the likelihood of a unilateral exercise of market power in the market for the manufacture and sale of Pancuronium, or (b) increasing the likelihood of coordinated interaction, and (c) increasing the likelihood that Pancuronium customers would be forced to pay higher prices;

- 2. by eliminating potential competition between Baxter and Wyeth in the market for the manufacture and sale of Vecuronium, thereby (a) increasing the likelihood that the combined entity would forego or delay the relaunch of ESI's Vecuronium and (b) increasing the likelihood that the combined entity would delay or eliminate the additional price competition that would have resulted from ESI's re-entry into the market for the manufacture and sale of Vecuronium;
- 3. by eliminating actual, direct, and substantial competition between Baxter and Wyeth, and reducing the number of competitors, in the market for the manufacture and sale of Metoclopramide, thereby (a) increasing the likelihood of a unilateral exercise of market power in the market for the manufacture and sale of Metoclopramide, or (b) increasing the likelihood of coordinated interaction, and (c) increasing the likelihood that Metoclopramide customers would be forced to pay higher prices;
- 4. by eliminating potential competition between Baxter and Wyeth in the market for the manufacture and sale of Propofol, thereby (a) increasing the likelihood that the combined entity would forego or delay the launch of ESI's Propofol and (b) increasing the likelihood that the combined entity would delay or eliminate the additional price competition that would have resulted from ESI's entry into the market for the manufacture and sale of Propofol; and
- 5. by eliminating potential competition between Baxter and Wyeth in the market for the manufacture and sale of NIIRTs, thereby (a) increasing the likelihood that the combined entity would forego or delay the launch of ESI's NIIRT and (b) increasing the likelihood that the combined entity would delay or eliminate the additional price competition that would have resulted from ESI's entry into the market for the manufacture and sale of NIIRTs.

## VIII. VIOLATIONS CHARGED

23. The Asset Purchase Agreement described in Paragraph 13 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

24. The Acquisition described in Paragraph 13, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twentieth day of December, 2002, issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark Secretary

SEAL: