

Governors not later than February 3, 2003.

**A. Federal Reserve Bank of Atlanta** (Sue Costello, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30303:

1. *CBS Banc Corp*, Russellville, Alabama; to merge with Community Financial Services, Inc., Bolivar, Tennessee, and thereby indirectly acquire The Bank of Bolivar, Bolivar, Tennessee.

2. *Coast Financial Holdings, Inc.*, Bradenton, Florida; to become a bank holding company by acquiring 100 percent of the voting shares of Coast Bank of Florida, Bradenton, Florida.

**B. Federal Reserve Bank of St. Louis** (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166-2034:

1. *Frontenac Bancshares, Inc.*, Earth City, Missouri; to become a bank holding company by acquiring 100 percent of the voting shares of Frontenac Bank, Earth City, Missouri.

**C. Federal Reserve Bank of San Francisco** (Maria Villanueva, Consumer Regulation Group) 101 Market Street, San Francisco, California 94105-1579:

1. *Utah Community Bancorp*, Sandy, Utah; to become a bank holding company by acquiring 100 percent of the voting shares of Utah Community Bank, Sandy, Utah.

Board of Governors of the Federal Reserve System, January 2, 2003.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 03-302 Filed 1-7-03; 8:45 am]

BILLING CODE 6210-01-S

## FEDERAL RESERVE SYSTEM

### Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at [www.ffiic.gov/nic/](http://www.ffiic.gov/nic/).

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 22, 2003.

**A. Federal Reserve Bank of Atlanta** (Sue Costello, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30303:

1. *Bancshares of Florida, Inc.* (formerly Citizens Bancshares of Southwest Florida), Naples, Florida; to acquire Florida Trust Company, Inc., Ft. Lauderdale, Florida, and thereby engage in trust company activities, pursuant to section 225.28(b)(15) of Regulation Y. These activities will be conducted in Florida.

Board of Governors of the Federal Reserve System, January 2, 2003.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 03-301 Filed 1-7-03; 8:45 am]

BILLING CODE 6210-01-S

## FEDERAL TRADE COMMISSION

[File No. 021 0171]

### Baxter International, Inc., and Wyeth Corporation; 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 January 18, 2003.

**ADDRESSES:** Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159-H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Comments filed

in electronic form should be directed to: [consentagreement@ftc.gov](mailto:consentagreement@ftc.gov), as prescribed below.

#### FOR FURTHER INFORMATION CONTACT:

Joanne Lewers, FTC, Bureau of Competition, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326-2667.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), 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 30 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 December 20, 2002), on the World Wide Web, at "<http://www.ftc.gov/os/2002/12/index.htm>." A paper copy can be obtained from the FTC Public Reference Room, Room 130-H, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326-2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159-H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. If a comment contains nonpublic information, it must be filed in paper form, and the first page of the document must be clearly labeled "confidential." Comments that do not contain any nonpublic information may instead be filed in electronic form (in ASCII format, WordPerfect, or Microsoft Word) as part of or as an attachment to email messages directed to the following email box: [consentagreement@ftc.gov](mailto:consentagreement@ftc.gov). Such comments 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 Agreement Containing Consent Orders To Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement containing consent orders ("Consent Agreement") from Baxter International Inc. and Wyeth. The Consent Agreement contains an order to maintain assets to preserve, among other things, the viability, marketability, and

competitiveness of the assets to be divested pending their divestiture. The Consent Agreement also contains a decision and order that is designed to remedy the anticompetitive effects of Baxter's proposed acquisition of the generic injectable pharmaceutical business of Wyeth. Under the terms of the Consent Agreement, the companies will be required to: (1) Divest all of Wyeth's assets relating to propofol to a Commission-approved acquirer; (2) terminate all of Baxter's rights and interests in GensiaSicor's pancuronium, vecuronium, and metoclopramide products, and divest all of its pancuronium, vecuronium, and metoclopramide assets to GensiaSicor; and (3) terminate Baxter's co-marketing agreement with Watson Pharmaceuticals, Inc. by March 14, 2004.

The proposed Consent Agreement has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the agreement and any comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed Consent Order.

Pursuant to an asset purchase agreement dated June 8, 2002, between Baxter and Wyeth, Baxter proposes to acquire from Wyeth substantially all of the assets related to Wyeth's generic injectable pharmaceutical business operated by Wyeth's ESI Lederle division for a total of \$316 million in cash and assumed liabilities. The Commission's complaint alleges that the proposed acquisition, if consummated, would constitute a violation of section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, in the markets for the manufacture and sale of: (1) Propofol; (2) pancuronium; (3) vecuronium; (4) metoclopramide; and (5) new injectable iron replacement therapies ("NIIRTs"). The proposed Consent Agreement would remedy the alleged violations by replacing in each of these markets the lost competition that would result from the merger.

#### *Propofol*

Propofol is a general anesthetic commonly used for the induction and maintenance of anesthesia during surgical procedures and as a sedative for patients who are mechanically ventilated. Although there are other anesthetic agents, there are many benefits associated with propofol

including the ability to quickly adjust the amount of sedation and its superior safety profile. Because propofol has a short duration profile, it is the preferred anesthetic agent for out-patient surgery. Annual U.S. sales of propofol total between \$375 and \$400 million.

The market for propofol is highly concentrated. AstraZeneca sells Diprivan®, the branded propofol product. Baxter markets the only generic propofol product, which is manufactured by GensiaSicor. Wyeth is seeking approval from the Food and Drug Administration ("FDA") for its own propofol product, and it is one of the two best-positioned firms to enter the market.

Entry into the propofol market requires lengthy development efforts because of the product's unique characteristics. Propofol is considered to be one of the most difficult injectable products to develop. Indeed, only one company has been able to introduce a generic propofol product. Propofol is manufactured using a complex process, and it requires the use of a preservative. The preserved formulation used for Diprivan® and the preserved formulation used for the generic propofol marketed by Baxter are both protected by patents. For this reason, any new entrant would have to develop a propofol product using a different preservative that does not infringe existing patents. Once a company has developed a viable product, it is also required to conduct studies and obtain approval from the FDA to market propofol. Clinical development and FDA approval for this particular generic drug takes several years.

The proposed acquisition would cause significant anticompetitive harm in the U.S. market for the manufacture and sale of propofol by eliminating potential competition between Baxter and Wyeth. With only two firms currently supplying propofol to customers in this market (Baxter and AstraZeneca), entry by Wyeth and the one other firm well-positioned to enter would likely increase competition and reduce propofol prices. Accordingly, allowing Baxter to acquire Wyeth's generic injectable business likely would reduce the number of rivals in the future from four to three and force customers to pay higher prices for propofol.

The proposed Consent Agreement preserves future competition in the market for propofol by requiring the parties to divest Wyeth's propofol assets to Faulding Pharmaceutical Company no later than 10 business days after the acquisition. Faulding is well-positioned to continue Wyeth's development efforts and poses no separate competitive

concerns as the acquirer of the propofol assets. If the Commission determines that Faulding is not an acceptable purchaser, or that the manner of divestiture is not acceptable, Baxter and Wyeth must divest the propofol assets to a Commission-approved buyer no later than 90 business days from the date the Order becomes final. Should they fail to do so, the Commission may appoint a trustee to divest the propofol assets. The Consent Agreement also requires the parties to license certain additional know-how that relates, but does not exclusively relate, to propofol to the propofol acquirer.

The Consent Agreement contains several provisions designed to ensure that the divestiture is successful. Baxter and Wyeth are required to provide transitional services to the propofol acquirer relating to regulatory approvals and manufacturing, and in responding to, and defending against, any lawsuit, investigation or proceeding relating to propofol. The Consent Agreement also requires Baxter and Wyeth to provide incentives to certain employees to continue in their positions until the divestiture is accomplished. For a period of six months from the date the assets are divested, Baxter and Wyeth will provide the propofol acquirer an opportunity to enter into employment contracts with individuals who have experience relating to Wyeth's propofol product. Baxter and Wyeth are also required to provide incentives to these individuals to accept employment with the propofol acquirer. For a period of one year following the divestiture date, Baxter and Wyeth are prohibited from hiring any employees of the acquirer of the propofol assets who have responsibility related to propofol. Finally, Baxter and Wyeth must take steps to maintain the confidentiality of confidential information related to propofol.

#### *Pancuronium*

Pancuronium is a rapid-onset, long-acting neuromuscular blocking agent used to temporarily freeze muscles during surgery or mechanical ventilation and to assist in the intubation process. Although pancuronium is an older drug, doctors continue to use it because it is an effective and inexpensive product with a known side-effect profile. The market for pancuronium in the United States is approximately \$2 million.

Pancuronium is a small and highly concentrated market. Baxter, Wyeth and Abbott are the only suppliers of generic injectable pancuronium in the United States. Currently, Baxter, which markets pancuronium pursuant to an exclusive

agreement with GensiaSicor, accounts for almost half of U.S. sales of the drug. Post-acquisition, Baxter would account for 74% of the sales of pancuronium in the United States, and the post-acquisition Herfindahl-Hirschman Index ("HHI") would be 6,152 points, representing a 2,496 point increase in the HHI. Post-acquisition, Abbott would be the only other supplier of pancuronium in the United States.

The market for the manufacture and sale of pancuronium is unlikely to attract new entrants because pancuronium is an older drug whose usage and price have declined over time. Although pancuronium is still an important drug, companies are unlikely to devote resources to developing an older drug with limited sales. Even if a supplier of other injectable drugs decided to develop pancuronium, it would be costly and time consuming to complete the necessary research and development, and to obtain the requisite approval from the FDA. Consequently, entry into the pancuronium market is not likely to occur in a timely manner, if at all.

The proposed acquisition would create a duopoly in the market for the manufacture and sale of pancuronium in the United States. Post-acquisition, Baxter and Abbott would be the only remaining suppliers of pancuronium. This is likely to lead to higher prices of pancuronium.

The proposed Consent Agreement preserves competition in the pancuronium market by requiring Baxter to terminate all of its rights and interests in GensiaSicor's pancuronium product and divest all of its pancuronium assets to GensiaSicor no later than five days after the acquisition. GensiaSicor is capable of marketing and selling its own pancuronium. It is a well recognized and respected company in the injectable pharmaceutical industry, and will be an able competitor in the market for the manufacture and sale of pancuronium.

#### *Vecuronium*

Vecuronium is an intermediate-acting neuromuscular blocking agent that temporarily freezes muscles during surgery, mechanical ventilation, or intubation. Vecuronium is a popular neuromuscular blocking agent with a superior side effect profile. The market for the manufacture and sale of vecuronium in the United States is approximately \$21 million.

The market for the manufacture and sale of vecuronium is highly concentrated. Baxter markets vecuronium under an exclusive supply agreement with GensiaSicor. Baxter and

Wyeth were the two leading suppliers of vecuronium in the United States, with a combined market share of 53%, until Wyeth temporarily suspended its vecuronium production in 2001. Prior to the announcement of the acquisition, Wyeth planned to re-enter the vecuronium market in the near future. Post-acquisition, the HHI would be 3,598 points, representing a 1,364 point increase in the HHI. There are only three other suppliers of vecuronium in the United States. Organon continues to market its branded vecuronium, and Abbott and Bedford supply generic vecuronium products.

Entry into the market for the manufacture and sale of vecuronium is unlikely because it is an older drug with established suppliers, and it is a difficult drug to manufacture. Although vecuronium continues to be an important drug, companies are unlikely to devote resources to entering this market because existing suppliers have become entrenched, making it difficult for new entrants to capture meaningful market share. In addition, vecuronium is a complicated drug to manufacture. Because of the unique manufacturing process involved in making vecuronium, entry would take longer than two years and cost hundreds of thousands of dollars.

The proposed acquisition is likely to result in anticompetitive harm in the U.S. market for the manufacture and sale of vecuronium. Absent the proposed acquisition, Wyeth would have re-entered this market. By acquiring Wyeth's vecuronium, Baxter would likely delay or forego the re-launch of Wyeth's vecuronium and eliminate any associated price competition.

The proposed Consent Agreement preserves future competition in the market for vecuronium by requiring Baxter to terminate all of its rights and interests in GensiaSicor's vecuronium product and divest all of its vecuronium assets to GensiaSicor no later than five days after the acquisition.

#### *Metoclopramide*

Metoclopramide is an antiemetic used for the prevention and treatment of nausea and vomiting for patients undergoing certain types of chemotherapy and for post-operative treatment. Metoclopramide is an older antiemetic that continues to be used because it is effective, has a known safety profile, and is considerably cheaper than newer antiemetics. Annual U.S. sales of metoclopramide total approximately \$13 million.

The market for metoclopramide is highly concentrated. Wyeth developed

the branded metoclopramide product, Reglan®. Baxter is the exclusive supplier of GensiaSicor's metoclopramide product. Wyeth and Baxter together represent over half of the sales of metoclopramide in the United States. Post-acquisition, the HHI would be 3,852 points, an increase of 936 points above the pre-Acquisition HHI. Only two other companies supply metoclopramide in the United States: Abbott and Faulding.

New entry into the market for the manufacture and sale of metoclopramide is difficult, expensive and unlikely to occur. Metoclopramide is an older drug with small sales relative to newer injectable anti-emetics. Therefore, firms do not consider the market for the manufacture and sale of metoclopramide to be an attractive entry opportunity. Several manufacturers have already exited the market and none are interested in re-entering. Even if firms that have exited were interested in re-launching their drugs, re-entry would likely take such firms an estimated two years or more.

The proposed acquisition would cause significant anticompetitive harm in the U.S. market for the manufacture and sale of metoclopramide by reducing the number of suppliers from four to three. The combined entity would account for over half of all sales of metoclopramide in the United States. The proposed acquisition is likely to lead to higher prices.

The proposed Consent Agreement preserves competition in the metoclopramide market by requiring Baxter to terminate all of its interests in GensiaSicor's metoclopramide and divest all of its metoclopramide assets to GensiaSicor no later than five days after the acquisition.

#### *New Injectable Iron Replacement Therapies*

NIIRTs are used to treat iron deficiency in patients undergoing hemodialysis. NIIRTs include both injectable iron gluconate and iron sucrose. Annual U.S. sales of NIIRTs total approximately \$225 million.

The market for the manufacture and sale of NIIRTs is highly concentrated. Watson markets Ferrlecit®, the only injectable iron gluconate product available in the United States. American Regent markets Venofer®, the only injectable iron sucrose product in the United States. Watson recently entered into a co-promotional agreement with Baxter, pursuant to which Baxter promotes Ferrlecit®.

Entry into the market for the manufacture and sale of NIIRTs is very difficult and time consuming. Because

of FDA-imposed New Chemical Entity exclusivity periods, the earliest that any company could file for regulatory approval of a generic iron gluconate product is February 2004. Similar provisions protect iron sucrose, though its exclusivity period expires in November 2003. Entry into the market for the manufacture and sale of NIIRTs is further complicated by a lack of raw material suppliers. Even if a new entrant were to locate a raw material supplier, both iron gluconate and iron sucrose are difficult products that would take more than two years to develop. Wyeth is the best-positioned firm to successfully develop a NIIRT product.

The proposed acquisition is likely to have anticompetitive effects in the market for the manufacture and sale of NIIRTs in the United States because it would eliminate potential competition between Baxter and Wyeth. The proposed acquisition would remove Wyeth as the best-positioned independent entrant into this market and prevent all associated price competition.

The proposed Consent Agreement preserves future competition in the market for the manufacture and sale of NIIRTs by requiring Baxter to terminate its co-marketing agreement with Watson within weeks of the expiration of Ferrlicit®'s New Chemical Entity exclusivity. This termination provides an incentive for Baxter to continue developing and ultimately launch the iron gluconate product that it will acquire from Wyeth.

Pursuant to the terms of the Order, the Commission has appointed William E. Hall as a Monitor Trustee to ensure Baxter's and Wyeth's compliance with all of the requirements of the Order. Mr. Hall has over 30 years of experience in the pharmaceutical industry and is well-respected in the industry. In order to ensure that the Commission remains informed about the status of the proposed divestitures and the transfers of assets, the Consent Agreement requires Baxter and Wyeth to file reports with the Commission periodically until the divestitures are accomplished.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Consent Agreement or to modify its terms in any way.

By direction of the Commission.

**C. Landis Plummer,**

*Acting Secretary.*

[FR Doc. 03-309 Filed 1-7-03; 8:45 am]

BILLING CODE 6750-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day-03-33]

#### Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498-1210.

*Comments are invited on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

*Proposed Project:* The Second Injury Control and Risk Survey (ICARIS 2) Phase 2—New—The National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC)—This project will use data from a telephone survey to measure injury-related risk factors and guide injury prevention and control priorities including those identified as priorities in Healthy People 2010 objectives for the nation. Injuries are a major cause of premature death and disability with associated economic costs of over \$150 billion dollars in lifetime costs for persons injured each year. Healthy People 2010 objectives and the recent report from the Institute of Medicine, Reducing the Burden of Injury, call for reducing this toll. In addition to national efforts, NCIPC funds injury control prevention programs at the state and local levels. These programs need data both to establish their prevention

priorities and monitor their performance. The use of outcome data (e.g., fatal injuries) for measuring program effectiveness is problematic because cause-specific events are relatively rare and because data on critical risk factors (e.g., was a helmet worn in a bike crash?; was a smoke detector present at a fatal fire?) are often missing. Because these risk factors are early in the causal chain of injury, they are what injury control programs target to prevent injuries. Accordingly, monitoring the level of injury risk factors in a population can help programs set priorities and evaluate interventions.

The first Injury Control and Risk Factor Survey (ICARIS), conducted in 1994, was a random digit dial telephone survey that collected injury risk factor and demographic data on 5,238 English- and Spanish-speaking adults (greater than or equal to 18 years old) in the United States. Proxy data were collected on 3,541 children <15 years old. More than a dozen peer-reviewed scientific reports have been published from the ICARIS data on subjects including dog bites, bicycle helmet use, residential smoke detector usage and fire escape practices, attitudes toward violence, suicidal ideation and behavior, and compliance with pediatric injury prevention counseling.

ICARIS-2, a national telephone survey about injury, which began in the summer of 2000, has collected data on more than 8,700 of the targeted 10,200 respondents to date. The first phase of the survey was initiated as a means for monitoring the injury risk factor status of the nation at the start of the millennium. The second phase of the survey is needed to expand knowledge in areas investigators could not fully explore, previously. By using data collected in ICARIS as a baseline, data collected in ICARIS-2 Phase-2 will be used along with data currently being collected (ICARIS-2 Phase-1) to measure changes and gauge the impact of injury prevention policies. The ICARIS-2 surveys may also serve as the only readily available source of data to measure several of the Healthy People 2010 injury prevention objectives. In order to more fully monitor injury risk factors and selected year Healthy People 2010 injury objectives, as well as evaluate the effectiveness of injury prevention programs, the second phase (ICARIS-2 Phase-2) of the current national telephone survey on injury risk is being implemented. The only cost to the respondents is the time involved to complete the survey.