PART IV

TREATMENT OF ADULT OBESITY

11

The Treatment of Obesity: An Overview

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In 1998, an expert panel assembled by the National Heart, Lung, and Blood Institute (NHLBI, 1998) conducted an exhaustive review of the safety and efficacy of treatments for obesity. It issued recommendations for selecting among interventions, based on an individual's body mass index (BMI) and risk of health complications. The panel's lengthy report was distilled by a joint committee into the *Practical Guide to the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults* (NHLBI & North American Association for the Study of Obesity [NAASO], 2000). This briefer document provides primary care practitioners with additional guidelines and tools for treating overweight and obese individuals. Both of these documents are essential reading for persons interested in weight management.

This chapter adheres to the recommendations of the joint NHLBI and NAASO (2000) panel, and provides additional detail about various treatment options. The chapter seeks to help practitioners identify the most appropriate therapy for a given individual. As such, it offers a framework for selecting from the dietary, behavioral, pharmacological, surgical, and other interventions described in the chapters that follow this one.

SELECTING TREATMENT

The decision to initiate weight loss should be based on an assessment of a patient's need to reduce, as described in this volume by Atkinson (Chapter 9) and Aronne (Chapter 18), and on the individual's behavioral readiness for weight loss, as discussed by Wadden and Phelan (Chapter 10). These factors, together with the BMI, suggest which interventions are likely to be most appropriate for a particular patient.

Treatment Algorithms

Aronne (Chapter 18, this volume) has reviewed the NHLBI and NAASO (2000) algorithm for selecting therapy (see Table 18.4 on page 396). Persons with a BMI of 25.0–29.9 kg/m^2 who have two or more risk factors are encouraged to consume a balanced low-calorie diet, to increase their physical activity (so that they eventually exercise 30 minutes a day most days of the week), and to modify inappropriate eating habits. Alternatively, prevention of weight gain is recommended for persons in the same BMI range who are not motivated to reduce or who have fewer than two risk factors. As BMI increases, so generally do the health complications of obesity and the need for more intensive intervention. Pharmacotherapy is an option for persons with a BMI $\geq$ 30 kg/m^2 (or a BMI $\geq$ 27 kg/m^2 in the presence of comorbid conditions) and who have failed to reduce using more conservative measures. Bariatric surgery is reserved for individuals with a BMI $\geq$ 40 kg/m^2 or those with a BMI $\geq$ 35 kg/m^2 who have significant comorbid conditions.

Wadden, Brownell, and Foster (in press) have proposed a stepped-care algorithm that, similar to that developed by the NHLBI and NAASO (2000) panel, recommends treatment based on the patient's BMI and risk of health complications (see Figure 11.1). The principal difference between the two schemes is the greater number of treatment options listed by the former algorithm and the stronger encouragement for persons with a BMI of 27–29 kg/m^2 to lose weight. The presence of a single risk factor, such as hypertension or Type 2 diabetes, would appear to provide ample reason to undertake weight loss. Moreover, prevention of weight gain for individuals who fall into the BMI range of 27–29 kg/m^2 is likely to require periodic bouts of caloric restriction, as well as increased physical activity, to reverse weight gain that occurs over the winter months or at other times. In overweight and obese adults, intentional weight loss, even when followed by weight regain, does not appear to be associated with (1) increased risks of morbidity or mortality, (2) adverse effects on metabolism or energy expenditure, or (3) the precipitation of eating disorders or depression (Foster, Sarwer, & Wadden, 1997; Gregg & Williamson, Chapter 7, this volume; National Task Force on the Prevention and Treatment of Obesity, 1994, 2000; Wadden, Foster, Stunkard, & Conill, 1996). Thus there do not appear to be strong reasons to dissuade persons with a BMI of 27–29 kg/m^2 from attempting to lose weight.

Treatment Selection

Treatment selection should be guided not only by the individual's BMI and health risks, but also by the patient's history of weight loss efforts. For example, we have encountered many obese males (BMI $\geq$ 30 kg/m^2) who were eligible for pharmacotherapy but who had never participated in a traditional behavioral program of diet and physical activity. The latter intervention is less expensive than pharmacotherapy and is associated with fewer risks of health complications. Pharmacotherapy may be useful with these individuals for maintaining weight loss, but is not necessary to induce it. By contrast, it is hard to argue that a woman with a BMI of 35 kg/m^2, Type 2 diabetes, and a marked history of weight cycling should enroll in yet another diet and exercise program. She is more likely to achieve long-term success with long-term pharmacotherapy or with bariatric surgery. Diet and activity modification will remain an important focus of treatment, but they would need to be supported by these other interventions. Patients should have tried a less intensive treatment option once or twice before selecting a more aggressive therapy, but it is not necessary to try the less intensive option again with each new practitioner.

Treatment options must also be selected with consideration of their safety, efficacy, and cost. Self-help programs, for example, are very attractive because of their safety and low cost, but they usually produce minimal weight loss (Womble, Wang, & Wadden, Chap-

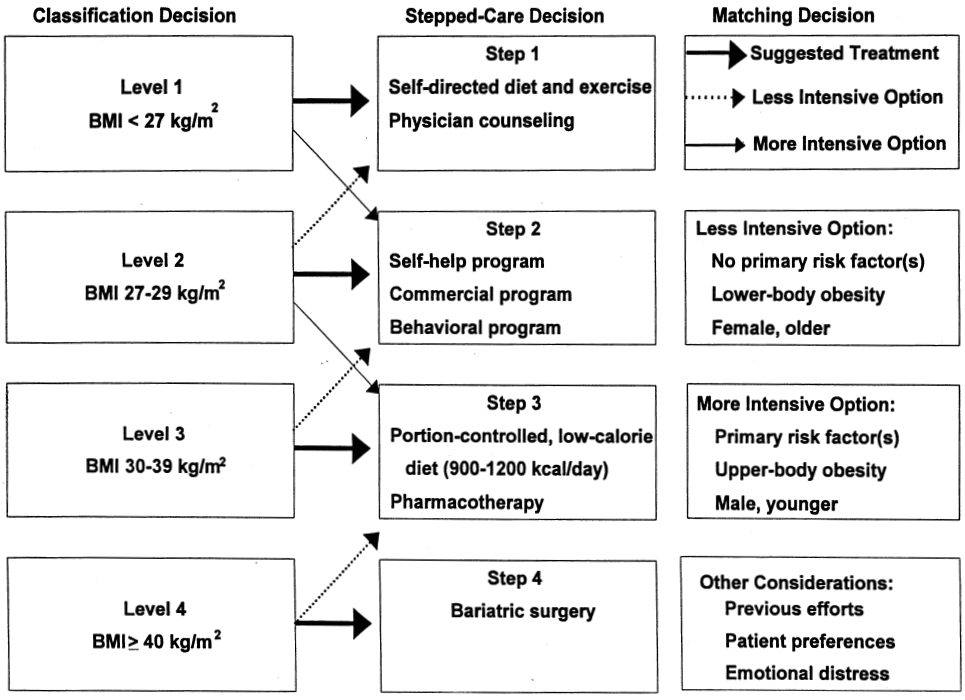

FIGURE 11.1. A conceptual scheme showing a three-stage process for selecting treatment. The first step, the Classification Decision, divides people into four levels based on body mass index (BMI). This level indicates which of four classes of interventions are likely to be most appropriate in the second stage, the Stepped-Care Decision. The interventions range from low-intensity, low-cost approaches, such as self-directed diet-and-exercise programs, to extremely aggressive and expensive interventions such as bariatric surgery. All individuals are encouraged to control their weight by increasing their physical activity and consuming an appropriate diet. When this approach is not successful, more intensive intervention may be warranted, with the most conservative treatment (i.e., lowest cost and risks of side effects) tried next. The thick, solid arrows between the boxes shows the class of treatments that is usually most appropriate for an individual when less intensive interventions have not been successful. The third stage, the Matching Decision, is used to make a final treatment selection, based on the individual's prior weight loss efforts, treatment preferences, and need for weight reduction (as judged by the presence of comorbid conditions or other risk factors). The dashed arrows point to treatment options for persons with a reduced need for weight reduction because of a reduced risk of health complications. The thin arrows show the more intensive treatment options for persons who, despite relatively low BMI levels, have increased risks of health complications. Adjunct nutritional or psychological counseling is recommended for patients who report marked problems with meal planning, depression, body image, or like difficulties. From Wadden, Brownell, and Foster (in press). Copyright by the American Psychological Association. Reprinted by permission.

ter 19, this volume). Thus such programs may not be a good choice for an individual who needs to lose approximately 10% of initial weight to improve a weight-related health complication.

Individual preferences also must be considered. Given that patients must actively participate in their weight management (i.e., by modifying eating and activity habits and/or by taking medications), they must find the therapy acceptable. Concerns about the safety of some approaches, including pharmacotherapy or surgery, must be respected in view of the history of complications associated with these interventions. Similarly, patients may raise objections to specific diet or exercise regimens. A health care provider can suggest that a pa-

tient try a specific approach for a week or two, as an experiment, with the hope that it will prove acceptable. It is inappropriate, however, to push patients to accept a single diet or exercise plan when there are so few data to inform patient–treatment matching (i.e., tailoring). Clearly, one size does not fit all. Kumanyika has discussed, in Chapter 20 of this volume, the importance of responding to individual differences and preferences in selecting an appropriate weight loss intervention.

TREATMENT OPTIONS: BMI < 30 kg/m^2

Approximately 36% of adult Americans have a BMI of 25.0–29.9 kg/m^2, placing them in the "overweight" category as defined by the NHLBI (1998) and the World Health Organization (1998). Surveys indicate that most of these individuals, when trying to lose weight, do so on their own—by dieting (i.e., restricting food intake), exercising, or both (Serdula, Collins, Williamson, Pamuk, & Byers, 1993). These persons also buy millions of diet books and exercise videos each year, although little is known about the effectiveness of these interventions.

Primary Care Physicians

Aronne (Chapter 18, this volume) has described the role of primary care physicians in preventing and treating obesity. This includes monitoring patients' weight (and BMI) on a regular basis, providing literature on healthy eating and activity habits, and assessing and managing weight-related health complications. Some physicians may wish to provide more intensive weight management, potentially by giving patients a structured treatment manual, having a registered dietitian consult in the office, or establishing an afternoon or evening clinic to provide brief check-in visits (i.e., to measure weight, collect food records, etc.).

Primary care physicians often report that they feel ill prepared to treat overweight individuals, whether because of lack of adequate training, poor reimbursement, or a sense of futility—a feeling "that nothing works" (Aronne, Chapter 18; Frank, 1993). Patients may well sense their physicians' lack of involvement. Nearly three-quarters of participants in a recent study reported that they looked to their doctors only a "slight amount" or "not at all" for advice about weight management (Wadden, Anderson, et al., 2000). Nearly 45% indicated that their doctor had not prescribed any of 10 common weight loss methods. These data suggest that physicians and their obese patients may have landed in a weight management stalemate: No one talks about the problem. On a more positive note, fewer than 10% of patients reported that they were treated disrespectfully by their doctors concerning their weight. Moreover, most respondents were quite satisfied with the medical care they received for their general health.

It is challenging for most primary care physicians to provide effective diet and exercise counseling in traditional office practice, because they are not equipped to meet with their patients on a weekly or biweekly basis—the frequency of care that is likely to produce the best results (at least in the short term). Nevertheless, physicians can play an important role in the management of overweight and obesity by providing an atmosphere in which patients can discuss their concerns and frustrations about their weight. Moreover, practitioners can provide a valuable service by familiarizing themselves with treatment options available in their community and using these resources (Aronne, Chapter 18). This includes identifying a registered dietitian with whom to establish a consultative relationship. (A local dietitian may be identified by calling 800-366-1655.) Physicians can similarly support their patients' participation in self-help or commercial programs by inquir-

ing at office visits about satisfaction with these programs and congratulating patients on weight loss or behavior change.

Self-Help and Commercial Programs

Self-Help Programs

Overweight individuals who are unable to reduce on their own, or with their physicians' advice, may benefit from the greater structure and support provided by self-help and commercial programs (reviewed in this volume by Womble et al., Chapter 19). Self-help programs charge no fee or only a nominal one (e.g., a dollar per week), and yet may induce weight losses as large as those produced by some of the most expensive proprietary programs. Latner and colleagues (2000), for example, recently reported that participants in a highly structured, group behavioral self-help program lost an average of 17.9 kg during the first 2 years and maintained a mean loss of 15.7 kg at 5 years. The 5-year findings were based on only the 21.6% of participants who remained in the program at this time, but these are still impressive results, particularly in light of the negligible costs of the program. Take Off Pounds Sensibly (TOPS) and Overeaters Anonymous (OA) offer additional low- or no-cost alternatives that are available nationwide (see TOPS Club, 2000, and OA, 1996). Few data, however, are available to evaluate the effectiveness of these latter two programs (Womble et al., Chapter 19).

Commercial Programs

Outcome data have become increasingly important to commercial weight loss programs because providers can no longer make claims of long-term success unless they have data to support them. Not surprisingly, no commercial programs now advertise that their participants "lose weight and keep it off forever," as they did prior to the Federal Trade Commission's (1997) action against several companies.

Weight Watchers has taken the lead among commercial programs in evaluating its results of treatment. A recent study revealed that patients who were randomly assigned to attend a conventional Weight Watchers program lost 6.0% of initial weight in 6 months (Heshka et al., 2000). Persons assigned to a self-directed weight loss approach that included two meetings with a registered dietitian lost 2.5% of initial weight. These results indicate that the Weight Watchers program, which combines group support with a sound program of diet, exercise, and behavior modification, can be of benefit to overweight and obese individuals at a reasonable cost (i.e., about $12 per week). Participants, on average, do not lose large amounts of weight, but losing as few as 2–3 kg after the holidays would appear to be better than continuously gaining weight. Moreover, even if participants do not lose a lot of weight, they do not lose a lot of money. In the absence of efficacy data from other commercial programs, it is hard not to select Weight Watchers as a first intervention for overweight individuals who want more structure and cannot find a self-help program.

Behavioral Weight Loss Programs

Weight Watchers and other commercial programs have incorporated many of the components of the behavioral treatment of obesity that was developed in university clinics in the late 1960s (Stuart, 1967). Wing has described, in Chapter 14 of this volume, the theoretical underpinnings of the behavioral approach, as well as its short- and long-term treatment results. Patients typically lose 8%–10% of initial weight during 4–6 months of weekly group treatment (Wing, 1998, and Chapter 14, this volume). Approximately 80%–85% of participants complete treatment. Thus, traditional behavioral interventions are likely to produce

greater weight loss than are most commercial programs, although this hypothesis has not been tested in randomized trials.

There are numerous accounts of the components of behavioral treatment, which include self-monitoring, stimulus control, problem solving, cognitive restructuring, social support, nutrition education, physical activity, and the use of reinforcement contingencies (Brownell, 2000; Wadden & Foster, 2000; Wing, 1998). Brownell (2000) has provided a 16-week, step-by-step manual that covers these topics in a detailed but user-friendly manner. Rather than repeat this description, this section briefly discusses some of the mechanics of behavioral treatment that we believe contribute to its successful induction of weight loss. This begins with the fact that behavioral treatment is very goal-oriented. Participants are given homework assignments (for changing eating, activity, and thinking habits), which are specified in terms that can be easily operationalized and measured. This is true whether the goal is walking after dinner five times a week for 20 minutes, keeping a daily record of food intake, decreasing the number of self-critical statements, or limiting breakfast to 275 kilocalories (kcal). Treatment sessions eschew lecturing by the group leader and instead are devoted principally to reviewing patients' completion of homework assignments and helping them find solutions to barriers.

Frequent Visits

Behavior change is facilitated by meeting with patients on a weekly basis. Frequent visits provide not only more opportunities for instruction, but also more opportunities for staff to review and reinforce patients' completion of food and activity records. Anticipation of weekly weigh-ins motivates most patients to adhere to the prescribed behaviors, and weight change provides a crude but critical measure of adherence. The failure to weigh participants each week is likely to result in suboptimal weight loss, as suggested by the results of a study by Goodrick, Poston, Kimball, Reeves, and Foreyt (1998).

Time-Limited Therapy

Most behavioral programs last 16–26 weeks. Treatment (at least during the weight loss induction phase) has a clear beginning and end, which appears to help patients pace themselves. They can set their sights on a specific date to complete treatment and achieve a sense of accomplishment, compared with the practice in open-ended therapy of having participants attend sessions indefinitely. Identifying a "treatment end date," however, is clearly a misnomer, given that patients require long-term behavioral or pharmacological treatment to maintain their weight loss. Even knowing this, patients usually prefer to divide maintenance therapy into time-limited blocks; this is similar to enrolling in a course for a semester, with the knowledge that additional courses will be needed.

Group Treatment

Behavioral treatment is typically delivered to groups of 10–20 persons. The use of closed treatment groups, in which the same patients begin and end treatment together, appears preferable to the use of open groups, in which new members may be added to the group at any point in treatment. The addition of new members after the first few weeks impairs the development of group cohesiveness and may contribute to the high attrition rates that characterize commercial programs that use open groups (Volkmar, Stunkard, Woolston, & Bailey, 1981). Moreover, it is difficult to establish a curriculum of behavior change, in which one week's session builds upon another, if patients in the same group are at different stages of treatment.

Group treatment is not only more cost-effective than individual therapy but also may produce larger weight losses. A recent study found that persons who requested individual therapy but were randomly assigned to group treatment nevertheless achieved significantly greater weight losses than participants who requested individual therapy and received it (Renjilian et al., 2001). The benefits of group treatment may derive not only from the support that patients provide each other, but also from a healthy dose of competition. Patients may push themselves to keep up with the group norm.

Treatment Flexibility

Although behavioral treatment as described here is highly structured, the treatment principles can be used to help patients adopt a variety of different eating and activity plans. Traditional behavioral interventions, for example, encourage patients to consume a balanced-deficit diet of approximately 1,200–1,800 kcal/day, as described by Melanson and Dwyer in Chapter 12 of this volume. Behavioral principles, however, can be used to facilitate adherence to diets that vary dramatically in their macronutrient or calorie content, including very-low-calorie diets (VLCDs) or plans that allow *ad libitum* intake of carbohydrate with only small amounts of fat. The same behavioral principles can be used to increase programmed exercise, lifestyle activity, or both, as described by Wing (Chapter 14, this volume). Thus "behavioral treatment" refers to the principles and techniques that are used to change eating and activity habits, rather than to the specific diet or exercise plan that is to be adopted.

Limitation of Behavioral Treatment

Traditional group behavioral treatment is appropriate for overweight or obese individuals who have failed to reduce on their own or who have not been successful with self-help or commercial programs. The greater intensity and structure provided by this approach should be of benefit. The greatest drawback of group behavioral treatment is its limited availability. Health care providers (in the United States) are encouraged to contact their local hospital, university psychology clinic, sports medicine clinic, or YMCA to determine whether they offer a closed-group behavioral program as described above. A local registered dietitian may also offer such treatment. In the absence of referral sources, practitioners may wish to use *The LEARN Program for Weight Management 2000* (Brownell, 2000). (The manual may be ordered at 800-736-7323.)

TREATMENT OPTIONS: BMI OF 30–39 kg/m^2

One-quarter of U.S. adults have a BMI $\geq$ 30 kg/m^2, which places them in the "obese" category. The algorithm in Figure 11.1 lists two options for persons with a BMI of 30–39 kg/m^2 who have failed to reduce using the less intensive (and less expensive) options described previously. The options are (1) a low-calorie, portion-controlled diet; and (2) pharmacotherapy.

Low-Calorie, Portion-Controlled Diet

The NHLBI (1998) recommended that persons with a BMI of 27–35 kg/m^2 who wish to lose weight reduce their intake by 300–500 kcal/day, with the goal of losing 10% of initial weight in 6 months. Persons with a BMI over 35 kg/m^2 are encouraged to reduce their intake by 500–1,000 kcal/day in order to achieve a comparable reduction in the same time. Caloric intake is restricted more severely with heavier individuals because they have to lose more weight (in absolute terms) to achieve a 10% reduction.

Although reducing daily caloric intake by a certain amount (e.g., 500–1,000 kcal/day) may sound easy, it frequently is not because people do not know their baseline energy requirements (to maintain weight). In addition, equations for estimating calorie requirements often miss the mark by 20% or more when applied to a given individual (Foster et al., 1988). This shortcoming has led some practitioners to simplify matters by prescribing a diet of 1,000–1,500 kcal/day for obese women and 1,500–1,800 kcal/day for men (Brownell, 2000; Wing, 1998). (Heavier individuals are usually instructed to aim for the higher end of the calorie range.) Following this approach, women are prescribed what the NHLBI (1998) has defined as a "low-calorie diet" (LCD): a diet providing 800–1,500 kcal/day. The diet of 1,500–1,800 kcal/day prescribed for men is sometimes referred to as a "balanced-deficit diet" (BDD), as discussed by Melanson and Dwyer (Chapter 12, this volume) in this volume. (This term actually refers to the balanced, or even, reduction in the macronutrient composition of the diet. The energy content of BDDs often ranges from 1,000 to 2,000 kcal/day.)

Structured Meal Plans and Liquid Meal Replacements

Wing has reviewed, in Chapter 14 of this volume, the use of structured meal plans and liquid meal replacements, which induce larger weight losses than those produced by a self-selected diet of conventional foods with the same targeted calorie goal. Ditschuneit, Flechtner-Mors, Johnson, and Adler (1999), for example, found that patients who met with a dietitian once a month and were prescribed a diet of 1,200–1,500 kcal/day that included two servings a day of a liquid meal replacement (i.e., SlimFast) lost 7.1 kg in 3 months, compared to a loss of 1.3 kg for participants who were instructed to consume a self-selected diet of the same caloric value. Portion-controlled servings, by providing foods of a predetermined quantity and calorie content, reduce obese individuals' tendency to underestimate their calorie intake—an underestimation that is as great as 50% when a self-selected diet of conventional foods is consumed (Bandini, Schoeller, Cyr, & Dietz, 1990; Prentice, Black, Coward, & Cole, 1996). By coming closer to their prescribed calorie goal, patients are more likely to achieve their desired weight loss. This is particularly important with individuals with a BMI $\geq$ 30 kg/m^2 who often feel that they have so much weight to lose. Portion-controlled foods may be useful not only for inducing larger initial weight losses, but also for facilitating the maintenance of weight loss (Flechtner-Mors, Ditschuneit, Johnson, Suchard, & Adler, 2000).

Very-Low-Calorie Diets

The use of liquid meal replacements evolved in part from the popularity in the 1980s of VLCDs, defined by the NHLBI (1998) as diets providing fewer than 800 kcal/day. VLCDs provide large amounts of protein (i.e., 70–100 g/day) to prevent the loss of lean body mass, and may be consumed as a liquid formula or as lean meat, fish, and fowl (referred to as a protein-sparing modified fast). Both diets appear to be safe when supplemented with adequate vitamins and minerals, and when provided to appropriately selected patients under careful medical supervision, as described previously (National Task Force, 1993; Wadden & Berkowitz, 2001). VLCDs, however, are associated with an increased risk of gallstones—a complication that can be prevented by taking ursodeoxycholic acid (Broomfield et al., 1988).

VLCDs produce reductions of approximately 15%–25% of initial weight in 8–16 weeks of treatment—losses approximately double the size of those produced in the same time by a BDD of 1,000–1,600 kcal/day composed of self-selected conventional foods (Anderson, Vichitbandra, Qian, & Kryscio, 1999; National Task Force, 1993; Wadden &

Bartlett, 1992). At least seven randomized trials have compared the short- and long-term results of these two dietary approaches (Miura, Arai, Tsukahara, Ohno, & Ikeda, 1989; Ryttig, Flaten, & Rössner, 1997; Togerson, Lissner, Lindroos, Kruijer, & Sjöström, 1997; Wadden, Foster, & Letizia, 1994; Wadden, Sternberg, Letizia, Stunkard, & Foster, 1989; Wing, Blair, Marcus, Epstein, & Harvey, 1994; Wing et al., 1991). Table 11.1 summarizes four of these studies and shows that patients treated by both approaches regained weight in the year following treatment. Those treated by a VLCD, however, regained substantially more weight, so that at follow-up (12 or more months after patents achieved their maximum weight loss) there were not statistically significant differences between the VLCD and the BDD. Only one study to date found a substantial advantage at follow-up for the VLCD (Miura et al., 1989). These findings raise questions concerning whether VLCDs are worth the greater expense (i.e., approximately $3,000 for a 6-month program), compared with a traditional BDD providing 1,000–1,500 kcal/day. Moreover, three studies compared liquid diets providing 420 kcal/day versus 800 kcal/day and found they produced equivalent weight losses, raising additional questions about the need for severe caloric restriction (i.e., <800 kcal/day) (Foster et al., 1992; Kanders, Blackburn, Lavin, & Norton; Ohno, Miura, Arai, Tsukahara, & Ikeda, 1989).

For these reasons, our research team has discontinued use of VLCDs in favor of a diet providing 900–1,000 kcal/day. This diet combines four servings of a nutritional supplement (OPTIFAST 800) with an evening meal that consists of a frozen food entree and a fruit and vegetable serving (Wadden et al., 1997). This regimen produced a loss of 17% of initial weight in 16 weeks, was well tolerated by patients, and required only minimal medical monitoring because of the higher calorie level. Patients were examined by a physician (and a biochemical profile was obtained) at baseline and at weeks 8 and 24. Thus a portion-controlled LCD can be provided at a substantially lower cost than a VLCD because of the reduced need for physician monitoring and laboratory tests.

Patients are likely to obtain optimal results with a portion-controlled LCD by participating in a structured behavioral program, as described previously. In addition, prior to treatment, patient and practitioner must devise a program to facilitate the maintenance of weight loss, given that patients appear just as likely to regain weight following a portion-controlled LCD as they are following a VLCD (Wadden et al., 1997). As noted previously, long-term use of a liquid meal replacement may help to facilitate the maintenance of weight loss (Flechtner-Mors et al., 2000).

Pharmacological Treatment of Obesity

Weight loss medications are another option for persons with a BMI $\geq$ 30 kg/m^2, or a BMI $\geq$ 27 kg/m^2 in the presence of obesity-related risk factors or comorbid conditions (NHLBI & NAASO, 2000; National Task Force, 1996). In our opinion, pharmacotherapy's greatest strength, particularly compared with traditional behavioral treatment, would appear to reside in facilitating the maintenance rather than the induction of weight loss. Sibutramine and orlistat, the two medications currently approved by the U.S. Food and Drug Administration for long-term use, have been shown to produce losses as great as 8%–10% of initial weight 2 years postbaseline, as long as patients remained on medication (Davidson et al., 1999; James et al., 2000; Sjöström et al., 1998). Long-term behavioral treatment, as reviewed by Perri and Corsica in Chapter 17 of this volume, appears to be equally effective; however, it is likely to require more time and effort (of both patient and provider), and it is rarely provided outside of research and hospital clinics. Thus pharmacotherapy has the potential to make effective treatment available to far greater numbers of persons, although this hypothesis remains to be tested.

TABLE 11.1 Comparison of Very-Low-Calorie Diets (VLCDs) versus Balanced-Deficit Diets (BDDs) providing 1,000–1,6000 kcal/day

Reference	Subjects	Mean pretreatment weight (kg)	Mean age (yr)	Treatment regimen	Mean treatment duration (wk)	Maximum mean weight loss (kg)	Mean weight loss at follow-up (kg)
Ryttig, Flaten, & Rossner (1997)	44 F, 37 M (42)	114.2	42.5	1. BDD (1,600 kcal/day) for 112 wk.	112	Wk 8: 7.2[a]	112 wk: 5.5
				2. VLCD (420 kcal/day) for 8 wk, followed by BDD (1,600 kcal/day) for 104 wk.	112	Wk 8: 9.2[b]	112 wk: 5.9
				3. VLCD for 8 wk, followed by BDD using nutrient packets for 104 wk.	112	Wk 8: 9.2[b]	112 wk: 5.7
Togerson et al. (1997)	74 F, 39 M (87)	110.9 126.15	47.1	1. VLCD (456 kcal/day for women, 608 for men) + BT for 12 wk, followed by BDD (1,200–1,800 kcal/day) + BT for 92 wk.	104	Wk 26: 15.9[a]	104 wk: 9.2
				2. BT + BDD for 104 wk.	104	Wk 26: 8.6[b]	104 wk: 6.2
Wadden, Foster, & Letizie (1994)	49 F (37)	106.3	39.3	1. BDD (1,200 kcal/day) + BT.	52	Wk 26: 11.9[a]	78 wk: 12.2
				2. BDD for 1 wk; VLCD (420 kcal/day) for wk. 2–17; BDD (1,000–1,200 kcal/day) for wk 18–52.	52	Wk 26: 21.5[b]	78 wk: 10.9
Wing et al. (1994)	93 F (74)	106.75	51.8	1 BDD (1,000–1,200 kcal/day) + BT for 1 yr.	50	Wk 26: 14.5	104 wk: 5.7
				2. VLCD (400–500 kcal/day) for wk 1–12 and 24–36 + BT.	50	Wk 26: 16.8	104 wk: 7.2

Note. F, female; M, male; number in parentheses = subjects remaining at longest follow-up; BT, behavior therapy. Values of maximum mean weight loss with different superscripts (*a* vs. *b*) are significantly different from each other.

In this volume, Bray (Chapter 15) has reviewed current and potential agents for the treatment of obesity, and Aronne (Chapter 18) has discussed the prescription of weight loss agents by primary care physicians. Several other thoughtful reviews of this topic are available (Atkinson & Hubbard, 1994; Bray, 1993; Bray & Greenway, 1999; National Task Force, 1996). Thus the present discussion is limited to four related issues: (1) the size of the weight losses to be expected with medication, (2) the relation between behavioral and pharmacological interventions, (3) methods to facilitate medication adherence, and (4) the long-term use of pharmacotherapy.

Size of Weight Losses

Sibutramine and orlistat induce mean reductions of approximately 7%–10% of initial weight during the first 6 months of treatment—a loss nearly identical to that produced by traditional behavioral treatment. Weight loss usually stops (i.e., plateaus) at this time, despite patients' remaining on medication (for up to 2 years). As many as 40% of participants treated by either medications may lose 10% or more of initial weight, but even the most successful individuals fall far short of the 25% reduction in initial weight that patients expect to achieve (Wadden, Berkowitz, Sarwer, Prus-Wisniewski, & Steinberg, 2001). Efforts to increase weight losses by combining sibutramine and orlistat (which have different and potentially complementary mechanisms of action) were not successful in a pilot study of this approach, but further studies are needed (Wadden, Berkowitz, et al., 2000). Combining weight loss medications with a strong behavioral program may yield larger weight loss.

Relation of Behavioral and Pharmacological Treatment

Currently approved pharmacological agents induce weight loss by modifying *internal* signals that regulate hunger and/or satiety (as with sibutramine) or by causing nutrient malabsorption (as with orlistat) (Wadden et al., 2001). Medications in the first group may reduce the desire to initiate (or to continue) eating. Behavior modification, by contrast, induces weight loss by helping patients modify the *external* environment (Craighead & Agras, 1991). For example, patients are instructed to select smaller portion sizes, to avoid convenience stores and fast-food restaurants, to store foods out of sight, and to avoid engaging in other activities while eating. The desire to eat is controlled by limiting exposure to events that precipitate eating. Thus pharmacotherapy and behavior therapy would appear to induce weight loss by different but potentially complementary mechanisms. Combining these two approaches could be expected to induce larger weight losses than either intervention used alone.

This belief is supported by the results of a study by Craighead, Stunkard, and O'Brien (1981). Patients who were treated weekly for 26 weeks by group behavior modification alone (i.e., without medication) lost an average of 10.9 kg (about 11% of initial weight). Those treated by pharmacotherapy alone (120 mg/day of fenfluramine), in brief monthly office visits, lost a significantly smaller 6.0 kg (about 7%). The combination of medication plus weekly group behavior modification resulted in a mean weight loss of 15.3 kg (about 16%). Thus medication and behavior therapy appeared to have additive effects.

The withdrawal from the market of fenfluramine and dexfenfluramine, because of their association with valvular heart disease, obviously limits the clinical significance of these findings (Connolly et al., 1997). A recent study, however, of sibutramine and behavior modification (the latter therapy is now often referred to as "lifestyle modification") yielded similar findings (Wadden et al., 2001). A total of 53 obese women were randomly assigned to one of three conditions, all of which received 1 year of treatment. Those in the

first group (i.e., drug-alone condition) were prescribed 15 mg/day of sibutramine and were instructed to consume 1,200 kcal/day and to exercise four to five times a week for 30 minutes per bout. Patients had 10 brief physician visits during the year to check their blood pressure and any side effects; however, they received no formal instruction in modifying their eating or activity habits. Patients in a second group (i.e., drug plus lifestyle) also received 15 mg/day of sibutramine and the same diet and exercise prescription. These participants, however, also attended weekly group sessions during the first 5 months at which they were instructed in behavioral methods of weight control, including keeping daily records of their food intake and physical activity. Sessions were led by psychologists, who followed *The LEARN Program for Weight Control* (Brownell & Wadden, 1998). Participants attended monthly meetings from months 5 to 12. Participants in the third group (i.e., combined treatment) received the same program, except during the first 4 months, they consumed 1,000 kcal/day of a portion-controlled diet. This consisted of four servings/day of a liquid diet (OPTIFAST 800), combined with an evening meal of a frozen food entree and a vegetable and a fruit serving. This diet was included to induce a larger initial weight loss, given previous findings that obese women were disappointed by modest weight losses (Foster, Wadden, Vogt, & Brewer, 1997).

Figure 11.2 shows that the addition of group lifestyle modification to sibutramine increased weight loss almost threefold. Patients who received the drug alone lost 4.1% of initial weight at the end of the year, compared with a loss of 10.8% for those who received the drug plus lifestyle modification. Women who received the drug plus the portion-controlled diet (i.e., combined treatment) lost 16.5% of initial weight—an outcome similar to that re-

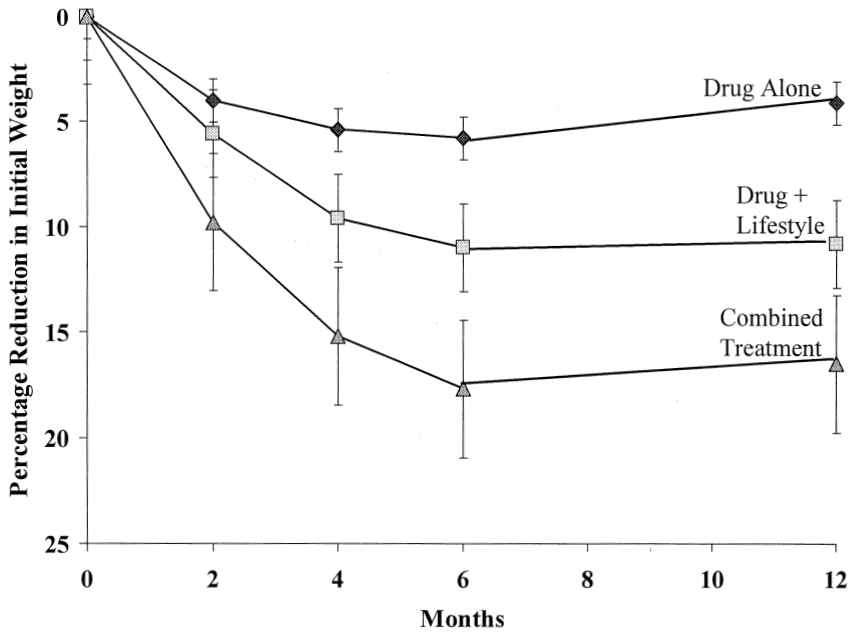

FIGURE 11.2. Percentage reduction in initial weight for women treated by sibutramine alone (i.e., drug alone) (n = 19), sibutramine plus group lifestyle modification (i.e., drug plus lifestyle) (n = 17), or sibutramine plus group lifestyle modification combined with a portion-controlled diet providing 1,000 kcal/day (i.e., combined treatment) (n = 17). From Wadden, Berkowitz, Sarwer, Prus-Wisniewski, and Steinberg (2001). Copyright 2001 by the American Medical Association. Reprinted by permission.

ported in a sibutramine trial that included a 1-month VLCD (Apfelbaum et al., 1999). These results show that although sibutramine alone (as typically prescribed in primary care practice) will induce weight loss, substantially better results are likely to be achieved by combining the medication with a patient's own efforts to modify eating and activity habits. Weight loss medications may facilitate the consumption of a healthier diet, but should not be considered a substitute for the patient's own efforts in this regard. A key challenge is to find effective ways of providing lifestyle modification during primary care visits (Wadden et al., 1997). Physicians who do not believe that they have the time or expertise to provide such counseling may wish to prescribe medication but refer patients to a dietitian or self-help program to obtain the lifestyle modification.

Combining pharmacotherapy with a group program of lifestyle modification required more time and effort of patients. However, the greater weight loss significantly improved patients' satisfaction with their treatment outcomes, including satisfaction with changes in their health and fitness, self-esteem, and body image. Satisfaction with all outcomes, including that with the medication, was positively related to patients' meeting their weight loss expectations. Prior to treatment, the women reported the number of pounds they expected to lose after 1, 3, 6, and 12 months of treatment. Patients, on average, expected at 1 year to lose the equivalent of 25% of their initial weight—a loss that eluded even patients who received combined treatment. However, the greater the percentage of their expected weight loss patients achieved, the greater their satisfaction with changes in their weight, health and fitness, body image, and related outcomes. (Correlations ranged from r = .62 to .72.)

Facilitating Medication Adherence

In addition to improving patients' eating and exercise habits, behavioral principles may be used to facilitate adherence to weight loss medications. This is an important issue, given findings, for example, that as many as half of persons prescribed antihypertensive agents do not achieve optimal control of blood pressure because of inadequate medication adherence (Dunbar & Stunkard, 1979). When prescribing weight loss agents, practitioners may wish to review several issues with patients. These include:

1. Explaining the mechanisms by which the weight loss medication works. This includes describing what the medication will do (i.e., increase satiety or block fat absorption), as well as what the patient should do (i.e., decrease exposure to food triggers, record food intake, etc.).
2. Describing the medication's possible side effects and how the patient should respond to them. This includes having the patient call the practitioner before he or she stops taking the medication.
3. Inquiring whether the patient or the patient's family members have any health concerns about the use of medications (particularly in view of the adverse effects of the fenfluramines) or about costs of medications (which are not covered by most insurance plans).
4. Describing the course of treatment (at least for the first year), outlining medication use and the frequency of office visits, and discussing behavioral goals of treatment.
5. Developing a medication schedule that identifies when and where patients will take their medication and what they should do in the event of missed doses. The more concrete the schedule, the better patients' adherence.
6. Having patients keep a daily medication log, at least during the first few months. This log should be reviewed at subsequent office visits.
7. Reviewing how much weight patients can realistically expect to lose during the first

6 months of treatment, and helping them define success in terms of non-weight-related outcomes. These might include improvements in health complications, increased fitness and mobility, or the ability to enjoy recreational or social activities that the individual has forgone because of excess weight (Wadden et al., 2001).

Long-Term Medication Use

Practitioners will also need to prepare patients for the slowdown in weight loss that typically occurs between the fourth and sixth months, after which most individuals stop losing weight altogether, despite remaining on medication. As shown in Figure 11.3, obese women treated by Wadden and colleagues (2001) expected to continue to lose weight from months 6 to 12. They were totally unprepared for the weight loss plateau that occurred at month 6, which is illustrated in Figure 11.2. Practitioners should inform patients that the weight loss plateau is to be expected (although it is not easily explained), and that medications work after the first 6 months to maintain the weight loss that has been achieved. This last point is critical, because most patients interpret the lack of continued weight loss as a sign that the medication is no longer working, and this leads them to discontinue therapy.

Discontinuing medication usually results in rapid regaining of lost weight, which paradoxically illustrates how well the medication was working to maintain weight loss. This finding was observed in a recent study, in which 24 patients who had completed 68 weeks of treatment with sibutramine were encouraged by their physician to remain on the medication indefinitely to facilitate weight maintenance (Womble, Wadden, Berkowitz, Sarwer, & Rothman, in press). As shown in Figure 11.4, the five women who remained on medication

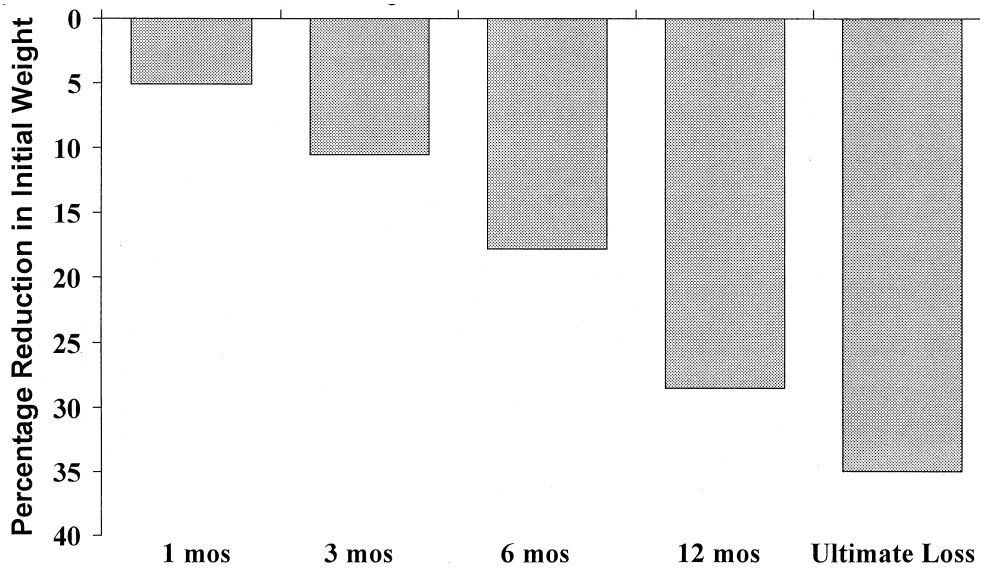

FIGURE 11.3. Patients' expected reduction in initial weight after 1, 3, 6, and 12 months of treatment. Prior to treatment, participants reported the cumulative number of pounds they expected to lose by each period. These values were converted to percentage reduction in initial weight. "Ultimate loss" reflects the weight loss patients hoped ultimately to achieve, even if not during the 12-month study. From Wadden, Berkowitz, Sarwer, Prus-Wisniewski, and Steinberg (2001). Copyright 2001 by the American Medical Association. Reprinted by permission.

at the 104-week assessment maintained their full end-of-treatment weight loss, whereas those who discontinued medication at week 68 or shortly thereafter regained about 6 kg from week 68 to week 104.

In order to be used on a long-term basis, weight loss medications must be both safe and effective. Orlistat and sibutramine both appear to be effective, as judged by 2-year placebo-controlled trials (Davidson et al., 1999; James et al., 2000; Sjöström et al., 1998). Both also appear to be generally safe, although sibutramine is associated in some patients with significant increases in blood pressure and pulse, and thus must be monitored closely (Hansen, Tourbo, Stock, Macdonald, & Astrup, 1999; Wadden et al., 2001). Studies are now needed to determine the best schedule for maintaining patients on medication over the long term in order to maintain their weight losses over the long term. For example, it may be possible to limit medication use to every other month, as shown with phentermine (Munro, MacCuish, Wilson, & Duncan, 1968) or to prescribe medication primarily during high-risk periods for weight gain, such as during the winter holidays. Regardless of whether we consider current medications or those yet to be discovered, they will have to be used on a long-term basis in the same fashion as agents for other chronic disorders, including hypertension, hyperlipidemia, and diabetes.

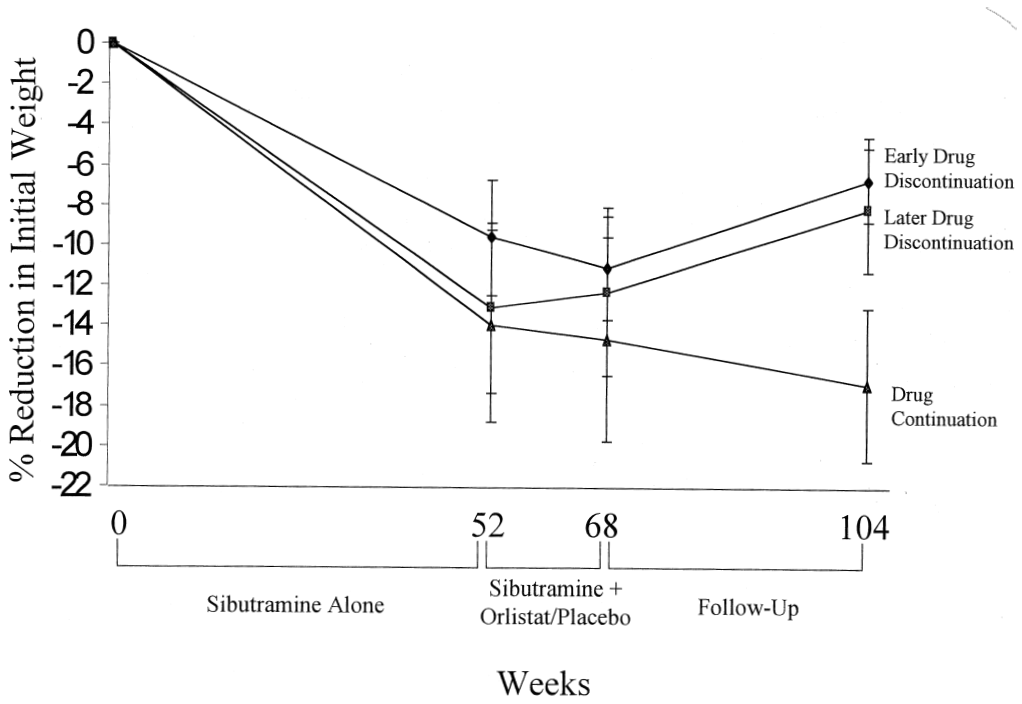

FIGURE 11.4. Change in body weight over 2 years in patients who discontinued sibutramine at week 68 (i.e., early drug discontinuation) (n = 13), who discontinued medication between weeks 68 and 104 (i.e., later drug discontinuation) (n = 6), and who continued medication until week 104 (i.e., drug continuation) (n = 6). During weeks 0–52, all participants received sibutramine. During weeks 52–68, all patients received sibutramine, while half were randomly assigned to orlistat and half to placebo. At the study's conclusion (week 68), all patients were encouraged to continue taking sibutramine to facilitate the maintenance of weight loss. Data from Womble, Wadden, Berkowitz, Sarwer, and Rothman (in press).

TREATMENT OPTIONS: BMI ≥ 40 kg/m^2

Persons with a BMI ≥ 40 kg/m^2 deserve special attention from health care providers. This is because extremely obese individuals typically experience more serious health complications, as well as more adverse psychosocial consequences, than do persons with lesser degrees of excess weight. The physical and psychosocial complications of extreme obesity are discussed in this volume by Field, Barnoya, and Colditz (Chapter 1), Latifi, Kellum, De Maria, and Sugerman (Chapter 16), and Wadden, Womble, Stunkard, and Anderson (Chapter 8). Practitioners must ensure that these individuals receive the medical care that they need, independent of their need for weight reduction.

Latifi and colleagues (Chapter 16) have described surgical interventions for the management of obesity, including vertical banded gastroplasty, gastric bypass, and gastric banding procedures. The gastric bypass would appear to be the treatment of choice for extremely obese individuals, given that the procedure induces an average loss of 25%–30% of initial weight and is associated with excellent long-term weight loss and improvements in comorbid conditions (Albrecht & Pories, 1999; Latifi et al., Chapter 16). Patients, however, must be fully informed of the risks of the procedures, which include an operative mortality rate of approximately 0.5%–1.0%. In addition, surgical candidates must understand that the gastric bypass will radically change their eating, in terms of reducing the amounts and types of foods that they can consume (particularly sweets and meats). At our program at the University of Pennsylvania, all candidates are screened not only by a surgeon and specialist in internal medicine, but also by a behavioral psychologist and dietitian. The latter two staff members describe the eating and activity habits that must be adopted after surgery; they assess the patients' readiness to make these changes (Wadden, Sarwer, et al., 2001).

Our opinion of bariatric surgery has changed dramatically over the past 20 years, from thinking that it bordered on the barbaric to now believing that the approach is underutilized. Bariatric surgery should be considered with all individuals who have serious obesity-related health complications and a BMI > 35 kg/m^2 (or a BMI > 40 kg/m^2 in the absence of major health complications). Candidates should have tried to lose weight using the safer, more traditional options of diet, exercise, and weight loss medication. Those, however, with a marked history of weight cycling (i.e., lost and regained a total of 50 kg or more) should consider bariatric surgery before embarking on another weight loss effort with traditional therapy.

IMPROVING THE MAINTENANCE OF WEIGHT LOSS

Bariatric surgery receives high marks because it is associated with excellent maintenance of weight loss for up to 15 years after surgery (Albrecht & Pories, 1999; Latifi et al., Chapter 16, this volume). By contrast, weight regain remains the Achilles's heel of both behavioral and pharmacological interventions. Remarkably little is known about the specific physiological and behavioral factors that contribute to weight regain, despite the reliability with which this occurrence is observed. By contrast, factors associated with the maintenance of weight loss are well known and include high levels of physical activity; consumption of a low-calorie, low-fat diet; regular monitoring of weight and food intake; and the use of positive coping strategies in response to lapses in diet and exercise adherence (Jeffery, Wing, Thorson, & Burton, 1998; Klem, Wing, McGuire, Seagle, & Hill, 1997; Wadden, 1995).

In this volume, Perri and Corsica (Chapter 17), as well as Wing (Chapter 14), discuss methods of facilitating patients' long-term adherence to these critical behaviors. Cooper and Fairburn (Chapter 22) propose a cognitive model that attributes weight regain in part to patients' negative body image. Obese individuals who are dissatisfied with their weight

and shape are unable to accept the modest 10% weight loss that behavioral and pharmacological therapies typically produce. Their frustration and disappointment ultimately lead them to abandon efforts needed to maintain the modest weight losses they have achieved. Several of the therapeutic interventions proposed by Cooper and Fairburn (Chapter 22) are used in nondieting approaches to weight management, as discussed by Foster and McGuckin (Chapter 24).

LOOKING AHEAD

This chapter has been written with the knowledge that the interventions described are likely to benefit the individuals who receive them but are inadequate to solve our nation's growing epidemic of obesity. This is because weight reduction therapy is currently available only to a minority of obese individuals, typically those who can pay out of pocket. Even with these persons, earnest efforts to modify eating and activity habits usually are no match in the long term for a toxic environment that explicitly encourages the consumption of large portions of high-fat, high-sugar foods and implicitly discourages physical activity, as a result of fundamental changes in the nation's work and leisure habits. Clearly, efforts are needed to improve the treatment of obesity, as well as to obtain recognition and reimbursement of this disorder. But far greater attention now must be devoted to the prevention of obesity, as described in this volume by Horgen and Brownell (Chapter 5) and Schmitz and Jeffery (Chapter 27), and to the treatment of childhood obesity, as discussed by Goldfield, Raynor, and Epstein (Chapter 26). Such efforts must attack the environment that lies at the heart of this disorder. This will require investigators and practitioners to work not only in the laboratory and consulting room but also in schools, workplaces, and other community settings. Those interested in the treatment of obesity must realize that the objects of their care are not only the individuals who present to them for treatment, but also the larger social and economic forces that shape our nation's eating and activity habits.

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