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FDA Approves Controversial Birth Control Drug

The Food and Drug Administration ("FDA") has approved the use of a highly effective, injectable drug that prevents pregnancy for three months. Although the drug, called Depo-Provera, is available in ninety countries and is currently being used by nine million women, it has been the subject of controversy for two decades in the United States.

The contraceptive was first developed by the Upjohn Company of Kalamazoo, Michigan, in 1957. The FDA refused to approve the drug in 1978 because of concerns raised by animal studies showing an increased risk of breast and other cancers. The drug, which is injected into the buttocks or arm, is a synthetic hormone that mimics one of the natural hormones controls the menstrual cycle. With a 99.6 percent effective rate, it is one of the most reliable contraceptives available.

Depo-Provera has been controversial with women's groups, which fear it will be used on low income women coercively.

But since 1978, the World Health Organization has conducted a nine-year, worldwide study of 11,000 women to determine if the drug increased rates of cancer. Overall, there was no additional breast cancer in Depo-Provera users. For women under thirty-five,

however, the breast cancer rate increased slightly. The study also found slightly increased rates of breast cancer among women younger than thirty-five who had used the drug for four years or less. Researchers concluded that any link between the drug and breast cancer was weak.

The same study also found that Depo-Provera protected women against endometrial cancer of the uterus.

The animal studies originally relied upon have also been discounted after researchers concluded that beagles, the animals on which the drug was tested, were not an appropriate animal model for studying the drug.

In approving the contraceptive this fall, the FDA cited worldwide studies and years of use that showed the overall risk of cancer, including breast cancer, "to be minimal, if any."

Many family planning and reproductive health organizations applauded the FDA's approval.

"We're glad that the FDA has recognized mounting worldwide evidence that Depo-Provera is extremely safe and effective," said Dr. Andrew Kaunitz, chairman of the Association of Reproductive Health Professionals, a group that promotes reproductive health. The FDA's approval of Depo-Provera this fall and the approval of Norplant, a time released implant which prevents pregnancy for five years, in December 1990, has greatly increased the choices available to American women.

"This drug presents another long-term effective option for women to prevent pregnancy," said Dr. David Kessler, the commissioner of Food and Drugs. "As an injectable, given once every three months, Depo-Provera eliminates problems related to missing a daily dose."

However, some women's groups still worry about the link to cancer.

"We are very sorry it was approved," said Cindy Pearson of the National Women's Health Network. "We are

concerned about bringing a drug linked to cancer into a country where the risk of breast cancer already is so high."

The most common side effects are weight gain and menstrual irregularities. Some women's menstrual cycles discontinue altogether. Research has also shown that the drug may contribute to osteoporosis, a disease that leaves bones thin, brittle, and easily breakable. As one of the conditions of approval, Upjohn agreed to continue studying the drug's link to osteoporosis.

Many women who cannot take birth control pills may be able to take Depo-Provera because it contains no estrogen.

The FDA warned that doctors prescribing the drug should make sure the patient is not pregnant. The drug also should not be used by women suffering from acute liver disease, unexplained vaginal bleeding, breast cancer, or blood clots in the legs, lungs, or eyes.

The company expects to price the drug in the range of birth control pills, which cost \$15 to \$25 a month. But health groups say they hope the drug will be priced within the reach of low-income women.

"It will be of little use to women if they can't afford to use it," said Dr. Kaunitz. He said that Norplant, which costs \$500 to \$800, is priced out of the reach of low-income women. ♦

GM's Gas Tanks are Fueling Safety Debate

In what could turn out to be the biggest controversy over automobile gas tank design since the Ford Pinto, consumer advocates have charged that General Motors ("GM") full-size pickup trucks should be recalled because they are susceptible to catching fire in a collision due to faulty design of the fuel tank. The National Highway Traffic Safety Administration

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("Safety Administration") has opened an investigation to determine whether there is a design defect, and the agency could order a recall.

Consumer groups claim that more people have died in post-crash fires involving GM trucks than any other vehicle. According to the Center for Automobile Safety, more than 300 people have been killed in fiery crashes involving GM pickups. In comparison, twenty-seven people died in 1971 to 1976 Ford Pintos, a car whose design was the subject of lawsuits and controversy in the 1970s.

"We believe that 1973 through 1987 full-size GM pickups are the Pintos of the '90s," said Thomas Smith, director of Public Citizen's office in Austin, Texas.

GM is the defendant in more than 100 lawsuits filed in connection with the fuel tank design. Already, the company has settled some of the suits with payments as large as \$1 million.

The pickup trucks with the allegedly faulty design were made from 1973 to 1987. Of the ten million built, approximately half are still on the road.

Company documents furnished to federal safety officials and also made public after settlement of a Texas lawsuit show that GM knew as early as 1983 that its trucks could be made "much less vulnerable" in collisions where the fuel tank might break open. But the design of the trucks was not changed until the 1988 model year, and GM says the change was made only for design and not safety reasons.

According to consumer advocates, the problem with the fuel tank is that it is located outside the vehicle's frame rails, where only a thin piece of sheet metal protects the tank. In a side-impact crash, the tank can be compressed between the striking vehicle and the frame, causing the tank to rupture. The gasoline, under pressure, can then spray from the tank.

"It just envelops the vehicle," said Clarence Ditlow, executive director of the Center for Auto Safety, a Washington, D.C., based consumer advocacy

organization. "With any ignition source, you have a fireball."

Competing pickup trucks made by Chrysler and Ford have the fuel tanks inside the frame rail.

Ditlow's organization has called for GM to recall the trucks. But GM so far has refused, saying that the trucks are safe and that they meet all federal motor vehicle safety standards.

"These trucks are absolutely safe to drive," said Robert Sinke Jr., GM director of engineering analysis. "This whole situation has been blown out of proportion."

The opening of the Safety Administration investigation is the first formal step in an administrative proceeding to determine the safety of the GM trucks. The government will review 70,000 documents provided to it by the automaker and will take the unusual step of conducting its own crash tests. If the investigation warrants it, the agency could ask GM to recall the trucks.

A GM spokesman said that the nation's leading automaker welcomed the opening of the Safety Administration investigation. "After a full investigation, we trust and believe the agency will conclude — as any fair reviewer would — that there is no basis upon which to conclude that these vehicles contain a safety-related defect." ♦

Will New Food Labels be Clearer or Just Cluttered?

By the summer of 1994, consumers will notice a big difference on the can of tuna and other foods they buy at the local supermarket: Every one of the 300,000 food labels on processed foods will be completely redesigned, giving shoppers more and better information about the foods they eat.

The new food labels will be the result of a complete overhaul of the food labeling system announced by the Food and Drug Administration ("FDA") in December 1992. The change re-

quires consistent nutritional information on labels for nearly all processed foods and defines such buzzwords as "light," "low sodium," and "high fiber" so those phrases mean the same thing for all foods.

Nutritionists, public health officials, and consumers are welcoming the new food labeling regulations as an important step in changing the typical American diet, which contains too much fat and sodium and not enough grains, fruits, and vegetables. Most importantly, the new labels will make it easier for consumers to calculate the amount of fat and sodium they are eating in a day.

"With this new label, American consumers don't need to worry about grams. If the label says a food contains 30 percent of their day's fat allotment, you know that it's going to be high in fat. If the label says it contains 3 percent, you can be sure that it's low-fat. For the first time, consumers don't have to pull out their calculators," said David Kessler, the FDA Commissioner.

A new food label will show fat, cholesterol, sodium, carbohydrates, and protein as a percentage of what is considered a healthy daily intake. In addition, the FDA reviewed more than 47,000 suggestions submitted by industry and consumers to determine exactly what kind of health and nutritional claim a food manufacturer can make. For example, the rules say that a food can be described as "light" or "lite" on the label only if it has 50 percent less fat than the food to which it is compared.

But some industry trade groups criticized the new labels, saying they will be cluttered and hard to understand.

"The side panel is going to be extremely dense with information," said Regina Hildwine, director of regulatory affairs for the National Food Processors Association. "A can of tuna fish has fourteen square inches on its label. It's going to take the better part of those fourteen square inches just to present this nutrition information, which doesn't leave an awful lot of room to identify the product." ♦