

**STATUS:** This meeting will be open to the public.

**ITEMS TO BE DISCUSSED:**

Correction and Approval of Minutes.  
Notice of Proposed Rulemaking on Federal Officeholder's and Candidates' Participation in Certain Non-Federal Fundraising Events.

Final Rules on Campaign Travel.

Consideration of Policy to Place First General Counsel's Reports on the Public Record.

Adoption of Policy to Prepare and Publish a Guidebook for Complainants and Respondents in Enforcement Matters.

Co-sponsorship of 2010 COGEL Annual Meeting.

Management and Administrative Matters.

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Mary Dove, Commission Secretary, at (202) 694-1040, at least 72 hours prior to the hearing date.

**PERSON TO CONTACT FOR INFORMATION:** Judith Ingram, Press Officer, Telephone: (202) 694-1220.

**Mary W. Dove,**

*Secretary of the Commission.*

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**FEDERAL TRADE COMMISSION**

[File No. 091 0053]

**Pfizer Inc. and Wyeth; Analysis of Agreement Containing Consent Order To Aid Public Comment and Statement of the Federal Trade Commission**

**AGENCY:** Federal Trade Commission.

**ACTION:** Notice of acceptance of 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 complaint and the terms of the consent order—embodied in the consent agreement—that settle these allegations.

**ADDRESSES:** Copies of the Statement of the Commission, the Agreement Containing Consent Orders, the Decision and Order (Redacted Public Version), the Order To Maintain Assets, the Complaint, the Analysis To Aid Public Comment, and other materials may be found on the Federal Trade Commission Web site, at <http://www.ftc.gov/os/caselist/0910053/index.shtm>, and may also be secured from the following address: Federal Trade Commission, Consumer Response Center, Public Reference Room, Room H-130, 600 Pennsylvania Avenue, NW., Washington, DC 20580.

**FOR FURTHER INFORMATION CONTACT:** Michael R. Moiseyev, Bureau of Competition, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326-3106.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 the Commission 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 thirty (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 October 14, 2009), on the World Wide Web, at <http://www.ftc.gov/opa/2009/10/pfizer.shtm>. 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.

**Analysis of Proposed Agreement Containing Consent Orders To Aid Public Comment**

**I. Introduction**

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") with Pfizer Inc. ("Pfizer"), which is designed to remedy the anticompetitive effects of its proposed acquisition of Wyeth. Under the terms of the Consent Agreement, Pfizer must divest to Boehringer Ingelheim Vetmedica, Inc. ("BI") Wyeth's U.S. animal health business ("Fort Dodge") in all areas of overlap, except for equine tapeworm parasiticides and equine herpesvirus vaccines. In the area of equine tapeworm parasiticides, the consent order requires Pfizer to return to Virbac S.A. ("Virbac") Pfizer's exclusive distribution rights for these products. In the area of equine herpesvirus vaccines, Pfizer is ordered to divest to BI Pfizer's equine herpesvirus products. The assets for each of the divestitures include all of the relevant intellectual property, customer lists, research and

development information, and regulatory materials, as well as two of Fort Dodge's three U.S. manufacturing facilities. These divestitures fully preserve the competition that the proposed acquisition would otherwise eliminate.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed Consent Agreement and the comments received to decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the accompanying Decision and Order ("Order").

Pursuant to an Agreement and Plan of Merger dated as of January 25, 2009, Pfizer proposes to acquire all of the issued and outstanding shares of Wyeth, whereby each outstanding share of Wyeth common stock will be converted into the right to receive \$33 in cash and 0.985 share of Pfizer common stock. Both parties manufacture human and animal health biological and pharmaceutical products. The combined firm would have projected worldwide revenues of almost \$72 billion. The Commission's complaint alleges that the proposed 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 U.S. markets for the manufacture and sale of: (1) Killed cattle respiratory vaccines; (2) modified-live cattle respiratory vaccines; (3) cattle reproductive vaccines; (4) cattle pasteurella vaccines; (5) lactating-cow mastitis treatments; (6) dry-cow mastitis treatments; (7) dairy cattle broad-spectrum antibiotics with low milk-withholding times; (8) cattle macrocyclic lactone parasiticides; (9) cattle benzimidazole parasiticides; (10) canine combination vaccines; (11) canine monovalent parvovirus vaccines; (12) canine monovalent coronavirus vaccines; (13) canine monovalent leptospira vaccines; (14) canine bordetella vaccines; (15) feline combination vaccines; (16) feline leukemia vaccines; (17) companion animal rabies vaccines; (18) companion animal cephalosporin antibiotics; (19) equine tapeworm parasiticides containing praziquantel; (20) equine herpesvirus vaccines; and (21) equine joint-injected steroids. The proposed Consent Agreement remedies the alleged violations by replacing in each of the relevant markets the lost

competition that would result from the acquisition.

## II. The Products and Structure of the Markets

The proposed acquisition of Wyeth by Pfizer would combine two of the largest animal health suppliers in the United States. The companies overlap in several animal health markets, and, if consummated, the transaction likely would lead to anticompetitive effects in each of the relevant markets. More specifically, the transaction would decrease the number of competing suppliers in the overlap markets, which number has a direct and substantial effect on the prices of animal health products. The evidence shows that customers are able to obtain lower prices by threatening to switch to another supplier or presenting the incumbent supplier with a rival's lower offer. Customers have stated that they generally can negotiate lower prices in markets with more participants and that, historically, they have seen prices rise in markets in which the number of market participants has declined.

Pfizer and Fort Dodge are the market leaders in the area of cattle health products. After the transaction, Pfizer would have over 60 percent of several of the relevant cattle product markets. In the cattle vaccines area, Pfizer and Fort Dodge have broad and significantly overlapping portfolios of respiratory, reproductive, and pasteurilla vaccines. Customers choose the specific vaccine products that most closely match their needs based on several factors, including, among others, disease risk assessments and relative prices.

Killed cattle respiratory vaccines prevent respiratory diseases in pregnant cattle without the risk of causing abortion. Pfizer and Fort Dodge account for over 50 percent of all killed respiratory vaccine sales in the United States. The most commonly used killed respiratory vaccine is the 5-way vaccine, which prevents infectious bovine rhinotracheitis, types 1 and 2 of bovine virus diarrhea, parainfluenza 3, and bovine respiratory syncytial virus. As a result of the acquisition, Pfizer would have 61 percent of the market for killed 5-way respiratory vaccines, leaving Novartis Animal Health ("Novartis") as Pfizer's only significant competitor.

Modified-live cattle respiratory vaccines prevent the same diseases as killed respiratory vaccines, but contain modified-live rather than killed antigens to stimulate greater protection. Because modified-live respiratory vaccines induce stronger immunities, most customers will use modified-live vaccines for non-pregnant cattle. Pfizer

and Fort Dodge account for over 53 percent of all modified-live respiratory vaccine sales in the United States. As with killed respiratory vaccines, the 5-way modified-live respiratory vaccine is the most commonly used modified-live cattle respiratory vaccine. As a result of the proposed acquisition, Pfizer would control over 68 percent of the 5-way modified-live respiratory vaccine market.

Cattle reproductive vaccines are used to prevent early- and late-stage abortions in pregnant cattle. The markets for cattle reproductive vaccines include, most significantly: (1) The market for modified-live 10-way vaccines, which contain modified-live viral respiratory and *Leptospira* antigens; (2) the market for killed 10-way vaccines, which contain killed viral respiratory and *Leptospira* antigens; and (3) the market for lepto/vibrio vaccines, which contain *Leptospira* and *Campylobacter fetus* antigens. After the acquisition, Pfizer would have 83 percent of the \$13 million modified-live 10-way market in the United States, with Intervet/Schering-Plough Animal Health ("ISP"), AgriLaboratories, Ltd. ("AgriLabs"), and BI accounting for 11 percent, 4 percent, and 2 percent, respectively. Pfizer also would control 76 percent of sales in killed 10-way vaccines, leaving Novartis with 18 percent and AgriLabs with 6 percent of this \$9 million market. Finally, in the lepto/vibrio vaccine market, Pfizer and Fort Dodge collectively account for almost 39 percent of this \$2.6 million market, and Novartis leads with 41 percent.

Cattle pasteurilla vaccines are used to prevent pneumonia as well as lesser respiratory infections in cows caused by *Pasteurella multocida* and *Mannheimia haemolytica* bacteria. Pfizer, Fort Dodge, BI, ISP, and Merial are the only significant suppliers of products in these markets in the United States. The proposed acquisition would reduce the number of competitors in these markets, leaving Pfizer significantly larger than any of its remaining competitors.

Lactating-cow and dry-cow mastitis treatments are used to treat infections of the udder that occur during either lactation or the dry period between pregnancies. The markets for lactating-cow and dry-cow mastitis treatments are highly concentrated, with Pfizer and Fort Dodge together accounting for more than 90 percent of sales in each of these markets.

Broad-spectrum antibiotic products with low milk-withholding times can be used to treat a large variety of infections

that affect dairy cows.<sup>1</sup> Pfizer's products are considered the most effective antibiotics for dairy cows and have a zero-day withholding period, while Fort Dodge's product has a low withholding period of two to four days. A generic version of one of Pfizer's products was recently introduced. As a result of the proposed acquisition, Pfizer would have a near monopoly in this \$162 million market.

Cattle macrocyclic lactone parasiticides are the newest and most effective class of cattle parasiticides in the United States. They are effective against both internal and external parasites. There are only three branded players in the \$118 million U.S. market: Pfizer, Fort Dodge, and Merial. Although generic versions of Merial's product are available, there are no generic versions of Pfizer's or Fort Dodge's products currently on the market. The proposed acquisition would significantly increase the concentration in this market, leaving Pfizer with approximately 42 percent of the market.

Cattle benzimidazole parasiticides are an older generation of parasiticides used primarily by cattle breeders to treat internal parasites, such as lungworms, tapeworms, and liver flukes. Pfizer, Fort Dodge, and ISP are the only suppliers to offer cattle benzimidazole parasiticides in the United States. After the proposed acquisition, ISP would be the only remaining constraint on Pfizer's ability to raise prices, accounting for 67 percent of this \$16 million market. Pfizer would control the remaining 33 percent of the market.

Beyond cattle health products, Pfizer and Fort Dodge are also two of only four major suppliers in the relevant companion animal vaccines and pharmaceuticals markets. In the majority of these markets, the transaction would reduce the number of competitors from four to three and give Pfizer between 50 and 100 percent of the market. As in the cattle vaccines area, Pfizer and Fort Dodge have broad and significantly overlapping portfolios of companion animal vaccines. Customers can choose the specific vaccine products that most closely match their needs based on several factors, including, among others, vaccination protocols recommended by

<sup>1</sup> To ensure that antibiotic-contaminated milk is not distributed, the United States Food and Drug Administration ("FDA") has set "withholding times" for each antibiotic product and mandates that any milk that is produced during the withholding period be discarded. A principal consideration for dairy farmers in purchasing antibiotics, therefore, is how quickly they can resume milk production after treatment.

veterinarians and disease risk assessments.

Canine combination vaccines prevent common canine diseases, such as those caused by canine distemper, adenovirus (types 1 and 2), parainfluenza, parvovirus, coronavirus, and *Leptospira*. Pfizer, Fort Dodge, Merial, and ISP are the four significant companies that supply canine combination vaccines in the United States. Total U.S. sales of canine combination vaccines are \$126 million. The proposed acquisition would reduce the number of significant suppliers of canine combination vaccines from four to three.

While parvovirus, coronavirus, and leptospira vaccines are all available as part of canine combination vaccines, the monovalent forms are administered as booster shots for puppies that have a particularly high risk of exposure to the disease. Pfizer, Fort Dodge, Merial, and ISP are the only four companies that supply canine monovalent parvovirus vaccines in the United States, a \$2.1 million market. The proposed acquisition would give Pfizer control of 66 percent of the canine monovalent parvovirus vaccine market.

The same four players—Pfizer, Fort Dodge, Merial, and ISP—are also the only four companies that supply canine monovalent coronavirus vaccines in the United States. The proposed acquisition would further entrench Pfizer as the dominant supplier with an 81 percent share of the \$2.3 million market for canine monovalent coronavirus vaccines.

In the market for canine monovalent leptospira vaccines, the proposed acquisition would combine the only two companies that currently supply such vaccines in the United States. Pfizer currently has a 53 percent share, and Fort Dodge controls the remaining 47 percent of this \$9.2 million market. The proposed acquisition would grant Pfizer complete control over the market for canine monovalent *leptospira* vaccines.

Canine bordetella vaccines are used primarily to prevent infectious tracheobronchitis, which is the most prevalent upper respiratory infection contracted by dogs in the United States. There are five suppliers of canine bordetella vaccines in the United States: Pfizer, Fort Dodge, ISP, Merial, and BI. Total U.S. sales of canine bordetella vaccines amount to \$53.3 million. The proposed acquisition would reduce the number of suppliers of canine bordetella vaccines from five to four, leaving Pfizer significantly larger than its three remaining competitors.

Feline combination vaccines are used to prevent common feline diseases, such as feline panleukopenia, rhinotracheitis,

chlamydia, and calicivirus. Pfizer, Fort Dodge, ISP, and Merial are the only significant suppliers of feline combination vaccines in the United States. Total U.S. sales of feline combination vaccines are \$28 million. The proposed acquisition would reduce the number of significant suppliers of feline combination vaccines from four to three, with Pfizer's sales considerably greater than those of its two remaining competitors.

Feline leukemia vaccines can provide effective protection against feline leukemia, a fatal disease that breaks down a cat's immune system to such an extent that it can no longer defend against otherwise harmless invasions by bacteria, viruses, or other sources of disease. Pfizer, Fort Dodge, Merial, and ISP are the only companies that supply feline leukemia vaccines in the United States, sales of which are \$38 million. The proposed acquisition would reduce the number of suppliers from four to three, with Pfizer significantly larger than its two remaining competitors.

Companion animal rabies vaccines are used to prevent rabies, a fatal and incurable neurological disease. Pfizer, Fort Dodge, Merial, and ISP are the only companies that offer companion animal rabies vaccines in the United States. U.S. sales of such vaccines total approximately \$60 million, and the proposed acquisition would reduce the number of suppliers of companion animal rabies vaccines from four to three.

Companion animal cephalosporins are a recent generation of broad-spectrum antibiotics that are effective against both gram-positive and gram-negative organisms and can be used to treat a wide range of infections. Pfizer and Fort Dodge are the only two suppliers of branded companion animal cephalosporins in the United States. The only other companion animal cephalosporins are generic human and animal cephalosporin products. These products, however, have limited competitive significance because of dosing differences found in the generic human products and a relative lack of technical and research support offered with the generic animal products. As a result of the proposed acquisition, Pfizer would have 70 percent of this \$52 million market.

In addition to cattle and companion animal products, the proposed acquisition also poses competitive concerns in three equine product markets: tapeworm parasiticides; herpesvirus vaccines; and joint-injected steroids. The market for equine tapeworm parasiticides containing praziquantel consists of products used

to treat tapeworms and other internal parasites, which are the leading cause of equine colic in the United States. Currently, Pfizer has a 33 percent share of this approximately \$22 million market; Fort Dodge has a 31 percent market share; and Merial has a 36 percent market share. The proposed acquisition would give Pfizer 64 percent of the market for equine tapeworm parasiticides, leaving Merial as its only remaining competitor.

Equine herpesvirus vaccines are used primarily for the prevention of equine rhinopneumonitis, an upper respiratory disease, which can cause abortion in pregnant mares. Pfizer, Fort Dodge, ISP, and BI are the only suppliers of equine herpesvirus vaccines in the United States, sales of which total \$30 million. The proposed acquisition would reduce the number of suppliers from four to three, with Pfizer significantly larger than its two remaining competitors.

Equine joint-injected steroids can be used to reduce joint inflammation, treat osteoporosis, and prevent lameness in horses. Pfizer has a 60 percent share of this \$7.3 million market, while Fort Dodge has a 40 percent share. The proposed acquisition would create a monopoly in the market for equine joint-injected steroids in the United States.

### III. Entry

Entry into the manufacture and sale of the relevant animal health vaccine and pharmaceutical markets would not be timely, likely, or sufficient in its magnitude, character, or scope to deter or counteract the anticompetitive effects of the proposed acquisition. Developing and obtaining United States Department of Agriculture approval (in the case of vaccines) for the manufacture and sale of each of the relevant products can take as many as five years due to substantial regulatory, technological, and intellectual property barriers. Similarly, obtaining FDA approval (in the case of pharmaceutical products) can take five to seven years for a currently developed product and as many as ten or more years for an entirely new product.

In addition to the regulatory, developmental, and manufacturing hurdles facing a potential entrant, many of the markets at issue are characterized by particular conditions that make new entry unlikely. For example, some products, such as vaccines for cattle, equine, and companion animals, are particularly difficult to manufacture, have relatively small profit opportunities, and have a high potential for adverse reactions and product failure. In other markets, such as those for companion animal vaccines, a

substantial initial investment is necessary because veterinarians tend to purchase all their vaccines from a single supplier; as a result, a new entrant must develop a large portfolio of vaccines in order to be a significant competitor.

#### IV. Effects of the Acquisition

The proposed acquisition would cause significant competitive harm to consumers in the relevant U.S. markets for cattle, companion animal, and equine health products by eliminating actual, direct, and substantial competition between Pfizer and Wyeth. The transaction would increase the likelihood that Pfizer will be able to unilaterally exercise market power, increase the likelihood of coordinated interaction between or among suppliers, reduce Pfizer's incentives to pursue further research and development, and increase the likelihood that consumers will pay higher prices. In each of the relevant markets, the evidence shows that consumers have experienced lower prices, increased research and development, and better service due to the competitive rivalry that exists between market participants—particularly that which currently exists between Pfizer and Wyeth. The evidence also shows that, when any of the competitors experienced supply problems, the remaining competitors increased their prices, and, conversely, that consumers were able to negotiate lower prices when new rivals entered the relevant markets.

#### V. The Consent Agreement

The proposed Consent Agreement preserves competition in each of the relevant markets alleged in the complaint by requiring that Pfizer divest the following assets to BI no later than ten days after the acquisition: All of the Fort Dodge assets relating to killed cattle respiratory vaccines, modified-live cattle respiratory vaccines, cattle reproductive vaccines, cattle pasteurized vaccines, lactating-cow and dry-cow mastitis treatments, dairy cattle broad-spectrum antibiotic products with low milk-withholding times, cattle macrocyclic lactone parasiticides, cattle benzimidazole parasiticides, canine combination vaccines, canine monovalent parvovirus vaccines, canine monovalent coronavirus vaccines, canine monovalent leptospira vaccines, canine bordetella vaccines, feline combination vaccines, feline leukemia vaccines, companion animal rabies vaccines, companion animal cephalosporins, and equine joint-injected steroids, as well as the Pfizer assets relating to equine herpesvirus vaccines.

The proposed Consent Agreement contains several provisions designed to ensure that these divestitures are successful. Pfizer must provide various transitional services to enable BI to compete against Pfizer immediately following the acquisition, including any technical assistance that BI may need. Pfizer also must provide BI with the regulatory approvals, brand names, marketing materials, customer contracts, and other assets associated with marketing and selling the divested products in the United States.

BI is a reputable supplier of animal health products and is well positioned to manufacture and market the divested assets and to compete effectively in the relevant markets. In the United States, BI's animal health revenues totaled approximately \$215 million in 2008. Moreover, the acquisition by BI does not present competitive problems in any of the relevant markets because it currently has either a very limited presence or no presence at all in each of those areas. With its resources, capabilities, and experience marketing animal and human health products, BI is well placed to replicate the competition that would be lost with the proposed acquisition.

The proposed Consent Agreement also preserves the existing competition in the equine tapeworm parasiticides market by requiring Pfizer to return to Virbac Pfizer's distribution rights for the relevant parasiticide products no later than ten days after the acquisition. In 2000, Virbac entered into a 15-year licensing agreement with Pfizer, under which Virbac grants Pfizer exclusive distribution rights to market and sell the equine tapeworm parasiticide products in the United States. Virbac is particularly well suited to acquire these assets because it currently manufactures the products and has the resources, technical capabilities, and experience to be successful in restoring the competition that would be lost if the proposed Pfizer/Wyeth transaction were to proceed unremedied.

If the Commission determines that either BI or Virbac is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures is not acceptable, Pfizer must unwind the sale(s) and divest the assets within six months of the date the Order becomes final to another Commission-approved acquirer. If Pfizer fails to divest within the six months, the Commission may appoint a trustee to divest the relevant assets.

The proposed remedy also allows for the appointment of an Interim Trustee, experienced in obtaining regulatory approval and the manufacture of

biologics, to oversee the required technology transfers. As part of the proposed remedy, Pfizer is required to execute an agreement conferring all rights and powers necessary for the Interim Trustee to satisfy his responsibilities under the Order to assure successful divestitures. The Commission has appointed Dr. Stephen J.D. Bell of Tunnell Consulting to be the Interim Monitor and it is anticipated that he will obtain support and assistance from his colleague, Mr. Arlo Millen. The monitors will ensure that the Commission remains informed about the status of the proposed divestitures and asset transfers.

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.

#### Statement of the Federal Trade Commission

The Federal Trade Commission has voted to accept a Consent Order in its investigation of Pfizer Inc.'s proposed acquisition of Wyeth. The Consent Order remedies the anticompetitive effects that the Commission believes are likely to result from the transaction in numerous markets for animal health products. After a thorough investigation, the Commission has concluded that the transaction does not raise anticompetitive concerns in any human health product markets. We write here to explain our decision, provide greater visibility into this important investigation, and, in the event that there are future such transactions, describe the framework that we used in our analysis.

The Commission allocated extensive resources to the investigation.<sup>2</sup> The price, quality, and availability of prescription pharmaceutical products has a tremendous impact on health care costs, and a significant part of the investigation focused on ascertaining whether the proposed transaction would adversely affect competition in human pharmaceutical markets. The Commission is dedicated to promoting competition in health care markets to ensure that costs are contained and to

<sup>2</sup> During the course of its comprehensive investigation, Bureau of Competition staff conducted nearly 200 interviews, and reviewed hundreds of thousands of documents produced by the parties and third parties. The investigation also involved close cooperation with foreign competition authorities, including those from Australia, Canada, the European Union, Mexico, New Zealand, and South Africa.

protect incentives for pharmaceutical companies to develop new medications.

## I. Background

Pfizer is the largest prescription pharmaceutical company in both the United States and the world, with \$48.4 billion in worldwide revenues for 2008. In addition to manufacturing and selling pharmaceutical products, Pfizer also researches and develops new pharmaceutical products. At the end of 2008, Pfizer had 114 products in various stages of clinical development. Based on the evidence gathered during the investigation, Pfizer's overall market share of pharmaceutical and biotech products totals about 9 percent in the United States.

At the time of the acquisition, Wyeth was the twelfth-largest prescription pharmaceutical company in the United States. Wyeth's worldwide annual revenue totaled about \$22.2 billion in 2008, \$16.8 billion of which was from pharmaceutical and biological sales. Like Pfizer, Wyeth also researches, develops, manufactures, and sells pharmaceutical products and is also a significant participant in the biologic and vaccine areas of human pharmaceuticals. Wyeth is the fourth largest biotechnology company by revenue in the world and has 18 biologic products in clinical development.

Although both Pfizer and Wyeth are substantial suppliers of human pharmaceutical products, their respective product portfolios are highly complementary. Staff's investigation evaluated numerous potential overlaps where the companies may compete against each other, either now or in the future. In particular, the investigation included significant analysis of four markets—treatments for renal cell carcinoma, *Methicillin-resistant Staphylococcus aureus* (or "MRSA" infections), osteoporosis, and Alzheimer's disease—to determine whether the transaction would undermine competition in those markets. Beyond these specific overlaps, the staff thoroughly investigated whether the transaction could have an impact on competition in human pharmaceutical markets more broadly, whether on innovation, the intellectual property landscape, clinical development, or marketing. The evidence demonstrates that it will not.

## II. Competitive Effects Analysis

Beyond the areas addressed by the Consent Order, the Commission analyzed three principal theories of potential competitive harm.

First, we assessed whether the merger might substantially reduce competition in any relevant human health market in which Pfizer and Wyeth currently compete. We conclude that it does not.

With respect to a small number of diseases or conditions, including renal cell carcinoma and MRSA infections, Pfizer and Wyeth both market treatments. Evidence gathered in the investigation showed that, although Pfizer and Wyeth produce drugs that target the same indications, their products are not close substitutes for—or indeed competitive with—each other. In addition, it appears that in these markets a sufficient number of other competitors will remain after consummation of the Pfizer/Wyeth transaction. Moreover, the products that these other companies offer are closer competitors to either the Pfizer or Wyeth products than the Pfizer and Wyeth products are to each other. Accordingly, Pfizer and Wyeth's consolidation is unlikely to facilitate the exercise of market power in any of these markets.

Second, we assessed whether the evidence supported a challenge based upon a theory that the transaction threatened to eliminate potential future competition in any relevant market. We conclude that it does not.

There are a small number of diseases or conditions for which Pfizer or Wyeth markets a product where the other company is developing a potentially competitive product, or both companies are developing products that could compete against each other in the future. Here, we considered not only the products that Pfizer and Wyeth are directly developing, but also products that other companies are developing in which Pfizer or Wyeth have a financial interest. For example, both Pfizer and Wyeth are developing products to treat osteoporosis. After careful investigation, though, we conclude that the transaction is not likely to affect competition in this market, based on non-public information that Pfizer's and Wyeth's products are unlikely to be close competitors.

We also extensively investigated Alzheimer's disease treatments. Alzheimer's disease is a progressive and terminal neurodegenerative disorder of the brain that is the sixth-leading cause of death in the United States, affecting approximately five million people. The number of Americans suffering from Alzheimer's disease is expected to grow exponentially, and expenditures on drugs to treat Alzheimer's disease are expected to more than double in the next ten years. The future competitiveness of this market, for both

economic and therapeutic reasons, is critical. Consequently, the Commission staff dedicated much of its time to investigating the competitive landscape in this market, and how the proposed transaction would affect it, if at all. Pfizer currently markets a product called Aricept, the leading drug on the market today to treat Alzheimer's disease, and has several other products to treat Alzheimer's disease in clinical development. Wyeth currently does not offer a product to treat Alzheimer's disease, but does have several products in development.

The explosive growth of the Alzheimer's disease patient population has caused the market for treatments to attract considerable attention. Besides Pfizer and Wyeth, a significant number of other companies, including both large and small pharmaceutical companies and biotechnology companies, have products in development for the treatment of the disease. As of today, there are approximately 50 companies with at least 66 products in various phases of development. Among those companies are 14 of the largest pharmaceutical companies in the world, as well as numerous small- and medium-sized pharmaceutical and biotechnology firms. While there are several different therapeutic approaches being pursued for Alzheimer's disease, Pfizer and Wyeth overlap in only a small number of these areas. In those therapeutic areas where they do overlap, there are several other companies also developing products.

Overall, the evidence demonstrates that Pfizer and Wyeth's products are unlikely to be sufficiently close competitors that the elimination of competition between them would affect the competitiveness of any relevant human health market. Rather, the most likely outcome is that they each will compete more closely with products from other companies.

Third, we assessed whether a combined Pfizer/Wyeth would have a greater ability to engage in anticompetitive bundling, block new drug development with a merger-created patent thicket, or adversely impact the market for basic research and innovation in any human health markets, but with a particular focus on Alzheimer's disease, the area of most significant overlap. We conclude that the proposed transaction is unlikely to affect the market(s) in any of these ways.

As part of its investigation, staff evaluated whether the acquisition would change the negotiating power between Pfizer and its customers such that consumers would be harmed because of unlawful tying, bundling, or

exclusive dealing by Pfizer. Prescription pharmaceutical customers (*e.g.*, insurance companies) set up bid processes for purchasing pharmaceutical products on a product-by-product (or category-by-category) basis and have generally resisted efforts by large pharmaceutical companies to bundle products across categories, unless the bundle is in the customer's best interest. We found no evidence that this acquisition would undermine customers' ability to prevent anticompetitive bundling. As a result, we conclude that the addition of the Wyeth portfolio of products to Pfizer's portfolio is not likely to enhance the merged entity's ability to engage in anticompetitive bundling, especially because the combined portfolio would contain few blockbuster drugs.

Staff also investigated whether the acquisition would create a patent thicket by virtue of the breadth of the combined companies' patent portfolio. A merger-created patent thicket could reduce or eliminate competition in human pharmaceutical products by enabling the combined firm to prevent other pharmaceutical companies from developing products through the enforcement of intellectual property rights. After evaluating the parties' respective patent portfolios in a number of areas where both firms are active, including, most notably, Alzheimer's disease, the evidence showed that the combination of the intellectual property of Pfizer with that of Wyeth would not pose any greater barrier to entry to third-party companies than the intellectual property held by the companies individually.

Finally, staff evaluated whether the transaction would decrease basic research or the pace of innovation in pharmaceutical markets by eliminating a leader in pharmaceutical research and development; changing the incentives of companies performing pharmaceutical research and development; or reducing the number of potential research, marketing, or funding partners. Pharmaceutical research and development is a dynamic field with multiple participants including both large and small traditional pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, and contract research organizations. The evidence does not indicate that the combination raises antitrust concerns in these respects.

Even within the discrete product areas where both Pfizer and Wyeth are actively pursuing research and development, such as treatments for Alzheimer's disease, we conclude that

the transaction is not likely to affect competition in basic research or innovation. Within Alzheimer's disease specifically, fundamental information about the disease, including its cause, how to diagnose it prior to the appearance of symptoms, and when intervention must occur to modify the disease, is still unknown. There is no scientific consensus about the most promising track for the treatment of Alzheimer's disease. As a result, it is a dynamic area of drug development, and the many companies working in this disease area are pursuing many different pathways with compounds that can have different effects and risk factors.

Although Pfizer and Wyeth are two of the most active companies pursuing research and development activities in the Alzheimer's disease area, it is unlikely that the combination of the Pfizer and Wyeth's Alzheimer's disease pipelines will diminish the incentives of Pfizer or any other company to compete in the research and development of Alzheimer's disease treatments. Further, the combination of Pfizer and Wyeth is not likely to affect the ability of other companies to continue to develop and ultimately introduce new products to treat Alzheimer's disease.

The Commission's extensive investigation and commitment of resources in this matter reflects its dedication to ensuring that pharmaceutical markets are competitive and that consumers have access to innovative and affordable medications. Although the Commission, based on the evidence gathered, determined that this transaction did not raise anticompetitive concerns in the markets for human pharmaceuticals, the Commission remains dedicated to ensuring that pharmaceutical markets are competitive. We will closely monitor these markets and continue to evaluate future transactions under the framework explained here to determine their effect on competition in the health care market, and, where appropriate, take action to ensure that any merger or acquisition does not undermine the pharmaceutical industry's competitiveness.

By direction of the Commission, Commissioner Harbour and Commissioner Kovacic recused.

**Donald S. Clark,**

*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2010 through September 30, 2011

**AGENCY:** Office of the Secretary, DHHS.

**ACTION:** Notice.

**SUMMARY:** The Federal Medical Assistance Percentages (FMAP) and Enhanced Federal Medical Assistance Percentages (eFMAP) for Fiscal Year 2011 have been calculated pursuant to the Social Security Act (the Act). These percentages will be effective from October 1, 2010 through September 30, 2011. This notice announces the calculated FMAP and eFMAP rates that the U.S. Department of Health and Human Services (HHS) will use in determining the amount of Federal matching for State medical assistance (Medicaid) and Children's Health Insurance Program (CHIP) expenditures, Temporary Assistance for Needy Families (TANF) Contingency Funds, Child Support Enforcement collections, Child Care Mandatory and Matching Funds of the Child Care and Development Fund, Foster Care Title IV-E Maintenance payments, and Adoption Assistance payments. The table gives figures for each of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Programs under title XIX of the Act exist in each jurisdiction. Programs under titles I, X, and XIV operate only in Guam and the Virgin Islands, while a program under title XVI (Aid to the Aged, Blind, or Disabled) operates only in Puerto Rico. The percentages in this notice apply to State expenditures for most medical services and medical insurance services, and assistance payments for certain social services. The Act provides separately for Federal matching of administrative costs.

Sections 1905(b) and 1101(a)(8)(B) of the Act require the Secretary of HHS to publish the FMAP rates each year. The Secretary calculates the percentages, using formulas in sections 1905(b) and 1101(a)(8)(B), and calculations by the Department of Commerce of average income per person in each State and for the Nation as a whole. The percentages must fall within the upper and lower limits given in section 1905(b) of the Act. The percentages for the District of