WEIGHT-LOSS DRUGS

HISTORY/EXISTING CONDITION:

The term "weight-loss drug" within this policy refers to any over-the-counter medication or prescription drug used for weight loss, whether or not it is designated as such by the manufacturer. Weight-loss drugs include benzene derivatives, laxatives, herbal preparations, amphetamines, appetite suppressants, serotonin reuptake inhibitors, neuropeptide-y inhibitors, hormones, beta-3 adrenergic receptor stimulants, and any others in the research and development phase. Weight-loss drugs have long been promoted as an effective treatment for "obesity," even though they very rarely produce long-lasting weight loss or improved health status, and often have serious side effects.

In 1893, thyroid extract was marketed under the brand names Frank J. Kellogg's Safe Fat Reducer, Corpulin, and Marmola. The weight loss it produced was mostly in lean tissue, and thyroid extract carried the risks of osteoporosis, increased heart rate, palpitations, sweating, chest pain, and sudden death. Laxatives for weight loss began being used extensively in the 1920s, and in 1936, dinitrophenol, a benzene-derived ingredient in World War I explosives, insecticides, and herbicides was used by 100,000 people. By increasing metabolic rate, dinitrophenol caused users to suffer skin rashes, cataract blindness, lost sense of taste, and death by hyperpyremia (fever due to increased metabolism).

In 1940, digitalis was used for weight loss. The use of amphetamines for weight loss was introduced in 1937, and by 1948, the drug was prescribed to two-thirds of weight-loss patients. In 1970, dieters consumed two billion amphetamine pills. They were prescribed to children until the late 1970s. The risks of amphetamines include accelerated heart rate, increased blood pressure, heart palpitations, dry mouth, blurred vision, hallucinations, psychiatric disorders (including paranoid psychosis), light-headedness, tremors, addiction, withdrawal problems, congestive heart failure, seizures, and sudden death.

Phenylpropanolamine (PPA), marketed as Dexatrim, Accutrim, Dex-a-Diet, Diadex, Prolamine, Propagest, and Unitrol became available over the counter in 1979. Poison Control Centers reported 47,000 complaints related to PPA use in 1989 alone. The risks of PPA include anxiety, disorientation, palpitations, headache, hallucinations, insomnia, nausea, vomiting, a rebound effect of fatigue and hyperphagia, dangerously high blood pressure, abnormal heart rhythm, heart and kidney damage, heart attack, strokes, psychosis, and death.

Approved by the Food and Drug Administration (FDA) in the 1970s for use individually, fenfluramine and phentermine (also known as fen-phen) became widely prescribed in combination in 1994 as a result of a single research study. By 1996, 18 million prescriptions were written for this off-label use of the drugs. Dexfenfluramine, marketed under the trade name Redux, was approved by the FDA in 1996. According to studies on file at the NAAFA
office, the risks of these three drugs include primary pulmonary hypertension, valvular heart disease, and neurotoxicity. Under fire from NAAFA and other consumer advocates and following studies which indicated that one-third of users of dexfenfluramine and fenfluramine had contracted valvular heart disease, the FDA strongly recommended halting the sale of these drugs, and drug companies withdrew dexfenfluramine and fenfluramine from the U.S. market in September, 1997.

After discontinuing the sale of fenfluramine and dexfenfluramine, some weight-loss centers and physicians immediately began prescribing ephedrine-based "herbal fen/phen," and distributing the combination of phentermine and Prozac, an SSRI anti-depressant (also known as fen-Pro).

Historically, weight-loss drugs have been subjected to very little testing; almost no long-term studies have been produced. Research indicates that risks of drugs such as fenfluramine, phentermine, and dexfenfluramine increase dramatically the longer the drugs are used. In addition, the drugs produce minimal weight loss, and upon discontinuing the use of any of the drugs, the weight is virtually always regained. For example, amphetamines produce an average loss of 10-20 pounds before the drug loses effectiveness, and dexfenfluramine produces an average of six pounds of weight loss when compared to a placebo. Further, anecdotal evidence suggests that consumers eager to speed weight loss frequently take multiple, more dangerous doses of weight-loss drugs. Vulnerable consumers have also been misled and harmed by unregulated herbal, so-called "natural," weight-loss drugs.

Despite the lack of effectiveness and the risks associated with every past weight-loss drug, over 50 new weight-loss drugs are currently up for approval, or are in the research and development stage. Xenical, which blocks intestinal enzymes from absorbing 30% of dietary fat, may be approved, and sibutramine, which slows dissipation of serotonin in the brain, was recently approved. A drug to regulate leptin, a satiety hormone secreted by fat tissue, is being developed. In addition, a drug to decrease appetite by blocking neuropeptide-Y and a drug to regulate metabolism by stimulating beta-3 adrenergic receptors are being researched.

Diet companies, obesity researchers and drug manufacturers continue to tout weight-loss drugs as a viable and desirable path to weight loss. Promoting and manufacturing weight-loss drugs is profitable, as evidenced by the over 300 million dollars consumers spent on dexfenfluramine alone in 1996. As long as fatness is stereotyped and derided, and as long as discrimination against fat people exists, consumers will continue to seek a "magic pill," and there will be a market for weight-loss drugs.

Weight-loss drug promoters emphasize the drugs' supposed health benefits and minimize risks related to taking the drugs, so that consumers cannot truly give informed consent prior to taking the drugs. People of all sizes are misled about the extent and severity of the health risks associated with being fat and are told that losing weight is the only way to attain good health. But scientific research on file at the NAAFA office has demonstrated that many fat people are already healthy, and that a person's health status can be improved independent of weight loss.
by making positive lifestyle changes in exercise, stress management, healthy eating, and positive social support.

Currently, the agency responsible for regulating weight-loss drugs, the Food and Drug Administration, appears to bow to pressure from drug companies to approve weight-loss drugs without requiring sufficient long-term testing, and has not demonstrated a commitment to guard the public's health.

**NAAFA'S OFFICIAL POSITION:**

Since weight-loss drugs fail to achieve permanent weight loss and can result in negative health consequences, since the governmental agency responsible for regulating weight-loss drugs has not protected consumers from dangerous weight-loss drugs, and since people taking diet drugs are rarely given sufficient information to allow them to give true informed consent, the National Association to Advance Fat Acceptance strongly discourages people of any size from taking drugs for the purpose of weight loss. Further, NAAFA condemns obesity researchers and drug manufacturers who profit from inadequately tested weight-loss drugs. In addition, because many consumers' motivation for weight loss is to escape size discrimination and weight-related social stigma and such motivation necessitates a political rather than medical response, and because health status can be improved independent of weight loss, NAAFA demands that the Food and Drug Administration denies approval of any weight-loss drug presented for approval that does not show clear health benefits apart from temporary weight loss.

**NAAFA ADVOCATES:**

That local, state, and federal legislatures introduce, pass, enact, and enforce legislation which protects consumers against dangerous or ineffective weight-loss drugs, whether prescription, over-the-counter, "all natural," or "herbal."

That state and federal regulatory agencies, such as the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC), adopt regulations to prevent endangerment to public health from weight-loss drugs, whether prescription, over-the-counter, "all natural," or "herbal."

That state and federal regulatory agencies, such as the FDA, pose the same question for weight loss drugs as for any other class of drug, i.e., "Does this treatment improve health?"

That federal regulations require all weight-loss drugs, whether prescription, over-the-counter, "all natural," or "herbal," to clearly display a health warning (similar to those found on cigarettes) regarding limited temporary results and possible hazards and side effects.

That financial ties between obesity researchers/diet drug advocates and diet drug manufacturers be disclosed in all regulatory hearings and published writing regarding the drugs.
That regulations be adopted that require drug manufacturers to publish five-year (minimum) follow-up studies and "success" rates. Information on all such statistics must be verifiable by objective outside researchers and clearly displayed on all weight-loss drugs and advertising.

That the Centers for Disease Control track morbidity and mortality caused by weight-loss drugs and weight regain when drugs are discontinued, and publicize the findings.

That researchers conducting epidemiological studies be required to obtain information on diet pill use by their subjects.

That the National Institutes of Health (NIH) and the FDA include input from consumer advocacy groups in establishing public health policy about weight-loss drugs.

That the NIH support independent research on the health effects of weight-loss drugs.

That local and state medical boards adopt policies against the use of weight-loss drugs.

That insurance companies and government programs deny payment for weight-loss drugs.

That consumer protection agencies, such as Consumers Union, conduct biannual studies on the efficacy of weight-loss drugs.

That advertising of weight loss drugs, whether prescription, over-the-counter, "all natural," or "herbal," be prohibited.

That institutions such as the military, hospitals, schools, mental institutions, or prisons provide adequate food and not force anyone to take weight-loss drugs.

That employers, schools, and judges never demand the use of weight-loss drugs as a condition for employment, promotion, admission, or avoiding incarceration.

That health care professionals and medical institutions never deny any medical treatment to patients who choose not to take weight-loss drugs.

That individuals considering taking weight-loss drugs study available literature on long-term results and side effects and carefully weigh the possible benefits against the risks of drug use.

That individuals considering taking non-prescription or "herbal" weight-loss drugs be aware that they are not safe or effective despite being non-prescription, "all natural," or "herbal."

NAAFA RESOLVES TO:

Advocate for the safety and emotional and physical well-being of consumers by attempting to influence public policy about weight-loss drugs.
Educate the public, the media, and potential weight-loss-drug users as to the low long-term success rates and possible negative health consequences of weight-loss drugs.

Promote alternatives to weight-loss drugs in a manner which is sensitive to the emotional and financial investment which many fat people have made in repeated weight loss attempts.

Create a Diet Drug Registry for people who have suffered negative health consequences as a result of taking weight-loss drugs.

Seek a "superfund" from drug manufacturers to pay for medical testing and treatment for those suffering negative health consequences as a result of taking weight-loss drugs.

Provide advice and emotional support to individuals who have suffered negative health consequences from taking weight-loss drugs.

Alert consumers to weight-loss drugs which have been determined to be dangerous, have lawsuits pending against them, or are being investigated by government agencies.

Assist plaintiffs and/or their attorneys engaged in litigation involving weight-loss drugs, by providing them with referrals to expert witnesses who might testify on their behalf.

Research documentation available through the NAAFA office