



Weight Loss Medications

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“I’ve tried everything I can think of to lose weight on my own. What do you think about weight loss drugs?”

If your job involves weight management counseling, this question probably sounds familiar. Whether you support or oppose the use of prescription drugs as a treatment for obesity, one thing is clear: the issue is not going to go away. Rather, it is likely to become even more visible, in view of recent reports on obesity, diet failures and new pharmacological developments in professional journals, consumer-oriented magazines and national newspapers. At least 30 prescription weight loss medications are in the research and development stage. Might one be the “magic bullet” for permanent, safe weight reduction?

Prevalence of prescription diet drug use from 1996 to 1998 is estimated at 2.5 percent of US adults (4.5 million people). Use is significantly higher among women than among men. Approximately 25 percent of the users have a body mass index less than 27, suggesting that a quarter of the users are using the medications inappropriately (1).

In an era of direct marketing of prescription medications, where consumers are urged to “Ask your doctor about... [a drug]” consumer demand can be quickly stimulated. The lessons learned from the commercial success of the infamous phen-fen will not be quickly forgotten. In 1992, 60,000 fenfluramine prescriptions were written. In 1997, in part as a result of an aggressive marketing campaign, 10 million were written for phen-fen (2).

Whether or not drugs are the answer to chronic overweight and obesity problems, fitness professionals need to understand that the people they work with in these settings are under tremendous pressure to seek drug therapy. Friends and family members often hold strong opinions, from very positive comments to suggestions

that they are “copping out” by taking such medications or cannot control their eating habits through some sort of weakness or laziness. We are beginning to understand that obesity and overweight are multi-faceted problems, involving diet and lifestyle choices, but also involving complex biochemical processes and overwhelming environmental influence (*e.g.* wide availability of high calorie foods). Helping people obtain unbiased information about weight loss medications is one role that fitness professionals can play.

Working *with* those clients who choose to use weight loss medication, which is increasingly being prescribed to adolescents and children, is the professional attitude, and gaining at least a basic knowledge of the drugs being used and developed, and how they work, is necessary. This article presents an overview of prescription weight loss medication.

Pro and con positions

The use of prescription drugs in the treatment of obesity is controversial. Those who support their use argue that obesity is an incurable disease. They liken it to hypertension — also incurable, but often well controlled with anti-hypertensive medication. Proponents of drug treatment for obese people argue that obesity can be similarly controlled (but not cured) with medication.

Proponents also suggest that the small amount of weight loss attributable to the medication improves insulin sensitivity, blood glucose levels, blood lipid levels and blood pressure. They suggest that medications can help “kick start” weight loss efforts that also include lifelong changes in diet and physical activity patterns (3).

Those who oppose the use of medications argue that they are of no real value in maintaining long-term weight loss and that the risks outweigh the benefits. They question if the relatively small amount of weight loss that is a result of prescription medications is clinically significant. Some see it as just another “quick fix.” They suggest that in theory medication is used as part of a comprehensive treatment program, but in practice, is a monotherapy.

Organizational recommendations have also been mixed. The Expert Panel on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults concluded that in carefully selected patients weight loss medications can complement a comprehensive treatment program that includes a low calorie diet, physical activity and behavior therapy. The entire report is available at <www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.htm> and can be downloaded free of charge (4).

The National Association to Advance Fat Acceptance (NAAFA) strongly discourages people of any size from taking drugs for the purpose of weight loss. They base their position on the fact that there are negative health effects associated with the drugs and that the consumer has not been protected from dangerous weight loss drugs in the past. NAAFA also condemns obesity research and drug manufacturers who profit from inadequately tested weight-loss drugs (5). In its position paper on weight management, the American Dietetic Association acknowledges pharmacotherapy but does not take a pro or con position (6).

However, the evidence that obesity contributes to health problems, and that obesity continues to surge unabated in this country, must make practitioners at least consider the use of pharmacological intervention in their most problematic clients or patients. In some cases, short term may be better than no term. It bears repeating: The challenge for fitness and nutrition professionals is to help people achieve their weight loss goals safely. Weight loss medication may be part of that plan.

Selection and continuance criteria

Candidates for weight loss drugs should meet the following criteria: BMI at or above 30, or 27 to 29.9 with co-morbidities such as type 2 diabetes, hypertension, heart disease or sleep apnea. Note that those with a BMI below 25 should not be prescribed weight loss medications since the risk of the medication outweighs any medically significant benefit.

Those who begin drug treatment as part of a comprehensive program should be evaluated to determine if the treatment is being successful.

Success is measured as follows:

- Drug therapy results in the loss of more than 2 kg of weight in the first month;
- Drug therapy results in a 5 percent weight loss by six months; and
- Co-morbid conditions have improved.

Available prescription weight loss medications

At the present time the FDA has approved only two drugs for long-term use in the treatment of obesity. One is sibutramine, sold as Meridia® or Reductil®, which is an appetite suppressant.

The other is orlistat (Xenical®), which blocks intestinal fat absorption. Several appetite suppressant drugs shown in the chart below are approved for short-term use, usually 12 to 16 weeks.

Rimonabant (Acomplia®) is approved for use in the US and in the 25 countries of the European Union, but its FDA approval application was withdrawn in mid-2007 because the FDA expressed concerns about its safety. The manufacturer intends to have further discussions with the FDA and intends to submit an approval application at a later date.

FDA-approved Weight Loss Drugs		
Group Name	Trade Names	Description
Sibutramine*	Meridia, Reductil	Long term appetite suppressant
Orlistat*	Xenical	Blocks intestinal fat absorption
Phentermine	Adipex, Phentride, Terenine	Stimulates the release of norepinephrine and produces a mild anorectic effect
Diethylpropion	Tenuate appetite suppressant	Short term (a few weeks)
Benzphetamine	Didrex	Short term (a few weeks) appetite suppressant
Phendimetrazine, Tartrate	Bontril, Obezine, Adipost	Short term (a few weeks) appetite suppressant
* Only weight loss drugs approved for long-term use		Chart adapted from references 7 and 12

Sibutramine

Sibutramine (Meridia®) is the only weight loss medication which suppresses appetite that is approved by the FDA for long-term use. Sibutramine is an example of a serotonin-norepinephrine reuptake inhibitor — because their cellular uptake is inhibited, serotonin and norepinephrine continue to circulate in the bloodstream and have an anorectic effect.

Studies have shown that sibutramine increases heart rate by about 3 to 4 beats per minute and increases blood pressure by about 2 mmHg. While all drugs that affect norepinephrine can increase heart rate and blood pressure, sibutramine appears to have a greater effect on these conditions than do other norepinephrine-related weight loss medications. Therefore, its use is contraindicated for patients with a history of coronary heart disease, congestive heart failure, arrhythmia or stroke (2).

A 2007 meta-analysis found that subjects who used sibutramine for 6 months lost 2.3 kg (5 lb) more than those who received a placebo (7). At one year, the average loss was 5.1 kg (11 lb) and 4.0 kg (about 9 lb) at 24 months. After one year, it appears that the medication assists in weight maintenance but not further weight loss.

Bray notes that 60 percent of the study participants who lost 2 kg (4.4 lb) within the first four weeks eventually lost more than 5 percent of their initial weight (8). Only 10 percent of those who did not lose 2 kg in the first four weeks eventually achieved this degree of weight loss. Although this is not predictive, monitoring the results after the first four weeks of treatment appears to be important.

Orlistat

Orlistat (Xenical®) is also approved by the FDA for long-term use and has a unique mode of action — the inhibition of pancreatic lipase, which results in reduced absorption of dietary fat. Approximately 30 percent of the dietary fat consumed is blocked when the diet contains about 30 percent of total calories from fat. Consuming orlistat with a low fat diet has little effect on fat absorption or blockage. Assuming that an individual consumes 2000 kcal per day, with about 30 percent of calories from fat, the recommended dose of orlistat would likely result in a 200 to 300 kcal/day deficit (9).

Orlistat is most effective and produces the least side effects when the meal contains a fairly even distribution of carbohydrate, protein and fat. Medication intake should be adjusted to dietary intake. Orlistat is effective when taken during a meal or up to one hour after a meal so adjusting one's medication is not difficult. A missed meal or a low fat meal would mean that orlistat is not consumed at that time. A high fat meal (greater than 30 percent of calorie from fat) should also be avoided. Taking a dose of orlistat with a high fat meal will likely result in greater gastrointestinal side effects (9).

Orlistat itself is not absorbed, therefore the side effects are associated with the malabsorption of the fat. Unabsorbed fat remains in the gastrointestinal tract and reported side effects include fatty stools, increased number of bowel movements, oily spotting, soft or liquid stools and fecal urgency. These symptoms tend to subside over time and a decrease in symptoms may be a result of learning how to alter the amount of fat consumed in the diet. However, it should not be underestimated how uncomfortable these side effects can be, especially in social and work situations.

Orlistat blocks fat absorption — and also blocks the absorption of the fat-soluble vitamins, so supplemental fat-soluble vitamins can be taken to offset any loss. The vitamin supplement is usually taken before bedtime to

ensure maximum absorption in the absence of the orlistat. At a minimum, supplemental fat-soluble vitamins should precede a dose of orlistat by two hours.

A 2007 meta-analysis of overweight and obese individuals reported that subjects who received orlistat lost an average of 2.7 kg (6 lb) more than those who received a placebo (10). Approximately 21 percent of the subjects in all the studies reviewed lost at least 5 percent of their body weight and 12 percent of subjects lost 10 percent or more. Studies have also shown some improvement in glucose tolerance and glycemic control in those diagnosed with diabetes.

Phentermine

Phentermine (the phen of phen-fen) is an example of a medication that stimulates the release of norepinephrine and produces a mild anorectic effect. It has been approved for short-term use since the 1960s and as many as 50 million prescriptions have been written worldwide. Despite its widespread use, the number of published studies of phentermine is small. One long-term study (36 weeks), three short-term studies and a 40-year history of use would suggest that it is relatively safe. Adverse effects have been described as minor, usually agitation or insomnia (2).

Is phentermine effective? In the long-term study, 108 obese women were assigned to one of three groups: continuous treatment (36 weeks), intermittent treatment (alternating four weeks of phentermine treatment and four weeks of no drug treatment) or placebo. All women received an initial 1000 kcal/day diet instruction and were weighed weekly. Those who received phentermine for 36 weeks lost an average of 12.2 kg (about 27 lb) compared to 13 kg (about 29 lb) for the intermittent treatment and 4.8 kg (about 11 lb) for those receiving a placebo. Short-term studies reported similar results (2).

Phentermine should not be tainted by association with the fenfluramines (the fen of phen-fen). The mechanism of action of phentermine is not the same as the fenfluramines, which are highly reactive to the serotonin receptor sites in heart valves.

In the late 1990s phen-fen (fenfluramine or dexfenfluramine combined with phentermine) became wildly popular and many consumers demanded prescriptions from their doctor. The fenfluramines became blockbuster drugs. Their use spread like wildfire and they were featured on the cover of *Time* magazine.

In 1997, reports of heart valve changes in some patients using fenfluramines began to emerge. In some cases the valvular abnormalities were asymptomatic and could only be detected with echocardiograms. In September 1997, fenfluramine and dexfenfluramine were voluntarily withdrawn from the US market because of the incidence of valvular regurgitation (the backward flow of blood due to incomplete valve closure). The initial reports suggested that as many as one-third of the users were exhibiting changes. A review of the data has shown that the incidence was not as high as originally thought, but valvular regurgitation was a side effect in 2 to 12 percent of fenfluramine users (11).

Duration played an important role. Those who used fenfluramines for less than four months (considered short-term) had a lower prevalence of heart valve changes than those who used them for more than four months. Both medications remain off the market. The American College of Cardiology recommends that those who have used fenfluramine or dexfenfluramine (with or without phentermine) get a physical exam to determine if echocardiography is necessary (11).

Given the risk of valvular abnormalities, people wonder why the FDA ever approved fenfluramines. The answer is that this side effect was totally unexpected. There was nothing in the medical literature that suggested that it would occur. In fact, the heart valve defects were discovered by sonographers in Fargo, North Dakota, who thought that there might be a connection between their obese patients' valve defects and their use of phen-fen (10).

The lessons learned from phen-fen (coupled with the past history of addictive diet drugs) have many practitioners feeling uneasy about the safety of weight loss drugs in general. No other weight loss medications have the same mechanism as the fenfluramines. Of those drugs that are currently approved by the FDA for weight loss, minor side effects are reported for all the medications but serious side effects appear to be rare.

Effectiveness for weight loss

In 2005, Li, *et al.* (12) published the results of an extensive review of randomized, controlled studies to determine the safety and effectiveness of pharmacological treatments on obesity. When the data from all the studies were pooled, the authors found that the average weight loss after 12 months of use was 4.45 kg (~10 lb) for sibutramine and 2.89 kg (~6 lb) for orlistat. These medications are the two that were studied most.

The effect of any obesity medication on weight loss is modest, realistically 3 to 8 percent of original body weight or 7 to 17 lb. It is important to note that people report that they wish to lose 30 percent of original body weight. This level of reduction is not likely to be achievable with the use of weight loss medications (3).

Effectiveness for reduction of disease risk

Unfortunately, not much is known about the effects of weight loss medications on disease risk. This is a result of the typical study protocol, which generally excludes obese patients with clinical conditions such as type 2 diabetes, hypertension or dyslipidemias, especially if these conditions are being treated with medications. It is known that weight loss itself reduces blood pressure, elevated blood glucose and elevated blood lipids.

Effectiveness, and the clinical significance of any weight loss, have always been troubling issues for the FDA. In 1938, the Food, Drug, and Cosmetic Act required drugs to show evidence of safety but not effectiveness. It was not until 1962 that the act was amended to require evidence of effectiveness. The critical question today, although there is no FDA mandate that it be answered, is “do the benefits outweigh the risks?” (13)

Since the time of the 1962 amendments the FDA has struggled with finding a way to judge the effectiveness of weight loss medications. The easily quantifiable way is to measure pounds lost in both the treatment and the placebo groups. Scientists in the 1970s were unable to define a way to determine if weight loss was “clinically significant.” In other words, if the treatment group loses an average of 5 pounds and the placebo group loses an average of 2 pounds (and this difference is statistically significant) then the drug is considered effective. But does the 3 pound weight loss by those who took the weight loss medication have any positive impact on health (*i.e.* clinical significance) such as lowering blood pressure or blood lipids? (13)

The lack of ability to answer the clinically significant question bothered scientists in the 1970s but it becomes even more critical today because millions more people are obese and weight loss medication use is higher than three decades ago. FDA guidelines for critical evaluation of weight loss drugs were written in 1996 and are in need of updating to address clinical significance and the risk to benefit ratio (14). An extensive meta-analysis published in 2005 identified only one study that measured the effect of a weight loss medication on health outcomes. In that study, the patients who received orlistat lost more weight than placebo and had a lower

incidence of diabetes after four years (7). Studies of sibutramine have shown no effect on fasting glucose or insulin levels in adults and only a small effect on HDL or triglycerides. While some weight may be lost, the medication does not appear to have a beneficial effect on the co-morbidities associated with obesity (*e.g.*, insulin resistant, dyslipidemias)(14).

NAAFA advocates that the FDA should deny approval of any weight loss medication that does not show health benefits. This organization suggests that the FDA pose the same question for weight loss medications as it does for other drugs: Does this treatment improve health? Approval at the present time is based only on the ability to produce weight loss.

Medications as part of a broader treatment plan

A reasonable expectation for an obese adult using a weight loss medication is that 3 to 8 percent more weight will be lost than will be lost without its use. Studies suggest that the outcome may be similar in adolescents and children, but there are far fewer studies upon which to draw conclusions. Sibutramine has been shown to be successful in some children for weight loss but it is contraindicated in children with hypertension and cardiovascular disease and in adolescents with pre-existing psychiatric disorders. Clearly, use of weight loss medications with children and adolescents must be done on a case-by-case basis (14). Whether the risks of such a weight loss outweigh the benefits are not known. However, it is known that maintenance of any weight loss requires a commitment to routine exercise and avoidance of excess calorie intake and that many people regain the lost weight. One recommendation is that weight loss medications be prescribed or continue to be prescribed only to those individuals who are committed to daily activity/exercise and healthy eating. In this way the medication becomes part of the treatment plan not a “quick fix.”

What does the future hold?

In 2001 approximately \$417 million was spent on weight loss medications, most of it as an out-of-pocket expense not covered by health insurance (15). Sibutramine costs about \$6.50 to \$7.00 per day, or about \$200 per month, while a 30-day supply of orlistat costs as much as \$380. It is estimated that the market for weight loss medications is over \$1 billion. That could easily change if a new medication that is safe and has better effectiveness than those currently on the market is approved.

Use of non-prescription weight loss supplements is also common. A 2002 survey found that 11 percent of women and 6 percent of men had used such supplements in the previous year. Nearly 74 percent of supplements contained stimulants — ephedra, caffeine and/or bitter orange. One in 10 users reported using a weight loss supplement for more than 12 months, suggesting that it is an integral part of their weight loss strategy. Long-term use was more common in men than in women. Unfortunately, many respondents did not talk to a health care professional about taking such supplements, even though many of them reported that they had been diagnosed with a chronic disease such as hypertension, heart disease, or diabetes (16).

Pharmaceutical companies are researching a variety of compounds most of them hormones and neurotransmitters that help to regulate food intake. The race to develop new (blockbuster) weight loss drugs continues. In the meantime, consumers should be aware that weight loss medications are not a panacea, have side effects and produce more weight loss when used with lifestyle modifications (*e.g.* exercise, dietary counseling) than when used alone (17).

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Examination (WLM09)

1. Weight loss medications should be used:
 - A. Upon patient request
 - B. As a sole therapy
 - C. With patients with a BMI <25
 - D. With all overweight type 2 diabetes
 - E. None of the above
2. What is the mechanism of action for sibutramine (Meridia®)?
 - A. Increases thermogenesis.
 - B. Blocks the uptake of serotonin and norepinephrine.
 - C. Increases insulin sensitivity.
 - D. Inhibits pancreatic lipase.
 - E. Enhances the action of other weight loss medications.
3. Which organization strongly discourages the use of weight loss medications?
 - A. National Institutes of Health (NIH)
 - B. Food and Drug Administration (FDA)
 - C. American Dietetic Association (ADA)
 - D. National Association to Advance Fat Acceptance (NAAFA)
 - E. None of the above. Each is neutral about the use of weight loss medications.
4. Which prescription weight loss medication increases heart rate by 3 to 4 beats per minute and increases blood pressure by about 2 mmHg?
 - A. Sibutramine
 - B. Orlistat
 - C. Phentermine
 - D. Phen-fen
 - E. None of the above
5. Which of the following weight loss medications is only approved for short-term use?
 - A. Sibutramine
 - B. Orlistat
 - C. Phentermine
 - D. Phen-fen
 - E. None of the above

6. What is the mechanism of action for orlistat (Xenical®)?
- A. Increases thermogenesis.
 - B. Blocks the uptake of serotonin and norepinephrine.
 - C. Increases insulin sensitivity.
 - D. Inhibits pancreatic lipase.
 - E. Enhances the action of other weight loss medications.
7. One of your clients is currently taking phentermine. He asks you if it is the same as phen-fen. How would you respond?
- A. Phentermine and phen-fen are exactly the same compounds.
 - B. Phentermine and phen-fen are essentially the same, except that phentermine is for short-term use and phen-fen is for long-term use.
 - C. Phentermine and phen-fen are not the same but their mechanism of action is exactly the same.
 - D. Phentermine stimulates release of norepinephrine, which is a different mechanism than that of phen-fen.
 - E. Phentermine is a new medication and it is not known how it compares to phen-fen.
8. A client mentions that she took phen-fen for about a year. She asks you if she should be concerned. How would you respond?
- A. A year is considered short-term use so there shouldn't be any concern.
 - B. A year is considered long-term use so you should see a doctor for a physical exam.
 - C. If it was a problem you would see symptoms. If you are asymptomatic, don't worry.
 - D. There was some concern about heart valve problems but if your blood pressure is normal then it isn't a concern for you.
 - E. The problems associated with phen-fen were overblown by the media. There is nothing to worry about.
9. It is known that weight loss:
- A. Improves blood pressure.
 - B. Improves blood glucose levels.
 - C. Improves blood lipid levels.
 - D. Is likely to be modest with the use of weight loss medications
 - E. All of the above
10. What is a reasonable expectation for an obese adult considering the use of a weight loss medication?
- A. That 3 to 8 percent more weight would be lost than if a weight loss medication were not used.
 - B. That 10 percent more weight would be lost than if a weight loss medication were not used.
 - C. That 30 percent of initial weight would be lost but that such a weight loss would take at least a year.
 - D. That 50 percent of initial weight would be lost but that the loss would take at least two years.
 - E. That no weight loss would occur but that co-morbid conditions would improve.

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