

Can Medication Cure Obesity in Children?

A Review of the Literature

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### Abstract

In recent years, policymakers and medical experts have expressed alarm about the growing problem of childhood obesity in the United States. While most agree that the issue deserves attention, consensus dissolves around how to respond to the problem. This literature review examines one approach to treating childhood obesity: medication. The paper compares the effectiveness for adolescents of the only two drugs approved by the Food and Drug Administration (FDA) for long-term treatment of obesity, sibutramine and orlistat. This examination of pharmacological treatments for obesity points out the limitations of medication and suggests the need for a comprehensive solution that combines medical, social, behavioral, and political approaches to this complex problem.

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### A Review of the Literature

In March 2004, U.S. Surgeon General Richard Carmona called attention to a health problem in the United States that, until recently, has been overlooked: childhood obesity. Carmona said that the “astounding” 15% child obesity rate constitutes an “epidemic.” Since the early 1980s, that rate has “doubled in children and tripled in adolescents.” Now more than 9 million children are classified as obese.<sup>1</sup> While the traditional response to a medical epidemic is to hunt for a vaccine or a cure-all pill, childhood obesity is more elusive. The lack of success of recent initiatives suggests that medication might not be the answer for the escalating problem. This literature review considers whether the use of medication is a promising approach for solving the childhood obesity problem by responding to the following questions:

1. What are the implications of childhood obesity?
2. Is medication effective at treating childhood obesity?
3. Is medication safe for children?
4. Is medication the best solution?

Understanding the limitations of medical treatments for children highlights the complexity of the childhood obesity problem in the United States and underscores the need for physicians, advocacy groups, and policymakers to search for other solutions.

### **What Are the Implications of Childhood Obesity?**

Obesity can be a devastating problem from both an individual and a societal perspective. Obesity puts children at risk for a number of medical complications, including Type 2 diabetes, hypertension,

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<sup>1</sup> Obesity is measured in terms of body-mass index (BMI): weight in kilograms divided by square of height in meters. A child or an adolescent with a BMI in the 95th percentile for his or her age and gender is considered obese.

sleep apnea, and orthopedic problems (Henry J. Kaiser Family Foundation, 2004, p. 1). Researchers Hoppin and Taveras (2004) have noted that obesity is often associated with psychological issues such as depression, anxiety, and binge eating (Table 4).

Obesity also poses serious problems for a society struggling to cope with rising health care costs. The cost of treating obesity currently totals \$117 billion per year—a price, according to the surgeon general, “second only to the cost of [treating] tobacco use” (Carmona, 2004). And as the number of children who suffer from obesity grows, long-term costs will only increase.

### **Is Medication Effective at Treating Childhood Obesity?**

The widening scope of the obesity problem has prompted medical professionals to rethink old conceptions of the disorder and its causes. As researchers Yanovski and Yanovski (2002) have explained, obesity was once considered “either a moral failing or evidence of underlying psychopathology” (p. 592). But this view has shifted: Many medical professionals now consider obesity a biomedical rather than a moral condition, influenced by both genetic and environmental factors. Yanovski and Yanovski have further noted that the development of weight-loss medications in the early 1990s showed that “obesity should be treated in the same manner as any other chronic disease . . . through the long-term use of medication” (p. 592).

The search for the right long-term medication has been complicated. Many of the drugs authorized by the Food and Drug Administration (FDA) in the early 1990s proved to be a disappointment. Two of the medications—fenfluramine and dexfenfluramine—were withdrawn from the market because of severe side effects (Yanovski & Yanovski, 2002, p. 592), and several others were classified by the Drug Enforcement Administration as having the “potential for abuse” (Hoppin & Taveras, 2004, Weight-Loss Drugs section, para. 6). Currently only two medications have been approved by the FDA for long term treatment of obesity: sibutramine (marketed as Meridia) and orlistat (marketed as Xenical). This section compares studies on the effectiveness of each.

Sibutramine suppresses appetite by blocking the reuptake of the neurotransmitters serotonin and norepinephrine in the brain (Yanovski & Yanovski, 2002, p. 594). Though the drug won FDA approval in

1998, experiments to test its effectiveness for younger patients came considerably later. In 2003, University of Pennsylvania researchers Berkowitz, Wadden, Tershakovec, and Cronquist released the first double-blind placebo study testing the effect of sibutramine on adolescents, aged 13-17, over a 12-month period. Their findings are summarized in Table 1.

Table 1

*Effectiveness of Sibutramine and Orlistat in Adolescents*

<b>Medication</b>	<b>Subjects</b>	<b>Treatment<sup>a</sup></b>	<b>Side effects</b>	<b>Average weight loss/gain</b>
Sibutramine	Control	0-6 mos.: placebo  6-12 mos.: sibutramine	Mos. 6-12: increased blood pressure; increased pulse rate	After 6 mos.: loss of 3.2 kg (7 lb)  After 12 mos.: loss of 4.5 kg (9.9 lb)
	Medicated	0-12 mos.: sibutramine	Increased blood pressure; increased pulse rate	After 6 mos.: loss of 7.8 kg (17.2 lb)  After 12 mos.: loss of 7.0 kg (15.94 lb)
Orlistat	Control	0-12 mos.: placebo	None	Gain of 0.67 kg (1.5 lb)
	Medicated	0-12 mos.: orlistat	Oily spotting; flatulence; abdominal discomfort	Loss of 1.3 kg (2.9 lb)

*Note.* The data on sibutramine are adapted from “Behavior Therapy and Sibutramine for the Treatment of Adolescent Obesity,” by R. I. Berkowitz, T. A. Wadden, A. M. Tershakovec, & J. L. Cronquist, 2003, *Journal of the American Medical Association*, 289, pp. 1807-1809. The data on orlistat are adapted from *Xenical (Orlistat) Capsules: Complete Product Information*, by Roche Laboratories, December 2003, retrieved from <http://www.rocheusa.com/products/xenical/pi.pdf>

<sup>a</sup> The medication and/or placebo were combined with behavioral therapy in all groups over all time periods.

After 6 months, the group receiving medication had lost 4.6 kg (about 10 pounds) more than the control group. But during the second half of the study, when both groups received sibutramine, the results were more ambiguous. In months 6-12, the group that continued to take sibutramine gained an average of 0.8 kg, or roughly 2 pounds; the control group, which switched from placebo to sibutramine, lost 1.3 kg, or roughly 3 pounds (p. 1808). Both groups received behavioral therapy covering diet, exercise, and mental health.

These results paint a murky picture of the effectiveness of the medication: While initial data seemed promising, the results after one year raised questions about whether medication induced weight loss could be sustained over time. As Berkowitz et al. (2003) advised, “Until more extensive safety and efficacy data are available . . . weight-loss medications should be used only on an experimental basis for adolescents” (p. 1811).

A study testing the effectiveness of orlistat in adolescents showed similarly ambiguous results. The FDA approved orlistat in 1999 but did not authorize it for adolescents until December 2003. Roche Laboratories (2003), maker of orlistat, released results of a one-year study testing the drug on 539 obese adolescents, aged 12-16. The drug, which promotes weight loss by blocking fat absorption in the large intestine, showed some effectiveness in adolescents: an average loss of 1.3 kg, or roughly 3 pounds, for subjects taking orlistat for one year, as opposed to an average gain of 0.67 kg, or 1.5 pounds, for the control group (pp. 8-9). See Table 1.

Short-term studies of orlistat have shown slightly more dramatic results. Researchers at the National Institute of Child Health and Human Development tested 20 adolescents, aged 12-16, over a three-month period and found that orlistat, combined with behavioral therapy, produced an average weight loss of 4.4 kg, or 9.7 pounds (McDuffie et al., 2002, p. 646). The study was not controlled against a placebo group; therefore, the relative effectiveness of orlistat in this case remains unclear.

### **Is Medication Safe for Children?**

While modest weight loss has been documented for both medications, each carries risks of certain side effects. Sibutramine has been observed to increase blood pressure and pulse rate. In 2002, a

consumer group claimed that the medication was related to the deaths of 19 people and filed a petition with the Department of Health and Human Services to ban the medication (Hilts, 2002). The sibutramine study by Berkowitz et al. (2003) noted elevated blood pressure as a side effect, and dosages had to be reduced or the medication discontinued in 19 of the 43 subjects in the first six months (p. 1809).

The main side effects associated with orlistat were abdominal discomfort, oily spotting, fecal incontinence, and nausea (Roche Laboratories, 2003, p. 13). More serious for long term health is the concern that orlistat, being a fat-blocker, would affect absorption of fat-soluble vitamins, such as vitamin D. However, the study found that this side effect can be minimized or eliminated if patients take vitamin supplements two hours before or after administration of orlistat (p. 10). With close monitoring of patients taking the medication, many of the risks can be reduced.

### **Is Medication the Best Solution?**

The data on the safety and efficacy of pharmacological treatments of childhood obesity raise the question of whether medication is the best solution for the problem. The treatments have clear costs for individual patients, including unpleasant side effects, little information about long-term use, and uncertainty that they will yield significant weight loss.

In purely financial terms, the drugs cost more than \$3 a day on average (Duenwald, 2004). In each of the clinical trials, use of medication was accompanied by an expensive regime of behavioral therapies, including counseling, nutritional education, fitness advising, and monitoring. As journalist Greg Critser (2003) noted in his book *Fat Land*, use of weight-loss drugs is unlikely to have an effect without the proper “support system”—one that includes doctors, facilities, time, and money (p. 3). For some, this level of care is prohibitively expensive.

A third complication is that the studies focused on adolescents aged 12-16, but obesity can begin at a much younger age. Little data exist to establish the safety or efficacy of medication for treating very young children.

While the scientific data on the concrete effects of these medications in children remain somewhat unclear, medication is not the only avenue for addressing the crisis. Both medical experts and

policymakers recognize that solutions might come not only from a laboratory but also from policy, education, and advocacy. A handbook designed to educate doctors on obesity called for “major changes in some aspects of western culture” (Hoppin & Taveras, 2004, Conclusion section, para. 1). Cultural change may not be the typical realm of medical professionals, but the handbook urged doctors to be proactive and “focus [their] energy on public policies and interventions” (Conclusion section, para. 1).

The solutions proposed by a number of advocacy groups underscore this interest in political and cultural change. A report by the Henry J. Kaiser Family Foundation (2004) outlined trends that may have contributed to the childhood obesity crisis, including food advertising for children as well as

a reduction in physical education classes and after-school athletic programs, an increase in the availability of sodas and snacks in public schools, the growth in the number of fast-food outlets . . . , and the increasing number of highly processed high-calorie and high-fat grocery products. (p. 1)

Addressing each of these areas requires more than a doctor armed with a prescription pad; it requires a broad mobilization not just of doctors and concerned parents but of educators, food industry executives, advertisers, and media representatives.

The barrage of possible approaches to combating childhood obesity—from scientific research to political lobbying—indicates both the severity and the complexity of the problem. While none of the medications currently available is a miracle drug for curing the nation’s 9 million obese children, research has illuminated some of the underlying factors that affect obesity and has shown the need for a comprehensive approach to the problem that includes behavioral, medical, social, and political change.

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