One of the few approved weight loss drugs bites the dust

By ACSH Staff — May 13, 2015

One important medical conditions in this country obesity has been an elusive target for researchers and drug companies. And now, since Orexigen the makers Contrave, have pulled the plug on the LIGHT [1] clinical trial, the number of new diet drugs has dropped from three to two. Why? It didn’t work.

The lack of an effective diet drug was severely impacted by the withdrawal of fen-phen by Wyeth in 1997, after excess cases of fatal pulmonary hypertension and cardiac valve damage were found in patients who took the drug.

Also unfortunate fen-phen was the only really effective weight loss drug. So much so that even after the drug was withdrawn, people who had been taking it still tried to obtain the drug, despite the increased cardiovascular risk.

Fen-phen was actually a combination of two drugs, phentermine and fenfluramine. It was quickly determined that the problem came from the fenfluramine (not even from the drug itself, but from a metabolite something that ACSH’s Dr. Josh Bloom explained in an op-ed [2] in Medical Progress Today in 2012.)

Dr. Bloom says, Whether science-based or fear-based, appetite suppressant diet drugs have undergone extra scrutiny since the fen-phen debacle. This particularly applies to cardiovascular toxicity, although most people fail to realize that what caused the problems with fen-phen was a specific problem, rather than a general one that would apply to all drugs in this class.

Contrave was approved by the FDA in September 2014, and joined a very short list of new diet drugs, which included Belviq and Qsymia (both approved in 2012).

One slight problem is that it doesn’t work. This is not especially surprising. Dr. Bloom explains, Contrave is a combination of bupropion the ingredient in the antidepressant Wellbutrin plus Naltrexone a drug that is primarily used to suppress alcohol and opiate cravings. It is not intuitively obvious why either of these drugs should work very well for weight loss.
Possibly more interesting is that the data used to gain approval for Contrave are now suspect. It would seem that the company may have used selective data in its approval application.

This is rather clear from the statement of Dr. Steven Nissen of the Cleveland Clinic, the lead investigator of the trial: Essentially, when they filed the patent the company chose what they were going to put in there and what they were going to leave out.

And this: "Frankly, the executives in the company never should have had access to the data. We felt it was in the public interest to take an unprecedented step and release the 50% data because we couldn't allow unreliable data to be used in clinical decision making. We had a duty to the public and also to the investment community, to tell the truth."

And in case that isn't enough: "Why would anybody take a drug, one that's available on the market, in a blinded, placebo-controlled trial if they think the drug produces a 41% benefit? So we considered the trial to be no longer scientifically viable."

Ouch.

Dr. Bloom concludes, Drug companies take a lot of unfair criticism, some of it arising from what could be intentional fraud or at best egregious carelessness. It taints the entire industry, however, this is an exception, not the norm. If anyone was intentionally fudging data for financial gain, I wish them well in their new residence. I hear the food isn't so good. Maybe they will lose weight.

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