

As Americans keep getting fatter, doctors ask: Where are the drugs?

December 22 2010, By Jeannine Stein and Shari Roan

In their quest to find drugs to curb obesity, scientists have had about as much success as long-term dieters who want to stay thin - which is to say, very little. In fact, the last year has been so bleak on the research front that some experts are questioning whether a long-desired safe and effective diet pill can be found.

Advisory panels for the [Food and Drug Administration](#) recommended against approval of two experimental [weight-loss](#) drugs this year - Lorqess in September and Qnexa in July - citing unacceptable risks for unimpressive benefits. Another drug, Meridia, was withdrawn from the market in October after it was linked to higher risks of heart attacks and strokes.

Earlier this month, an advisory panel did finally recommend approval of a weight-loss drug: Contrave, a combination of two existing drugs, the antidepressant bupropion and the anti-addiction medication naltrexone. (FDA rulings for all three drugs are expected next year.) But it did so with a marked lack of enthusiasm, citing the medication's poor effectiveness and a need to closely track [health risks](#), such as [high blood pressure](#), once the drug is in broad use.

As drug after drug falters or falls by the wayside, doctors who treat [obese patients](#) are growing increasingly frustrated. They say that the agency's standards for approving anti-obesity drugs are overly stringent and fail to recognize the health risks associated with carrying extra weight - at a time when almost 34 percent of U.S. adults are obese and

almost 6 percent are morbidly obese, and when study after study has shown that the most that can be hoped for from diets and exercise, on average, is a 10 percent loss of body weight sustained for at least one year.

So gloomy is the climate for these drugs that some experts fear drug companies will out-and-out abandon the anti-obesity market.

"Every big company is going to get out of the game, and [venture capitalists](#) are not going to invest in the smaller companies to develop drugs," Dr. Donna Ryan, past president of the Obesity Society, said in October during that group's annual meeting in San Diego. "Everybody in the obesity field is upset. There is a lot of anger."

Obesity drugs in the U.S. certainly don't have a terrific track record. Fen-phen, a combination of appetite suppressants fenfluramine and phentermine, was hugely popular in the 1990s but was pulled from the market in 1997 after it was linked with primary pulmonary hypertension, a potentially fatal condition, and heart-valve problems. But the new generation of medications was supposed to be more finely crafted, and therefore safer and better.

The only prescription medication approved solely for weight loss is orlistat, a drug that inhibits fat absorption that is sold under the trade name Xenical or as a weaker over-the-counter version, Alli.

And though an FDA advisory committee did recently endorse expanding eligibility for Lap-Band surgery to allow people with less-extreme obesity to be candidates, obesity experts say that not everyone is eligible for surgery and that this decision, in any case, does nothing to serve people who are overweight, not obese.

The FDA treats drugs for obesity "as if they were in a different

category," said Judith Stern, professor of nutrition and internal medicine at the University of California-Davis. "I think (it is) not taking it seriously as a disease, and I have no clue why. We have a problem that affects over 65 percent of the adult population ... the FDA should be jumping through hoops to give approval."

FDA officials would not comment on this year's advisory committee votes nor on its philosophy on obesity drugs. But in an era when the agency is holding all new drugs to more rigorous safety standards, it's clear that most of the new offerings haven't cut the mustard in the key equation of whether benefits outweigh potential risks.

"I understand the frustrations people have - but I don't think we have great medications," said Dr. Abraham Thomas, division head of endocrinology at Henry Ford Hospital in Detroit, who was acting chairman on the FDA advisory panels that reviewed Meridia and Lorcress (also known by its generic name, lorcaserin) and a member of the panel that reviewed Qnexa.

"It's a balance," Thomas added. Each panel carefully weighs a drug's effectiveness against its safety. If weight-loss results look good, then potential side effects (unless they're extremely serious) might not be weighed so heavily. But if a drug isn't very effective, "then the safety issues become magnified." So, for example, in the case of lorcaserin, panel members were hesitant to recommend approval because trials "barely proved" effectiveness, Thomas said.

Obesity experts counter that the agency and its expert panels don't properly appreciate the health risks associated with obesity - diabetes, heart disease, stroke, osteoarthritis, certain types of cancers and, possibly, dementia.

"They are framing weight loss as a cosmetic problem," Ryan said.

"Obesity is a medical problem."

They point to studies showing that even modest weight loss - what might be considered just a drop in the bucket when measured against a person's total weight - can have surprisingly large effects. A 10 percent drop in weight can reduce the risk for Type 2 diabetes, lower blood pressure and help counter other problems such as sleep apnea and high blood cholesterol.

They say that a diet medication could be the catalyst needed to jump-start a successful weight loss program. "In my office a patient will come in and say, 'You know, doctor, I've lost some weight through diet and exercise, but I need something to help me kick-start (a serious weight loss program),' " said Dr. Ken Fujioka, director of nutrition and metabolic research at the Scripps Clinic in San Diego.

And they note that while several studies show that diet and exercise can produce about the same weight-loss percentages as medication, such programs - which can include supervised fitness instruction and pre-made meals - may not be realistic or affordable for most people, let alone viable for the long haul.

"When you look at interventions, they're done with volunteers and there are all kinds of people on the team, like psychologists and trainers," said Dr. Arya Sharma, professor of medicine at the University of Alberta in Canada. "You'll see the lengths they go to keep people motivated, and in the end they may get 3 percent to 5 percent weight loss."

Finally, most people can't maintain significant weight loss for more than a year or two through diet and exercise alone in part because the body kicks into a starvation mode and begins to conserve energy. Getting around this thorny problem has become one of the most significant scientific questions in the field - and may possibly, say obesity

specialists, be a place where diet pills could help.

Some, such as Dr. Sidney Wolfe, director of the not-for-profit health research group Public Citizen, feel that more caution - not less - is in order when assessing these drugs. Contrave "is another drug that increases blood pressure and pulse, and it's possibly going to be approved - and that is a huge mistake. Losing weight is meaningless if it is nullified by increasing cardiovascular risks."

Wolfe knows that some doctors are frustrated by a lack of obesity medications. But that, he said, isn't justification for approving drugs that may have serious side effects. "If the overall benefits are outweighed by the risks, that's it. The FDA is part of the public health service, and we have to be aware that if they approve a drug, a doctor can prescribe it ... why would any doctor want to prescribe a drug like that?"

But obesity experts argue that risks can be managed. In a September statement to the FDA advisory panel regarding Meridia and the increased risk of cardiovascular events, officials from the Obesity Society noted that "the drug is intended for use in patients who do not have established cardiovascular disease." They note that other medications for serious disorders have been approved despite known adverse side effects.

It certainly makes sense to carefully scrutinize potential health risks of any new [obesity](#) medication, especially because they have to be taken for a year or even longer, Ryan said. But diet drugs should not be held to a higher safety standard than other types of medications.

"Safety is important," Ryan said. "That is not to say that they have to be as safe as water."

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