FDA approves new obesity drug

Meridia does not pose risk of heart valve damage, officials say

WASHINGTON (AP) — The Food and Drug Administration approved the first new obesity drug since a ban of two popular diet remedies left overweight Americans clamoring for help — but the new medicine poses a serious risk, too.

Knoll Pharmaceutical's Meridia is "moderately effective" at helping patients shed pounds — in studies, they lost about 7 to 11 more pounds than mere dieters, the FDA said Monday.

But Meridia can cause increases in blood pressure and pulse rate that may endanger certain patients, the FDA warned.

"We still have some concern," said FDA's Dr. James Bilstad, who urged doctors to rigorously check patients' blood pressure and pulse and to prescribe it only to the seriously obese. "This drug should not be used for those who want to lose simply a few pounds."

But the FDA said Meridia does not appear to pose the risk of heart valve damage that forced September's ban of the nation's most popular diet drugs, Redux and fenfluramine, the "fen" in fen-phen.

The agency approved Meridia Saturday night over the objections of its own scientific advisers, who called the drug too risky.

But because of Meridia's side effects, no one with poorly controlled hypertension, heart disease or irregular heartbeat or who has survived a stroke should use the drug, the FDA cautioned. And it is only for the seriously obese, as measured by body mass index — the relationship of weight to height — of 30 or greater, such as someone who is 5 feet, 6 inches and weighs 185 pounds.

Knoll pledged Monday to educate doctors and patients to use Meridia responsibly. "We are going to actively discourage cosmetic use of this medication," said Carter Eckert, president of Knoll.

But Knoll cannot sell Meridia for a few more months. The Drug Enforcement Administration is determining how strictly to control prescriptions, after the FDA determined Meridia could pose a small risk of addiction and recommended limiting refills unless patients first return to a doctor.

Some 58 million Americans are overweight, and obesity experts welcomed Meridia as a desperately needed option — particularly after September's ban of Redux and fenfluramine.

"It's great news for dieters," said Dr. John Foreyt of the Baylor College of Medicine.

But Foreyt said he hoped September's diet-drug scare had convinced dieters that Meridia is only for the seriously obese. "It's not to be used willy-nilly," Foreyt said. Plus, Meridia "will not help in the absence of changing your diet and being a little more active."

Consumer activists urged Meridia users not just to see a doctor for regular blood pressure tests, but to check themselves regularly with an at-home blood pressure monitor.

"If you catch a rise, you can stop it" by simply stopping the drug, said Lynn McAfee of the Council on Size and Weight Discrimination. "People have to be responsible about this."

Meridia, known chemically as sibutramine, works a little differently than fenfluramine and Redux did. They fooled patients into feeling full by boosting production of a brain chemical called serotonin. Meridia, on the other hand, slows the body's dissipation of the serotonin it naturally produces.

But doctors don't know why Meridia would raise blood pressure — especially if patients lost weight. On average, Meridia patients' blood pressure increases two to three points and their pulse speeds up four to five beats a minute.

Meridia Use

FDA cautions patients with these conditions:

- hypertension
- heart disease
- irregular heartbeat
- history of stroke
- moderate obesity

HELEN CLANCY/THE BATTALION

Commission backs use of dietary labels

WASHINGTON (AP) — Makers of dietary supplements should use science to back claims that their products actually help people's health, a presidential commission said Monday — but it backed off forcing companies to submit evidence to the government.

Ultimately, consumers will have to do their own homework before buying supplements to make sure they're not wasting their money, the Commission on Dietary Supplement Labels concluded.

"It behooves the public ... to do a fair amount of investigation on their own," said panel chairman Malden C. Nesheim, professor of nutrition at Cornell University.

The commission issued its final report Monday on how a 1994 law should be implemented. It recommended that nutritional claims be "supported by scientifically valid evidence."

It urged manufacturers to make that evidence available publicly, but commissioners dropped a recommendation in their draft report calling for companies to submit a summary of evidence to the Food and Drug Administration.

Industry officials complained that the law does not require them to submit this information, Nesheim said, and they said disclosing it could help their competitors. He said consumer groups also complained that it could look like companies had some sort of FDA approval when, in fact, they did not.

Responsible companies will supply the information to consumers who ask for proof that their products actually work, Nesheim said.

"Informed and interested consumers ought to start asking for that," he said.

The law requires manufacturers to assure dietary products are safe, and it spells out what claims can be made on labels and how these claims must be backed up.

But it allows manufactures to sell these products without any outside experts or scientists evaluating them first. Under the law, the FDA acts only if trouble is suspected.

The report is now in the hands of Donna Shalala, the secretary of Health and Human Services, who has 90 days to decide whether to propose the recommendations as formal rules.

The commission also recommended:

—The FDA be given more money to identify and investigate supplements that pose hazards. "There must be a strong and reliable enforcement system," it said.

—Dietary health claims on the labels of supplements should be based on the same "significant scientific agreement" that is required for conventional foods.

—The industry consider establishing a scientific committee to review labels.

—The FDA establish a panel to review herbal products that companies wish to market as preventive and therapeutic.

—Specific guidelines for the content of labels including warnings when appropriate and guidance on using terms such as "stimulate" and "promote."

The FDA had no comment on the report Monday.

Experimental brain cancer surgery shows potential

NEW YORK (AP) — An experimental treatment that tricks tumors into swallowing poison has shown promise in brain cancer patients.

The therapy shrank tumors by at least half in nine of 15 patients. In one of those patients, the cancer disappeared for five months before recurring; in another, it was gone for nearly two years before returning.

"We haven't cured anybody, and it's not likely we can at this point" because it's too early in the treatment's development, said Richard J. Youle of the National Institute of Neurological Disorders and Stroke.

The small study, which was designed to look for side effects rather than test the treatment's effectiveness, is reported in the December issue of the journal Nature Medicine. In an accompanying editorial, Dr. Robert Martuza of the Georgetown University Medical Center called the result impressive but stressed that it must be confirmed by further work.

Nearly all the cancers in the study originated in the brain, rather than migrating from elsewhere in the body. About 18,000 Americans are expected to get cancers arising in the brain this year; less than half will be of the types treated in the study.

The patients had recurring, growing brain cancers that hadn't been cured by standard therapy.

The experimental treatment took advantage of brain cancer's appetite for iron. To attract iron, tumor cells sprout chemical hitching posts that grab transferrin, a substance that shuttles iron in the brain.

For the treatment, researchers yoked molecules of transferrin to molecules of diphtheria toxin. The toxin was altered so it would not harm normal cells, but it would still poison cancer cells that sucked it in with the transferrin.

Child psychologists urge special treatment for sister of Iowa septuplets

DES MOINES, Iowa (AP) — When Mikayla McCaughey got a peek at her tiny brothers and sisters in the intensive care unit, she saw only a lot of babies — not seven instant rivals for Mommy and Daddy's attention.

For the first 21 months of her life, the family revolved around Mikayla, then the only child of Bobbi and Kenny McCaughey. But before Mikayla turns 2, four little brothers and three sisters — all born last Wednesday — should be home from the hospital.

"I tell my patients that it would be like a husband bringing home a much younger, very attractive woman and telling his wife, 'Look at how beautiful she is, how warm and wonderful. Now I expect you to love her and be nice to her,'" said child psychologist Alice Sterling Honig of Syracuse University.

Child psychologists say the McCaugheys must be careful not to get so busy with the septuplets that they ignore Mikayla.

Nancy Segal, a psychology professor at California State University-Fullerton and director of the school's Twin Studies Center, said little research has been done on the effects of multiple births on older siblings, but mishandled relationships can lead to resentment, withdrawal and anger toward the parents and brothers and sisters.

"What happens is that people in their great excitement at a multiple birth begin to lavish attention on the multiples and really tend to exclude that older child," Ms. Segal said.

McCaughey said last week that his oldest child was thrilled when she first saw the family's new additions. "I brought her down yesterday and she just kind of sat there in my arms and said: 'Baby! Baby!'" he said.

But the McCaughey family has said that Mikayla does not yet understand that the seven babies are her parents' and that they eventually will come home. Six were in serious condition Monday; one was in fair condition.

The family has made sure to focus attention on Mikayla and involve her when gifts are given, said her aunt, Michele Hepworth, who has cared for Mikayla since Mrs. McCaughey was confined to bed nine weeks into the pregnancy.

When the family was given a new van, Mikayla's name was written on the side along with those of her brothers and sisters. When Gov. Terry Branstad stood with the family to talk about donations for a new house, he had a stuffed Winnie the Pooh for Mikayla.

"She's going to be a wonderful big sister," Ms. Hepworth said. "She loves to play with baby dolls all the time, cradles them and puts them to sleep."