NEWS BRIEFS RELATED TO ANIMAL TESTING

(You can assume that both Greenfield and Kline believe that you as readers are familiar with these and other facts related to animal testing and the drug industry. Ron Kline is Director of Pediatric Bone Marrow Transplantation at the University of Louisville.)

1. P&G in plan to create web site on animal testing research

Procter & Gamble Co. said it and other organizations would develop an Internet site for the exchange of information about how to reduce the use of animals in product testing. P&G said it would be part of a coalition that will develop a site on the World Wide Web. Other coalition members include the Humane Society of the United States, the Center for Alternatives for Animal Testing at the Johns Hopkins University School of Public Health, the U.S. Department of Agriculture, the Food and Drug Administration and the National Institutes of Health. The Web site will allow scientists, educators, veterinarians and others to obtain information about alternatives to animal use in product testing. Animal-rights activists have criticized Cincinnati-based Procter & Gamble for years because of the company's continuing use of animals in product testing. The company has said it is working to reduce the number of laboratory animals it uses, but would not provide specific numbers.

By The Associated Press
02/28/99 Updated 01:25 PM ET

2. Schering-Plough under investigation

(AP) — Schering-Plough, maker of the blockbuster allergy drug Claritin and Dr. Scholl's footcare products, is among the targets of a federal criminal probe into price manipulation in the pharmaceutical industry.

The investigation is focusing on whether Schering-Plough, based in Kenilworth, NJ, caused "unlawful inflation" of government reimbursements...
for some drugs, the company stated in a filing with the federal Securities and Exchange Commission. "The company is cooperating with the investigation," Schering-Plough spokeswoman Denise Foy said Wednesday.

In its annual report, filed Tuesday with the SEC, Schering-Plough also revealed that its top two executives are being penalized financially for manufacturing programs that are holding up the launch of a crucial new allergy drug.

The company said the federal departments of Justice and of Health and Human Services, along with some states, were probing practices of Schering-Plough and other pharmaceutical companies regarding the average wholesale price reported to the government for certain drugs. Some government reimbursements are based on that price. The U.S. attorney's office in Boston is investigating whether the average wholesale price set by the companies "exceeds the average price paid by dispensers and, as a consequence, results in unlawful inflation of certain government drug reimbursements." The SEC filing does not identify the drugs involved, and Foy would not name them. Investigators also want to know if the company cheated Medicaid on payments designed to ensure the government pays the lowest price for the drugs.

Federal prosecutors in Boston are looking into possible criminal violations by other drug companies, including Bristol-Myers Squibb, which has its research headquarters in Princeton, N.J., and TAP Pharmaceuticals, The Wall Street Journal said Wednesday. Samantha Martin, a spokeswoman for the U.S. Attorney's Office in Boston, told The Associated Press on Wednesday she would neither confirm nor deny the investigation.

Schering-Plough recently has been named in at least 10 class-action lawsuits accusing the company of concealing news of manufacturing problems that delayed the release of Clarinex, an allergy drug meant to succeed the popular non-sedating antihistamine Claritin. The company, which has a heavy focus on respiratory medications, had hoped to launch Clarinex by the start of the spring allergy season.

Claritin, which accounts for $3 billion of Schering-Plough's $9.8 billion in annual sales, loses patent protection in December 2002. The Food and Drug Administration has said it will not approve sales of Clarinex until the
company corrects manufacturing problems at plants in Kenilworth and Union, N.J., and Manati and Las Piedras, Puerto Rico. Bob Consalvo, a Schering-Plough spokesman, said the company is continuing to address the problems, which involve the plants not following production and quality control procedures required by the FDA.

Consalvo could not say when all the problems would be resolved. The plants are still operating, but some production lines have been shut down temporarily for upgrades and other changes. Amid the problems, Schering-Plough's top two executives are feeling a financial pinch.

The SEC filing stated that because of the delay of Clarinex, the company cut chief executive officer Richard Jay Kogan's bonus last year by 9.7%, or $300,000. He also received the minimum salary under his contract, $1.3 million. Altogether, he received $9.5 million in salary, bonus and stock awards, down from $12.1 million a year earlier, but got an additional $10.5 million in stock options.

In addition, the company eliminated a bonus for the president and chief operating officer, Raul Cesan. He had received a $1.2 million bonus in 1999. Cesan drew $3.9 million in stock and salary in 2000, down from $6.3 million in 1999. Cesan also received $7.8 million in stock options in 2000. Shares of Schering-Plough were down $1.95, or more than 5%, to close at $35.75 Wednesday on the New York Stock Exchange.

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3. Parliament approves animal-testing ban

BRUSSELS, Belgium (AP) — The European Parliament voted Tuesday to ban sales of all new cosmetic products tested on animals, including makeup, shampoos and shower gels.

Pending approval from the 15 European Union member nations, the legislation would immediately prohibit cosmetics for which alternative testing exists. By January 2005, the ban also would apply to all new cosmetics using animal-tested ingredients, even if alternative tests have not been developed. "Those products should no longer be sold," said German socialist member Dagmar Roth-Behrendt, who wrote the bill.
The ban also would apply to imported products. The 8,000 animal-tested cosmetic ingredients already on the market would not be affected. The 626-member European Union assembly meeting in Strasbourg, France, easily approved about 30 amendments to strengthen EU rules on cosmetics. The Parliament also passed an amendment to label animal-tested products rather than those using alternative methods such as clinical cell or bacterial testing.

The European Parliament and the European Commission have been wrangling over the issue since they postponed a 1998 plan to ban animal-tested products because companies lacked alternative methods. The only EU countries that ban cosmetic animal testing are Britain, Austria and the Netherlands. Most of Europe's cosmetic testing is done in France and Italy.

The European cosmetic industry, with annual sales around $39 billion, has opposed the ban, arguing that they still do not have many alternatives to animal testing. The legislation goes the 15 EU governments for consideration and return to the Parliament for a final vote.

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4. FDA questions Synthroid's dosages
By Andrew Clark, Reuters

WASHINGTON — The Food and Drug Administration has ruled Abbott Laboratories must seek approval to keep selling the thyroid drug Synthroid, the No.3 most-prescribed medicine in the U.S., saying it has a "history of potency failures." The ruling raises the prospect that the drug, which millions of Americans take daily, could be pulled from the market, although FDA officials said Friday they would act cautiously and analysts said such drastic action was unlikely.

"We have not made any final decisions," said FDA spokeswoman Susan Cruzan. "A lot of patients are on this drug, and we do want to keep in mind patient needs."
Synthroid, known generically as levothyroxine sodium, has been used for more than 40 years by people with low natural levels of thyroid hormones. Abbott says the safety and efficacy of the drug has been "extensively studied and validated" over that time and it is working with the FDA to resolve the issue.

The agency, citing manufacturing and potency problems, decided in 1997 to regulate levothyroxine drugs and require them to go through its drug approval process. Thyroid replacement therapy requires precise dosages and sub- or super-potent tablets can pose safety risks, the agency says.

Two other manufacturers have since received approvals from the FDA, but Synthroid maker Knoll Pharmaceuticals, which Abbott bought, instead petitioned the agency to rule its drug "safe and effective" and exempt it from testing.

The FDA’s denial of that petition in late April was first reported by the Wall Street Journal Friday. In a letter, the agency said: "The history of potency failures ... indicates that Synthroid has not been reliably potent and stable." Abbott shares fell 36 cents, or 0.7 %, to $51.62 in New York Stock Exchange trading on Friday.

The decision apparently leaves Abbott facing a mid-August deadline to obtain an approval that usually takes 10 to 12 months.

"If these products are not the subject of an approved application by Aug. 14, they are subject to regulatory action," Cruzan said, adding the agency is "examining what our course of action will be." Abbott said it had already notified the FDA of its intent to submit an application and was "working cooperatively with the agency to meet the filing timeframes."

Analysts say they seriously doubt the FDA would go as far as to bar the drug while it considers the application. "What in the world would you be doing to take a product off the market that people need daily while you do it. That's not sensible," said Salomon Smith Barney analyst Anne Malone. "I don't think it will get pulled."

"I am confident that this is not a big issue," said Morgan Stanley analyst Glenn Reicin. "(The application) will obviously be filed in the next couple of months and they'll do the review and it will stay on the market."
But consumer groups urged the agency to take a tough stand. "If the company cannot meet the FDA's safety standards, then Synthroid should be removed from the marketplace," said Tim Fuller, executive director of the Gray Panthers, senior citizens' advocacy group. The other companies that have FDA approval for their levothyroxine drugs are King Pharmaceuticals and Jerome Stevens Pharmaceuticals, which has a marketing agreement on the drug with Watson Pharmaceuticals.

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5. Bayer agrees to buy CropScience

FRANKFURT, Germany (AP) — Germany's Bayer said Tuesday it has agreed to buy agrochemical company Aventis CropScience, known for its controversial genetically modified corn StarLink, for about $4.9 billion. Bayer expects to cut about 4,000 jobs to save money in the wake of the deal.

"Acquiring Aventis CropScience will make us a world leader in crop science and substantially boost Bayer's earnings power," Chairman Manfred Schneider said in a statement. Bayer said the purchase of CropScience from Aventis and Schering will increase its profits. French-based Aventis owns 76% of Aventis CropScience while Schering has a 24% stake. Bayer is also assuming $1.7 billion in debt as part of the deal.

But it expects to realize about $460 million a year in cost savings from combining overlapping research and other operations and cutting jobs. Bayer said it would increase its borrowing to pay for the acquisition.

Bayer, a 138-year-old company, is facing some tough business challenges. In August, it withdrew its prime anti-cholesterol drug Baycol worldwide after it was linked to more than 50 deaths. The move cost Bayer its No. 3-selling drug, and the company warned the withdrawal would cut 2001 earnings about $720 million.

On Tuesday, it said it would slash another 1,250 jobs at its pharmaceuticals unit separate from the jobs expected to be cut in the crop sciences business.

The withdrawal of Baycol, marketed as Lipobay in many countries, raised speculation that Bayer might sell its drug business to focus on polymers,
agricultural products and industrial chemicals — a move Schneider has resisted.

For Aventis, the sale of its crop science division is another step in its planned refocusing on its core pharmaceuticals business. It has said it expects to gain some $5 billion from the deal. Still, all liability connected with Aventis' genetically modified corn StarLink will remain with Aventis. Last year, the corn found its way into food products such as taco shells even though it wasn't approved for human consumption.

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6. Tap Pharmaceuticals will pay $875 million

Tap Pharmaceuticals will pay $875 million, the largest criminal fine ever for health care fraud, to settle charges that its marketing efforts encouraged doctors to overbill the government and patients for cancer treatments. Six Tap managers also were indicted by a federal grand jury on felony charges that they were offering doctors kickbacks and bribes for prescribing the company's prostate cancer drug, Lupron. Those offers included golf and ski outings, medical equipment and grants used for bar tabs and office Christmas parties, according to investigators.

Some doctors received free samples of Lupron, or bought the drug for less than Tap told the government it charged, then billed health programs hundreds of dollars per dose. "They were saying, 'Doctor, if you buy our drug, look at what we can do for you,' " says Michael Loucks, who led the investigation for the U.S. attorney in Massachusetts. "That's a crime."

Government investigators say Tap's marketing practices cost state and federal health programs $145 million. Medicare patients also overpaid, because many were charged 20% of the inflated bills.

Tap is the only company charged so far with encouraging doctors to charge insurers for free samples, but state and federal prosecutors are investigating marketing and pricing practices of more than a half dozen other manufacturers. Bayer earlier this year agreed to pay $14 million to settle concerns about its pricing and marketing practices.
As part of the agreement, Tap pleaded guilty to charges that it violated the federal Prescription Drug Marketing Act. The company, a joint venture of Abbot Laboratories and Japan's Takeda Chemical Industries, said it has taken steps to prevent similar problems.

"Selling samples is clearly inappropriate, and our company should not have been involved," says Thomas Watkins, president of Tap. But Tap does not admit wrongdoing over its pricing or other marketing practices, Watkins says.

The U.S. attorney's office began investigating Tap after the pharmacy chief of Tufts Health Plan reported that Tap offered him a grant if he would reverse the health plan's decision not to include Lupron on its list of approved drugs.

Another whistle-blower, former Tap sales executive Douglas Durand, filed a lawsuit in 1996 against the company over its marketing practices. Under federal law, the whistle-blowers will share in the settlement. Durand will get $77.9 million. Dr. Joseph Gerstein and Tufts Health Plan will share $17.2 million.

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