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## An Epidemic of Obesity Myths

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Consumer Freedom

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The Center for Consumer Freedom is a nonprofit coalition supported by restaurants, food companies, and consumers, working together to promote personal responsibility and protect consumer choices.

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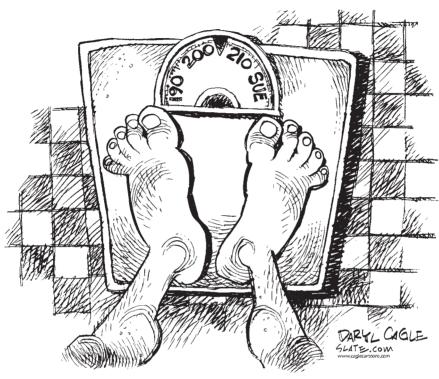
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## **An Epidemic of Obesity Myths**

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—Daryl Cagle

#### Introduction

t's been called as dangerous as terrorism and compared to the Black Death and a massive SARS outbreak. But what is the truth about obesity?

Overblown rhetoric about the "obesity epidemic" has itself reached epidemic proportions, sending the public and the media into a frenzy over the nation's waistline. Policy makers have responded with knee-jerk solutions, such as zoning restrictions on restaurants and convenience stores and taxes and warning labels on certain foods. Meanwhile, trial lawyers are strategizing to bring large-scale lawsuits against restaurants and food companies.

Activists, politicians, bureaucrats, and lawyers rely on commonly repeated obesity statistics for their shock value. These figures include:

- 400,000 Americans die every year as a result of obesity.
- 65 percent of the country is overweight or obese.
- Obesity costs Americans \$117 billion a year.

In this report, the Center for Consumer Freedom (CCF)—a nonprofit coalition supported by restaurants, food companies, and consumers working together to promote personal responsibility and protect consumer choice—exposes the major flaws and exaggerations in the obesity statistics and research repeated time and again.

While extreme obesity remains a genuine health risk, this report documents the extent to which many researchers and academics are actively questioning obesity hype. Relying on peer-reviewed publications and esteemed health experts, it outlines the scientific evidence rebutting obesity hysteria.

The 2004 edition of this report exposed many flaws in the widely publicized conclusion from the Centers for Disease Control and Prevention (CDC) that excess weight kills 400,000 Americans a year. After months of intense pressure from CCF and top-notch reporting from *Science* magazine and *The Wall Street Journal*, the CDC admitted serious errors in its conclusion. In April 2005 a vastly superior study concluded that excess weight results in fewer than 26,000 deaths annually.

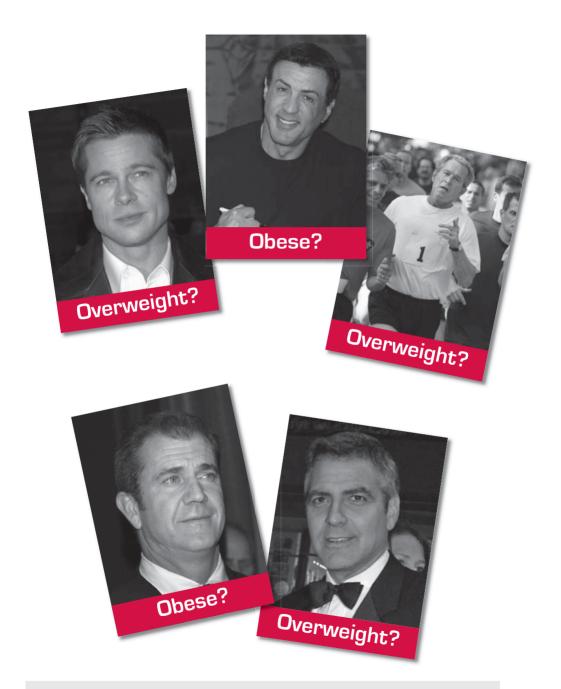
Critical media analysis and editorials from dozens of national newspapers followed. *The Baltimore Sun* called the CDC's 400,000-deaths statistic "The Chicken Little scare of 2004." *Scientific American* published a damning article titled "Obesity: An Overblown Epidemic?" It reported that "a growing number of dissenting researchers accuse government and medical authorities—as well as media—of misleading the public about the health consequences of rising body weights."

The latest edition of *An Epidemic of Obesity Myths* provides a timeline of the unraveling of the CDC's inflated 400,000-deaths statistic. It also brings new evidence to bear against many other obesity myths.

This report also details how the \$46 billion weight-loss industry is helping to generate obesity hysteria to justify government insurance coverage for obesity drugs and treatments. The pharmaceutical industry in particular is putting its enormous resources behind research that grossly exaggerates the health risks and costs of being overweight, as well as its prevalence. Once they convince us of the "problem," drug manufacturers will peddle the (lucra-

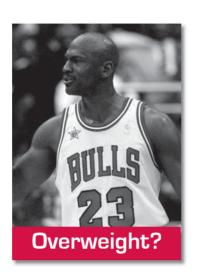
tive) "cure." An April 2005 article in *The New York Times* quoted Donna Ryan, an obesity researcher affiliated with Louisiana State University, saying: "Everybody is just foaming at the mouth to make money from obesity drugs."

This report is by no means intended to dismiss the genuine health risks of obesity for the heaviest individuals. Nonetheless, the public has been force-fed many obesity myths by agenda-driven special interests. Their success would invite regulation, legislation, and litigation—which can drive up the cost of food for consumers and limit selection. This report is intended to provide policymakers, the media, and the public with an easy-to-understand resource about the issue—before they fall prey to one of the greatest tall tales ever told.



According to the federal government's standards for "overweight" and "obese," all these celebrities and millions of other Americans are officially fat despite being perfectly healthy.

# Myth: 65 Percent of Americans Are Overweight or Obese





Thirty-five million Americans went to sleep one night in 1998 at a government-approved weight and woke up "overweight" the next morning, thanks to a change in the government's definition.

The federal government defines "overweight" and "obese" using the body mass index (BMI), a simple calculation based only on height and weight. "Normal" weight is defined as a BMI between 18.5 and 24.9. "Overweight" is defined as a BMI between 25 and 29.9. "Obese" is a BMI of 30 or higher.

Are these classifications meaningful? According to the government standard, Tom Cruise, Sylvester Stallone, and Mel Gibson are technically obese. So are sluggers Sammy Sosa and Barry Bonds, boxer Mike Tyson, quarterback Donovan McNabb, and wrestling superstar The Rock. And if politics

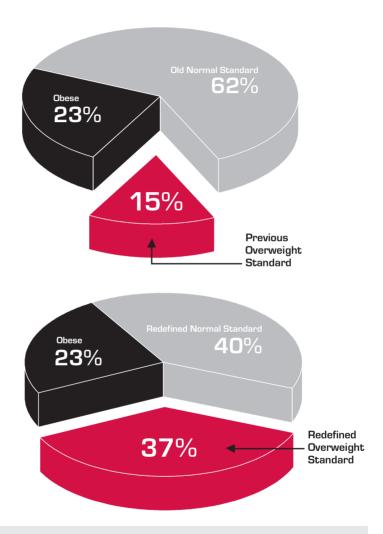
is your thing, it turns out that California Governor Arnold Schwarzenegger—a bodybuilding legend—is obese, too.

It's not just the official category of obesity that has been affected by numerical hocus-pocus. Thirty-five million Americans went to sleep one night in 1998 at a government-approved weight and woke up "overweight" the next morning, thanks to a change in the government's definition. That group includes currently "overweight" celebrities like Will Smith and Pierce Brosnan, as well as NBA stars Kobe Bryant and LeBron James. It even includes George W. Bush, considered the most fit president in U.S. history. "Overweight" had previously been defined as a BMI of 27.8 for men and 27.3 for women; in 1998 it was lowered to a BMI of 25 for both genders.

The 1998 redefinition prompted a group of researchers to criticize the new threshold in *The American Journal of Public Health*. They wrote:

"Current interpretations of the revised guidelines stigmatize too many people as overweight, fail to account for sex, race/ethnicity, age, and other differences; and ignore the serious health risks associated with low weight and efforts to maintain an unrealistically lean body mass ... This seeming rush to lower the standard for overweight to such a level that 55% of American adults find themselves being declared overweight or obese raises serious concerns."<sup>2</sup>

A research letter published in *JAMA* (the journal of the American Medical Association) reported that 97 percent of players in the National Football League are technically



By redefining the definition of "overweight" the federal government made more than 35 million Americans overweight—more than doubling the size of the category. In 2004, the redefinition counts an additional 22% of Americans as officially fat.

overweight and more than 50 percent are obese.<sup>3</sup> The NFL responded by calling the BMI "bogus," since it "doesn't consider body muscle versus fat."<sup>4</sup>

"Before calling it an epidemic, people really need to understand what the numbers do and don't say."<sup>5</sup>

> Rockefeller University professor Jeffrey Friedman in *The New York Times*, 2004

#### The CDC's Website on the Body Mass Index

"Overweight may or may not be due to increases in body fat. It may also be due to an increase in lean muscle. For example, professional athletes may be very lean and muscular, with very little body fat, yet they may weigh more than others of the same height. While they may qualify as 'overweight' due to their large muscle mass, they are not necessarily 'over fat,' regardless of BMI."

"Adults who are overweight do not necessarily have an excess of body fat."



6'3"	Height	6'3"
220 lbs	Weight	220 lbs
27.5	BMI	27.5



-CDC web site, 2005



"Fat's Overlap; Many of the experts who decide you need to shed pounds work for the industry that profits from their declarations"

#### Who Made Millions Fat Overnight? Xavier Pi-Sunver

In 1997 a front-page exposé in the Newark Star-Ledger noted:

"Eight of the nine members of the National Institutes of Health task force on prevention and treatment of obesity have ties to the weight-loss industry, either as consultants to pharmaceutical companies. recipients of research money from them, or advisers to for-profit groups such as Weight Watchers."8

Case Western Reserve University professor Paul Ernsberger describes how financially conflicted researchers control the government's pronouncements on obesity:

"Medical beliefs about obesity are shaped by expert panels that are highly selective in the data they consider. Experts included on government consensus panels have been disproportionately drawn from the ranks of diet clinic directors, which might explain the congruence between panel recommendations and the economic interests of the diet industry. In short, economic factors encourage a systematic exaggeration of the health risks of obesity."9

Many of America's most influential obesity experts receive significant financial support from the \$46 billion weight-loss industry. 10 These experts help drive obesity hype by churning out a steady stream of studies, alarmist public pronouncements, and treatment guidelines.

The notion that 65 percent of Americans are overweight or obese derives in part from a 1998 decision to redefine "overweight," which cast more than 35 million Americans into that category. This decision was made by a National Institutes of Health obesity panel chaired by Xavier PiSunyer, one of the most influential obesity researchers in the country.

Over the years, Pi-Sunyer has received support from virtually every leading weight-loss company, including Novartis, Sanofi-Aventis, Ortho-McNeil, Wyeth-Ayerst, Knoll, Weight Watchers, and Roche.<sup>12, 13, 14</sup> He has served on the advisory boards of Wyeth-Ayerst, Knoll, <sup>15</sup> Abbott, Johnson & Johnson, and McNeil Nutritionals.<sup>16</sup> He once headed up the Weight Watchers Foundation, and is currently a board member of that organization.<sup>17</sup> Pi-Sunyer gave the "obesity overview" presentation on behalf of Knoll, maker of the weight-loss drug Meridia, at a 1996 FDA advisory panel hearing on the drug.<sup>18</sup> He has also been paid to sign his name to ghost-written journal articles used to promote the dangerous weight-loss combination known as "fen-phen."<sup>19</sup>

Xavier Pi-Sunyer is an advisory council member of the American Obesity Association, which is best described as the lobbying arm of the weight-loss industry and is examined in greater detail later in this report. He is the former president of the pharmaceutical industry-funded North American Association for the Study of Obesity (NAASO is also examined later in this report) and heads a NAASO-affiliated research institute that

is also supported by the weight-loss industry. He has influenced international obesity policy through his membership in the pharmaceutical industry–funded International Obesity Task Force,<sup>20</sup> which plays a key role in determining policy for the World Health Organization.

Pi-Sunyer has chaired the National Institutes of Health Task Force on the Treatment of Obesity since 1995, when he also led the industry-funded NAASO. In 1998, when his NIH panel redefined the official standard for "overweight," he served as editor of NAASO's journal, *Obesity Research*.<sup>21</sup>

In addition to Pi-Sunyer, the 1998 NIH panel included a number of other financially conflicted researchers, such as Claude Bouchard, Graham Colditz, and Shiriki Kumanyika, each of whom is profiled later in this report.<sup>22</sup>

The decision to redefine "overweight" was a big boost to the diet drug industry. In April 2005 *The New York Times* reported: "[M]any drug industry analysts see a potentially even bigger market if such a drug also catches on among the more than 60 percent of adults in this country who are statistically overweight, those with a body mass index of 25 or more."<sup>23</sup>

The weight-loss industry appears to appreciate the flawed BMI standard. In 2001, Roche, maker of the weight-loss pill Xenical, promised a donation to NAASO

for every individual screened during "BMI Awareness Week."<sup>24</sup> In 2005, the American Cancer Society ran an event called the "Great American Weigh In" at Weight Watchers.<sup>25</sup>

#### **Experts Criticize the Body Mass Index**

Obesity experts warn that the BMI standard suffers from a number of serious limitations in measuring the percentage of body fat—a generally recognized standard for judging *true* obesity.

"When a standard such as BMI is used, its limitations must also be presented. In particular, equating the terms *increased BMI* and *obese* can be quite misleading, since excess body mass calculated solely from height and weight may be due only to excess fat, only to excess [lean body mass], or to any combination of the two."<sup>26</sup>

—Letter in JAMA, June 2005

"The BMI doesn't give a precise readout. It can be horrible as an individual gauge."<sup>27</sup>

—Cleveland Clinic Foundation Chief Academic Officer and Case Western Reserve University Department of Cardiovascular Medicine Chairman Dr. Eric Topol

"BMI does have numerous limitations that we professionals have chosen to ignore, or at least to tolerate. We have done this on the grounds that its advantages have outweighed its disadvantages. Any expression of doubt over the validity of the key obesity indicator would have undermined the message at a time when politicians and the general public needed to hear a clarion call

for action. This herd loyalty to a pragmatic indicator was challenged for the first time by the devotees of waist-hip ratio (WHR) and then by the promoters of waist circumference."<sup>28</sup>

-Obesity Reviews, 2001

"There is increasing evidence that these [BMI] cut-off values are not valid for all populations ... If obesity were defined as BF% [body fat percentage] greater than 25% in males and greater than 35% in females, 7% of the females and 8% of the males would be falsely classified as obese with the BMI-based formula."<sup>29</sup>

-European Journal of Clinical Nutrition, 2001

"Our results indicate that a single BMI standard should not be used: rather, a standard should be developed for each population. This conclusion is in agreement with work by other researchers, who also found BMI inconsistencies between groups."<sup>30</sup>

—International Journal of Obesity and Related Metabolic Disorders, 1998

#### **BMI Report Cards**

As of June 2005, legislators in 12 states have proposed putting students' BMI on their report cards.<sup>31</sup> Arkansas and Pennsylvania have already adopted such a measure. In addition to all the problems associated with the BMI, many studies have found that it is a particularly poor measure of body composition in children.

"...the validity of BMI as a measure of adiposity [excess fat] in children has not been established. There are well-known limitations regarding the use of BMI. For example, BMI

is generally defined in adults as an index of adiposity that is largely independent of stature; however, this property of BMI in adults does not necessarily hold true in children ... In addition, validity studies using BMI to identify children with excess adiposity have generally documented low to moderate sensitivities, which indicate only a poor to fair identification of those who are truly overweight, as determined from %BF ... Health care professionals should, therefore, note that children and younger adolescents, particularly boys, who are tall for their ages may have large BMI values as a consequence of stature rather than excess adiposity."<sup>32</sup>

-Pediatrics, 2001

"...use of BMI during adolescence can lead to overestimation of the extent of increase in body fat, since the increase in BMI at younger ages includes increases in lean body mass."<sup>33</sup>

—Lancet, 2005



—The Center for Consumer Freedom

"In both infancy and childhood, a given BMI can embrace a wide range of percentage body fat ... BMI is of limited use as a measure of body fatness in individuals in both infancy and childhood. The development of BMI with age may be disproportionately due to either FFM [fat free mass] and FM [fat mass] at different time points."<sup>34</sup>

—International Journal of Obesity, 2000

"However, the present study has demonstrated that the relationship between BMI and fatness in individuals is poor, both in infancy and childhood. Obesity is an excess of body fat, not an excess of body weight."<sup>35</sup>

—International Journal of Obesity, 2000

"The potential pitfalls of using BMI as an index of fatness in early life have been noted previously, but, paradoxically, much of our understanding of the development of fatness is based only on such proxy measures ... The actual relationship between early fatness and later obesity is unknown, and will remain so until whole-body fatness is measured at each time point." <sup>36</sup>

—International Journal of Obesity, 2000

#### Consequences of Using the BMI

Despite the substantial limitations of the BMI standard, researchers continue to rely on it as their primary measure of obesity. In fact, essentially all obesity statistics have been calculated using the BMI. University of Alabama obesity researcher David Allison insists, "Analysts need to start retreating from relying solely on BMI."<sup>37</sup> An article in QJM,

the monthly journal of the Association of Physicians in Great Britain, warned in 2000:

"General applicability of BMI is challenged by results from studies of individual populations ... Although BMI is a generally convenient measure, it lacks a theoretical foundation, and may be compromised by ethnic, cultural or lifestyle differences. Nonetheless, BMI has been used as a generic risk factor in epidemiological research of many pathological conditions, has been adopted as the main or sole measure of obesity in numerous clinical trials, and subsequently has been incorporated into clinical guidelines concerning screening for and treatment of various common diseases. Thus the weaknesses of the BMI could have important implications for public health specialists, for researchers and for clinical practitioners in many fields." 38

Likewise, research published in 1998 in the *International Journal of Obesity* found:

"The results show that the relationship between percent body fat and BMI is different among different ethnic groups. This should have public health implications for the definition of BMI cut-off points for obesity, which would need to be population-specific ... It is known that the relationship between BMI and body fat is age- and gender-dependent ... A stocky person is likely to have more muscle mass/connective tissue than a slender person with the same body height. Thus, at the same BMI, the slender person will have more body fat ... The consequences of the different relationships between body fat and BMI are evident. As increased body fat and not increased weight or BMI is the risk factor for excess mortality, cut-off points

for obesity (based on the BMI) could be different for different populations and as a result, population-specific (rather than general) cut-off points have to be defined."<sup>39</sup>

Commenting on a report claiming that more than half the players in the National Basketball Association are overweight according to the BMI standard, University of Louisiana researcher George Bray argued: "No one has ever suggested the BMI is the only criterion to use." And yet [the BMI is] the only criterion used by government regulators who claim that 65 percent of Americans are too fat. And, unfortunately, nearly every study that attempts to assess the health consequences of obesity or the cost of obesity uses the BMI.

"We have stopped the epidemic of obesity. Between 1999-2000 and 2001-2002 there were no significant changes among adults in the prevalence of overweight, obesity, or extreme obesity."<sup>41</sup>

—Journal of the American Dietetic Association, 2005

# Myth: Obesity Kills 400,000 Americans Annually

On March 9, 2004, the heads of the Department of Health and Human Services, National Institutes of Health (NIH), and Centers for Disease Control and Prevention (CDC) stood in front of a packed press conference to announce the conclusions of a CDC study that attributed 400,000 deaths each year to poor diet and physical inactivity. <sup>1,2</sup> USA Today typified the press coverage the next day with its lead story, "Obesity on Track as No. 1 Killer."<sup>3</sup>

A little over one year later, a scientifically superior study conducted by researchers from the CDC and the NIH found that obesity and overweight were responsible for fewer than 26,000 deaths per year—one-fifteenth the CDC's original 400,000-deaths estimate.<sup>4</sup> Despite sustained publicity surrounding the larger number,<sup>5</sup> a CDC spokesman told *The New York Times* that the agency would not take a position on the new paper because "We're too early in the science." A month later the agency reluctantly accepted the findings of the report.

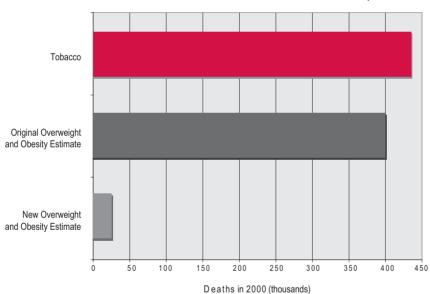
The CDC has made no comment on the findings of an internal audit of the 400,000-deaths study's errors. A summary of the internal review committee's findings noted:

"While there was at least one error in the calculations and both the presentation of the paper and limitations of the approach could have been expressed more clearly, the fundamental scientific problem centers around the limitations in both the data and the methodology in this area."

"Reframing the Debate: Avoid a list of individual attributes and misleading terms like obesity, and do not rush to judgment about the growing prevalence of obesity."8

—From an Institute of Medicine report, "Estimating the Contribution of Lifestyle-Related Factors to Preventable Death", 2005

#### Actual Causes of Death in the United States, 20009, 10



#### Timeline of a Great Unraveling

March 9, 2004 – The heads of the Department of Health and Human Services, the Centers for Disease Control and Prevention, and the National Institutes of Health announce

a study published in *JAMA* attributing 400,000 deaths in the year 2000 to poor diet and physical inactivity."<sup>11</sup>

March 31, 2004 — CDC director Julie Gerberding requests \$6.9 billion from Congress for the agency's 2005 budget, saying:

"[W]e must also remain vigilant against long-standing public health concerns like physical inactivity and poor nutrition. Together these account for an estimated 400,000 deaths per year in this country." 12

May 7, 2004 — *Science* magazine reports that "some researchers, including a few at CDC, dismiss [the CDC's 400,000-deaths statistic], saying the underlying data are weak."<sup>13</sup> The article continued:

"They argue that the paper's compatibility with a new antiobesity theme in government public health pronouncements—rather than sound analysis—propelled it into print ... Several epidemiologists at CDC and the National Institutes of Health (NIH) echoed [these concerns] but declined to speak on the record. 'I don't want to lose my job,' said one CDC staffer who does research in the area. Critics also object that the authors added an arbitrary number of deaths from poor nutrition (15,000) to the obesity category. A CDC scientist says internal discussions on these issues got 'very contentious' months before publication and left some feeling that the conclusions were not debatable."

**June 21, 2004** — Congressman Henry Waxman (D-CA) formally requests a Government Accountability Office investigation of the CDC's death estimate.<sup>14</sup>



June 23, 2004 — CDC National Center for Chronic Disease Prevention and Health Promotion acting director Dr. George Mensah asks the CDC's Dr. Stephen Thacker to conduct an internal review of the 400,000-deaths study.<sup>15</sup>

August 15, 2004 — CDC researchers Katherine Flegal and David Williamson and National Institutes of Health researcher Barry Graubard co-author a study in *The American Journal of Epidemiology* critiquing the method used in the CDC's original study. The authors conclude:

"Existing estimates of the number of deaths attributed to overweight and obesity were calculated by using a method likely to produce biased estimates, when the effects of obesity vary by age or other characteristics. Estimates of deaths attributable to overweight and obesity arrived at by using this approach may be biased and should be viewed cautiously." <sup>16</sup>

A second paper—published in *The American Journal of Public Health* by Flegal, Williamson, and two other CDC researchers—also criticizes the 400,000-deaths paper's methods. The authors warn:

"Our examination suggests that given present knowledge about the epidemiology of obesity, and especially the impact of age on mortality risks associated with obesity, it may be difficult to develop accurate and precise estimates. We urge caution in the use of current estimates on the number of deaths attributable to obesity and also urge researchers to devote greater efforts to improve the data and methods used to estimate this important public health statistic." <sup>17</sup>

Significantly, both studies were submitted for publication in 2003, months before the 400,000-deaths study appeared in *JAMA*.

October 2004 — The CDC committee reviewing the 400,000-deaths study submits its findings to the agency's Chief of Science. The report is not released publicly.

**November 23, 2004** — *The Wall Street Journal* publishes a front-page story on errors in the 400,000-deaths study. (See facing page).

**December 3, 2004** — A follow-up article in *The Wall Street Journal* reveals additional problems with the CDC's methodology:

"Critics of the study say the estimate was inflated not just by the statistical mistakes the CDC acknowledged last week, but also by the authors' scientific approach. The number of obesity-related deaths could be less than half of the 400,000 estimated in the flawed CDC study, according to some scientists familiar with the debate." 18

University of Alabama professor David Allison, who developed the methodology used in the CDC study, admits in the story that measuring obesity-attributable deaths "is an evolving science."

**January 18, 2005** — The CDC publishes an erratum in *JAMA* admitting to a mathematical error. The estimate of overweight- and obesity-attributable deaths is lowered to 365,000 per year.<sup>19</sup>

**January 19**, **2005** — *The Wall Street Journal* reports on the CDC's correction, noting:

"The CDC hopes to put behind it not only the embarrassment of the computational errors but the controversy over the high-profile study that began simmering inside the agency even before it was published. Some scientists

## THE WALL STREET JOURNAL.

November 23, 2004

# CDC Study Overstated Obesity as a Cause of Death

By Betsy McKay

A widely quoted federal study that concluded obesity is poised to overtake tobacco as the leading cause of preventable death inflated the impact of obesity on the annual death toll by tens of thousands due to statistical errors ...

Since its release, the study has been cited repeatedly by officials including Secretary of Health and Human Services Tommy Thompson, members of Congress and makers of weight-loss drugs seeking to draw attention and funding to anti-obesity efforts. The study's flaws could undercut those efforts, as well as the arguments of plaintiff attorneys pressing for litigation against high-fat restaurant chains, and activists seeking Medicare funding for obesity-related surgeries ...

At the same time that Dr. Gerberding and the study's three other authors were writing up their research, two experienced CDC obesity epidemiologists completed papers arguing that the traditional method of calculating deaths caused by obesity—which Dr. Gerberding and her colleagues used—inflates the tally, because it doesn't properly factor in age and risk factors such

as smoking. Those two papers were published in July and September, months after the disputed study, but were cleared for publication by the CDC before it came out. Neither paper directly addressed the study's findings.

But even before the disputed study was published, several scientists at the CDC expressed misgivings to their superiors about its methodology and findings, according to documents and people familiar with the debate ...

"I am worried that the scientific credibility of CDC likely could be damaged by the manner in which this paper and valid, credible, and repeated scientific questions about its methodology have been handled," wrote Terry Pechacek, associate director for science in the CDC 's Office on Smoking and Health, in an April 30 e-mail shortly after the study was published. Dr. Pechacek wrote to colleagues that he had warned two of the paper's authors, as well as another senior scientist, "I would never clear this paper if I had been given the opportunity to provide a formal review." ...

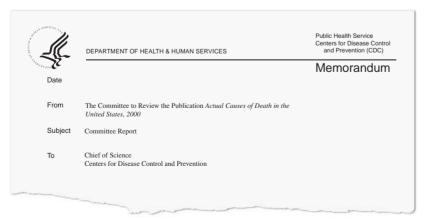
Drs. Gerberding and Snider conceded that the views of dissenting scientists hadn't been properly heeded.<sup>20</sup>

at the CDC expressed misgivings about the study's methodology and findings before publication, and complained that their comments were ignored, according to internal documents and people familiar with the debate. They warned that the approach the authors were using didn't take into account recent advances in methodology and could inflate the final obesity tally."<sup>21</sup>

The *Journal* also reports that the CDC refused to release the full internal report:

"After criticism of the original study surfaced among scientists last spring, CDC director Julie Gerberding, one of the study's four authors, ordered an inquiry. That probe has also been completed, though the CDC wouldn't release a copy of its final report yesterday." <sup>22</sup>

**February 9, 2005** — The CDC's internal review committee releases a summary of its report, which concludes that the underlying methodology used to estimate obesity-attributable deaths had significant limitations:



"The paper published by Mokdad, et al., *Actual Causes of Death in the United States*, 2000, has provoked significant controversy both inside and outside the agency. While there was at least one error in the calculations and both the presentation of the paper and limitations of the approach could have been expressed more clearly, *the fundamental scientific problem centers around the limitations in both the data and the methodology in this area.*" (emphasis added)

The report also notes: "The scientists expressed concerns and did meet with some of the authors but they were not convinced that their perspectives were listened to or that requests for data were acknowledged."<sup>24</sup>

February 25, 2005 — Responding to an op-ed<sup>25</sup> by the Center for Consumer Freedom calling on the CDC to formally retract its embattled 400,000-deaths study, CDC Chief of Science Dixie Snider writes in the *Atlanta Journal Constitution:* "...we cannot and should not let this discussion of scientific methodology detract from the real issue." According to the CDC's website, Snider's job is "maintaining the integrity and productivity of CDC's scientists by resolving controversial scientific issues." In spite of the fanfare with which the CDC announced its original finding of 400,000 annual obesity-related deaths, Snider adds, "we should not let the focus on deaths attributable to obesity distract us from this serious health issue."

**February 28**, **2005** — Following Snider's astounding comments, the editorial board of *The Washington Times* 

joins CCF in calling on the CDC to publicly retract the flawed study.<sup>28</sup> Describing Snider's comments as "dangerous reasoning," the *Times* editorial argues:

## The Washington Times

It's clear that over the concerns of its own researchers the CDC shamefully pushed a scientifically flawed study to reach some politically correct end. Since then, it has not given contrary evidence publicity equal to the original report. Nothing less than a full retraction of the original study and an apology to the American people can amend these egregious mistakes."

**April 20, 2005** — A team of researchers from the CDC and the NIH publish a bombshell study in *JAMA* attributing 25,814 deaths to obesity and overweight annually.<sup>29</sup> The study stands in stark contrast to the CDC's original estimate, which was *15 times higher*. CDC Chief of Science Dixie Snider says the agency won't take a position on the new study, insisting, "We're too early in the science."<sup>30</sup>

#### The Associated Press reports:

"Being overweight is nowhere near as big a killer as the government thought, ranking No. 7 instead of No. 2 among the nation's leading preventable causes of death, according to a startling new calculation from the CDC ... The Centers for Disease Control and Prevention estimated Tuesday that packing on too many pounds accounts for 25,814 deaths a year in the United States.

**April 22-May 10, 2005** — Opinion leaders across the country take the CDC to task for its handling of the obesity-death estimate. The editorial board of *The New York Times* writes:

## <u> Ehe New York Times</u>

[The new study's] estimate has exploded like a bombshell amid the health officials struggling to control the undeniable upsurge of obesity here and abroad. It leaves the C.D.C., in particular, with a lot of explaining to do ... The C.D.C. needs to say, loud and clear, whether it believes the estimates. The whole notion of what constitutes normal weight and overweight may have to be rethought.<sup>32</sup>

A Washington Post editorial notes:

# The Washington Post

In seeking to push obesity into the forefront of public health concerns, CDC has indeed published, if not "hyped," incorrect information about the links between obesity and death ... CDC spokesmen explain that the disparities are explained by the fact that the study of obesity and its relationship to mortality is "evolving." Fair enough, but the original report, which was criticized even before its publication, also contained serious methodological and calculation errors, which CDC was slow to acknowledge and now tries to play down.<sup>33</sup>

May 6, 2005 — *Science* magazine reports: "Scientists agree that Flegal's study is superior."<sup>34</sup>

May 19, 2005 — Scientific American prints an article titled "Obesity: An Overblown Epidemic?"<sup>35</sup> questioning much of the hype about obesity. (See facing page).

May 25, 2005 — The CDC responds to a Freedom of Information Act request by CCF and releases the agency's internal review committee report.<sup>36</sup>

In the report, a number of the committee members suggested that the CDC submit an official correction to *JAMA* regarding the methodological problems. One wrote: "If possible, the proper formula should be used to calculate the deaths attributed to obesity. If using the published assumptions but the more suitable equation leads to different estimates, an erratum should be submitted." Yet the CDC's subsequent erratum to *JAMA*, which lowered the estimate to 365,000 deaths, only addressed mathematical errors—and not the substantial methodological problems raised in the review committee's report.

The report also indicates that the authors of the original study apparently knew they were using the "wrong formula" before the study was published.

May 31, 2005 — In a new "frequently asked questions" document posted on the agency's Web site, the CDC writes:

"Is CDC changing its estimate of obesity-related deaths?

"Yes. We are no longer going to use the previous annual es-

# SCIENTIFIC AMERICAN

May 2005 www.sciam.com

**Excerpted** 

#### Obesity: An Overblown Epidemic?

A growing number of dissenting researchers accuse government and medical authorities—as well as the media—of misleading the public about the health consequences of rising body weights.

By: W. Wayt Gibbs

...[Dissenting scientists] allege, however, that experts are blowing hot air when they warn that overweight and obesity are causing a massive, and worsening, health crisis. They scoff, for example, at the 2003 assertion by Julie L. Gerberding, director of the Centers for Disease Control and Prevention, that "if you looked at any epidemic—whether it's influenza or plague from the Middle Ages—they are not as serious as the epidemic of obesity in terms of the health impact on our country and our society." (An epidemic of influenza killed 40 million people worldwide between 1918 and 1919, including 675,000 in the U.S.) ...

These new results contradict two previous estimates that were the basis of the oft-repeated claim that obesity cuts short 300,000 or more lives a year in the U.S. There are good reasons to suspect, however, that both these earlier estimates were compromised by dubious assumptions, statistical errors and outdated measurements ...

Media coverage of the obesity epidemic surged in 1999 following a report in the *Journal of the American Medical Association* by David B. Allison and others that laid about 300,000 annual deaths in the U.S. at the doorstep of obesity. The figure quickly acquired the status of fact in both the popular press and the scientific literature, despite extensive discussion in the paper of many uncertainties and potential biases in the approach that the authors used.

Like election polls, these estimates involve huge extrapolations from relatively small numbers of actual measurements. If the measurements—in this case of height, weight and death rates—are not accurate or are not representative of the population at large, then the estimate can be far off the mark. Allison drew statistics on the riskiness of high weights from six different studies. Three were based on self-reported heights and weights, which can make the overweight category look riskier than it really is (because heavy people tend to lie about their weight). Only one of the surveys was designed to reflect the actual composition of the U.S. population. But that survey, called NHANES I, was performed in the early 1970s, when heart disease was much more lethal than it is today ...

Surprisingly, none of these problems was either mentioned or corrected in a March 2004 paper by CDC scientists, including the agency's director, that arrived at a higher estimate of 400,000 deaths using Allison's method, incorrect formula and all. Vocal criticism led to an internal investigation at the CDC; in January the authors published a "corrected" estimate of 365,000 obesity-related deaths a year, which they labeled as stemming from "poor diet and inactivity." The new figure corrected only data-entry mistakes, however ...

The new analysis suggests that it is still far from certain whether there is any measurable mortality toll at all among overweight and obese Americans as a group. Even among the moderately and severely obese (those whose BMI exceeds 35), the plausible annual mortality found in the 1988–1994 survey ranges from 122,000 extra to 7,000 fewer deaths than one would expect based on the death rates of "healthy weight" people.

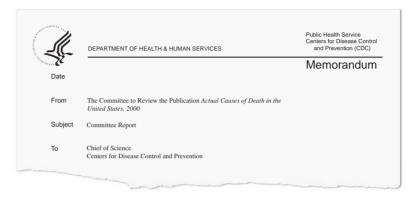
timate of 365,000 deaths from poor nutrition and physical inactivity. Instead, CDC will state, 'The latest study based on a nationally representative sample of U.S. adults estimates that about 112,000 deaths are associated with obesity each year in the United States.'"<sup>37</sup>

June 2, 2005 — CDC Director Julie Gerberding hosts a press conference aimed at "clearing the confusion" about the CDC's role in addressing overweight and obesity. Saying she is "very sorry for the confusion that these scientific discussions have had," Gerberding emphasizes that "It is not OK to be overweight."<sup>38</sup> Gerberding also insisted: "We don't want people to artificially hide controversies. We want to get them out in the open." Her commitment to being "out in the open" comes only a few days after internal CDC documents reveal that much of the internal debate over the validity of the CDC's original study was ignored by the authors. Gerberding was one of these authors.



—The Center for Consumer Freedom

## Internal Review and Dissent: Quotes from the CDC's Analysis of Its 400,000-Deaths Study



- "Methods used to calculate number of deaths due to obesity were incorrect and possibly miscalculated ... The use of the improper formula is a rather serious mistake to make. At the time this study was being conducted, the scientific literature had several papers describing potential bias. Following Allison et al. [which attributed 300,000 deaths to overweight and obesity per year] in using an incorrect method was not justified. From the cross-clearance, it seems as if this bias from the wrong formula was pointed out to the authors..."
- "The knowledge about inappropriate use of adjusted relative risks in certain attributable-fraction formulas was in the literature prior to the preparation of this manuscript and was apparently shared with the authors prior to publication..."
- "This review has clarified that we should no longer be using the relatively simple methodology of the model used by several of those previous papers [which arrived at the estimates of 300,000 and 400,000 deaths annually]..."

"My general conclusion is that the Mokdad et al. paper [the 400,000-deaths study] makes some bold statements, bolder than the original McGinnis and Foege paper [attributing 300,000 deaths to poor diet and physical inactivity in 1990], which might have been better off being presented as a policy exercise rather than a scientific study; the estimates seemed a combination of scientific calculation and expert opinion. Furthermore, the scientific reviewers of the paper who mentioned the problems were not taken as seriously as they could have been..."

"The [CDC's] clearance process appears to have been begun in good faith, though given dissent, it veered off path. This likely happened since the Director is a co-author and presumably approved the paper. I think if the scientists had believed that their concerns were being considered, the issue of clearance may not have arisen. Estimation based on best educated guesses should be acknowledged as such up front: for this paper the experience of the authors supports their ability to make some decisions with weak data, though some decisions may ultimately be incorrect..."

## The CDC's Transparent Excuses for Downplaying the Flegal Study

CDC Claim: We shouldn't focus so much on obesity-related deaths.

Writing in *The Atlanta Journal-Constitution*, CDC's Dixie Snider argued: "We should not let the focus on deaths attributable to obesity distract us from this serious health issue." Echoing Snider's comments, *USA Today* reported:

"The debate about the number of deaths 'is not where the discussion ought to be,' says Bill Dietz, director of the CDC's division of nutrition and physical activity. 'To me, the issue is that the diseases associated with obesity are impairing people's quality of life and contributing to the steady rise in medical costs."<sup>40</sup>

The CDC has, to put it mildly, changed its tune on the importance of obesity deaths. In March 2004, when the CDC released the original 400,000-deaths study, agency director Gerberding told a crowded press conference: "The fact that more than a third of deaths in America each year are related to smoking, poor eating habits and physical inactivity is both tragic and unacceptable." In subsequent months, the "obesity kills" mantra quickly became the central theme of the agency's public statements on obesity. Gerberding herself used the 400,000-deaths estimate in Congressional testimony to justify the agency's \$6.9 billion budget request. It was the only obesity-related statistic she cited during her testimony.

An internal CDC memorandum, written by Gerberding and other authors of the 400,000-deaths study, reveals what the agency really thinks about the importance of measuring obesity-related mortality:

"Although significant scientific questions remain about how best to assess the actual causes of death, it remains a public health priority to identify those deaths that could be prevented or delayed substantially in the population."

#### CDC Claim: The science of measuring obesityattributable deaths is still evolving.

It is of course true that science is evolving. But it's difficult to believe the CDC's claim that "we're too early in the science" to take a position on the number of obesity-related deaths. It didn't have this concern when it engaged in a massive pub-

licity campaign surrounding the 400,000-deaths number. At the time, the CDC chose to ignore significant problems with that statistic. Internal CDC documents indicate that the agency knew it was using the "wrong formula."<sup>45</sup>

## CDC Claim: We were merely updating an old obesity-death study, not developing a new method of measurement.

To justify using an outdated and highly controversial methodology, the CDC claims that it was simply updating a study from 1993, which estimated the number of deaths from poor diet and physical inactivity at 300,000 annually. Commenting on the "considerable media coverage" and "letters from some scientists about our methods and assumptions," CDC's Donna Stroup explained in an Institute of Medicine publication that the 400,000-deaths study "was a classic replication study: its methodology was largely similar to that of the earlier study, in order to allow for comparisons of the 1990 and 2000 estimates."

But the 400,000 estimate did not use the methodology of the 1993 paper. It relied on an entirely different method developed in 1999 by the University of Alabama's David Allison. According to recently released internal CDC documents:

"At the time this study was being conducted, the scientific literature had several papers describing potential bias. Following Allison et al in using an incorrect method was not justified. From the cross-clearance, it seems as if this bias from the wrong formula was pointed out to the authors."

### CDC Claim: This is just one study to measure obesity-related deaths. It is not definitive.

Numerous other studies, many of which are noted later in this report, indicate only a small relationship between obesity and mortality.

#### **Research Driven by Politics**

Following the controversy over the CDC's 400,000-deaths study, the agency convened a panel of experts at the Institute of Medicine to discuss measuring the burden of "lifestyle-related factors" like obesity. The panel suggested that the CDC and other public health agencies pursue a research agenda that "offers the strong justification needed to persuade policymakers of the public health importance of reducing the impact of preventable lifestyle-related risks."<sup>48</sup> The panel's other suggestions included:

- "Motivate the public to demand policy intervention around preventable illness."
- "Portray lifestyle-related risks as a public health concern rather than an individual problem."
- "Highlight the social costs of under funding the public health surveillance systems that could answer questions about lifestyle-related risks and enable society to use trillions of health care dollars more effectively."

#### A Better Study

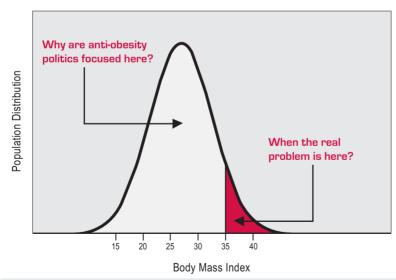
The CDC's original estimate of 400,000 deaths in 2000 stands in stark contrast to a study published by a team of researchers from the CDC and the NIH, which determined

that overweight and obesity were responsible for 25,814 deaths in the United States in 2000.<sup>49</sup>

"We should no longer be using the [CDC's] relatively simple methodology." 50

— Dr. Rachel Ballard-Barbash, Associate Director of the National Cancer Institute's Applied Research Program

The more recent study, published in *JAMA*, found that putting on a few extra pounds is not a lethal mistake. The study, led by CDC researcher Katherine Flegal, found no link between being overweight (a BMI between 25 and 29.9) and an increased risk of death. In fact, Flegal's research indicates that being overweight may actually be safer than being a "normal" weight.



According to a study by CDC researchers, only those with a BMI of 35 or higher face a statistically significant increased risk of mortality.

(Source: Behavioral Risk Factor Survelance System, 2004)

Flegal's team attributed 111,909 deaths each year to obesity. But when they add their obesity estimate to their estimate of overweight-attributable deaths (which is a negative number) they conclude: "... for overweight and obesity combined, our estimate was 25,814 excess deaths." According to their findings, "overweight" saves 86,094 American lives each year.

The vast majority of deaths associated with obesity (82,066 of 111,909) come from individuals with a BMI of 35 and above. According to *The New York Times'* Gina Kolata, just 8 percent of the population has a BMI in this range.<sup>51</sup> Meanwhile, the government continues to warn that 65 percent of Americans—those with a BMI of 25 and above—weigh too much.<sup>52</sup>



—The Center for Consumer Freedom

## Five Reasons To Accept Dr. Flegal's Findings Over the CDC's 400,000-Deaths Estimate

The findings of the CDC's own internal review committee were critical of the methods used to estimate 400,000 obesity-attributable deaths. Committee member Rachel Ballard-Barbash, who is associate director of the National Cancer Institute's Applied Research Program, wrote: "...we should no longer be using the [CDC's] relatively simple methodology." A second member suggested that the study was never a "'state-of-the-art' attempt to estimate the health burden" of overweight, obesity, and other causes of death. A summary of these findings concluded that "the fundamental scientific problem centers around the limitations in both the data and the methodology in this area."

In terms of both data and methodology, the study by Dr. Flegal's team of researchers is far superior to the 400,000-deaths study. The latter study relied on calculations from a 1999 *JAMA* study by University of Alabama professor David Allison. His study blamed obesity for 300,000 deaths in 1990.<sup>53</sup> The CDC's study increased that number to 400,000, noting: "We used the same procedure reported by Allison et al. to estimate annual overweight-attributable deaths." Dr. Flegal's study is superior for the following reasons:

"Scientists agree that Flegal's study is superior."55

-Science, 2005

The Flegal Study Used Much More Recent Data
Despite having access to more recent data, the CDC based its 400,000-deaths conclusion on information dating as far back as 1948. Allison and his colleagues relied on six population studies to calculate the mortality risk

from excess weight. The average start date of these studies was 1963 and the average end date was 1983. Consequently, the 400,000-deaths estimate assumed that our ability to treat high blood pressure, diabetes, heart disease, and other illnesses linked to obesity has not improved in more than a generation.

Allison admits in his 1999 study that this is a problem. "When most of the cohort studies used were initiated," he writes, "there were fewer intervention strategies to reduce risk factors associated with obesity and fewer medical therapies for postponing death from obesity-related diseases." Despite this, Allison made no adjustment to his findings.

Allison's Cohort Studies	Years Studied
Alameda County Health Study	1965–1975
Tecumseh Community Health Study	1959–1985
Framingham Heart Study	1948–1980
Americans Cancer Society Prevention Study	1960–1972
Nurses Health Study	1976–1992
NHANES I Epidemiologic Follow-up Study	1971–1992

Allison had access to much more recent data, but failed to use it. He relied on the NHANES III dataset collected by the CDC during 1988-1994 to determine the *prevalence* of obesity. Yet he failed to use either NHANES II or NHANES III in calculating the *risk* of obesity.

Allison has actually criticized other researchers for using one of the very same cohorts that he relied on for his 300,000-deaths study. In a letter published in *JAMA* in 2003, he wrote:

"... Peeter, et. al. looked at a cohort of individuals residing in Framingham, Mass beginning in approximately 1948 ... Since 1948, treatments for cardiovascular disease have improved and mortality rates have been reduced. For this and other reasons, the true effect of BMI on longevity of mortality rate may change over time." <sup>57</sup>

By using more current data through 2002, Flegal's team observed a dramatic decline in the risk of obesity. In fact, the most recent data show no increased risk among those with a BMI under 35:

"Excess deaths associated with obesity (BMI > 30) were calculated as 298,808 according to the NHANES I relative risks, 26,917 according to the NHANES II relative risks, or 43,640 according to the NHANES III relative risks. In all 3 cases, however, the majority of deaths associated with obesity were associated with BMI 35 and above: 186,498, 21,777, or 57,515 deaths respectively. (NHANES III relative risks produced a negative estimate for BMI 30 to < 35) For overweight (BMI 25 to <30), the data consistently suggest no excess deaths overall ... the largest difference [in deaths] is due to the inclusion of the mortality data from NHANES II and NHANES III, which decreased estimates by 63% or more relative to NHANES I mortality data alone ... Relative to NHANES I, the more recent data from NHANES II and NHANES III suggest the possibility that improvements in medical care, particularly for cardiovascular disease, the leading cause of death among the obese, and its risk factors may have led to a decreased association of obesity with total mortality. Cardiovascular risk factors have declined at all BMI levels in the US population, but, except for diabetes, the decline appears to be greater at higher BMI levels."58

The CDC itself has acknowledged the importance of examining newer data:

"Earlier estimates only reflected the obesity-related health risks that people experienced in the 1970s. The newer data (some with mortality follow-up through 2000) appear to reflect a real decline in the risks of dying from obesity-related diseases like heart disease. Big improvements in the control of risk factors for heart disease, such as better drug management of high blood pressure and cholesterol, may have resulted in far fewer people dying today as a result of obesity."<sup>59</sup>

# The Flegal Study Used Nationally Representative Data Only one of the six population studies Allison used to calculate the likelihood of death from excess weight was nationally representative. The others overrepresented whites and Americans from upper socioeconomic classes. In 1985, a study

appearing in The Annals of Internal Medicine explained:

"The databases on which height-weight tables are based have sampling and design problems ... The largest databases, those of the Build studies and the American Cancer Society study, are not particularly representative of the United States as a whole. These studies disproportionately include men, whites, members of the upper and middle classes, and persons under age 60 ... The Framingham Study and other studies based on community or occupational samples likewise do not represent the population." 60

Discussing the 400,000-deaths study, the Flegal team notes:

"Previous estimates used data from a variety of studies to estimate relative risks, but the studies had some limitations. Four of the 6 included only older data (2 studies ended follow-ups in the 1970s and 2 in the 1980s), 3 had only self reported weight and height, 3 had data only from small geographic areas, and 1 study included only women. Only one dataset, the National Health and Nutrition Examination Survey (NHANES) I, was nationally representative." <sup>61</sup>

By using only the CDC's nationally representative NHANES I, NHANES II, and NHANES III datasets, the researchers' estimate of 25,814 obesity-attributable deaths better represents the American population and avoids problems associated with relying on geographically constrained samples.

If Allison's team had limited itself to only the nationally representative data from NHANES I, they would have reported 13 percent fewer deaths.

It may seem counterintuitive that overrepresenting whites and upper socioeconomic classes would increase the number of deaths, but there's a simple explanation. Many studies show that African-Americans have little, if any, increased mortality risk from obesity.<sup>62 63</sup> For instance, a 1999 study published in *The New England Journal of Medicine* found: "Black men and women with the highest body mass indexes had much lower risks of death."<sup>64</sup>

The Flegal Study Controlled for the Influence of Age
It is widely recognized that older people have a lower risk of death from obesity. Allison's method, which failed to

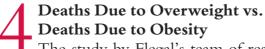
account for age, led to an overestimation of deaths. Months before the CDC's 400,000-deaths announcement was made, Flegal and her co-authors submitted for publication two papers that pointed to this problem. Writing in *The American Journal of Epidemiology*, they argued:

"Existing estimates of the number of deaths attributed to overweight and obesity were calculated by using a method likely to produce biased estimates, when the effects of obesity vary by age or other characteristics. Estimates of deaths attributable to overweight and obesity arrived at by using this approach may be biased and should be viewed cautiously." 65

The second paper, published in *The American Journal of Public Health*, warned:

"Our examination suggests that given present knowledge about the epidemiology of obesity, and especially the impact of age on mortality risks associated with obesity, it may be difficult to develop accurate and precise estimates. We urge caution in the use of current estimates on the number of deaths attributable to obesity and also urge researchers to devote greater efforts to improve the data and methods used to estimate this important public health statistic." 66

In light of Flegal's findings, *Science* magazine reported in May 2005: "Allison concedes that in retrospect, his decision not to stratify by age was a mistake."



The study by Flegal's team of researchers found that

being overweight (BMI 25 to 29.9) may *prolong* the lives of more than 85,000 people each year. In fact, some of Allison's data supports this theory.

"Allison concedes that in retrospect, his decision not to stratify by age was a mistake." 67

—Science, 2005

While most of the 300,000 deaths claimed by Allison's study derive from the "obese" category, some derive from the "overweight" category. But his own data show no statistically significant relationship between being "overweight" and having an increased risk of death. In fact, 17 of Allison's 60 reported relationships indicate that being overweight has a (statistically insignificant) protective effect. The failure to report a significant relationship between overweight and increased mortality is not surprising. Most studies find little or no increased risk associated with being overweight. A separate study by David Allison found that the lowest risk of death occurred at a BMI of 27.69 If the overweight deaths had been excluded from Allison's 300,000-deaths study, it would have reported 17 percent fewer deaths.

Flegal's Study Reported the Range of Risk
Allison failed to report a level of uncertainty in his conclusion. This uncertainty is measured by confidence intervals, which reflect the range of what the real number could be. If the confidence intervals include the possibility of zero elevated risk, the risk is considered statistically insignificant. An editorial accompanying Flegal's JAMA study points out:

"An important and possibly overlooked contribution by the study by Flegal et al is the formal calculation of confidence intervals around the estimate of obesity-related deaths. When relative risk estimates are only modestly elevated, as in the case of obesity, very small changes in the relative risk translate to large differences in the population-attributable fraction. Thus, it should come as no surprise that the 95% confidence interval around the estimate of 112,000 deaths ranges from 54,000 to 170,000, greater than a 3-fold difference reflected within the range. Although the other studies that previously estimated obesity-attributable death did not include confidence intervals, the estimates from those studies should be assumed to have underlying uncertainty at least as great."<sup>70</sup>

Commenting on the study in the CDC's internal review committee report, Dr. Rachel Ballard-Barbash, associate director of the National Cancer Institute's Applied Research Program, wrote:

"...It is common practice in medical and science journals today to require that confidence intervals be provided even within tabular summaries of data. Therefore, one might question why *JAMA* did not require such confidence intervals. Because casual readers tend to focus on tabular summaries, it is likely many readers had a misimpression of the range about these estimates."<sup>71</sup>

Keeping in mind the concept of confidence intervals and statistical significance, three points stand out:

• Flegal's conclusion that being overweight entails a lower risk than being a normal weight is statistically significant. The 86,000 lives saved from overweight have confidence

intervals that range from 161,000 lives saved to 11,000 lives saved.

- As noted above, Flegal reported a (statistically insignificant) protective effect of BMI 30-35 in the most recent dataset. It is also true that the combined data from NHANES I, II, and III show no statistically significant mortality risk for BMI 30-35.
- The final conclusion that overweight and obesity combined cause excess deaths is not statistically significant. The number of 25,814 deaths from overweight and obesity combined has a range from 86,284 lives *saved* to 137,913 lives *lost*.

#### **A Shared Problem**

"Our estimates may be biased toward higher numbers due to confounding by unknown variables."

-David Allison in JAMA, 1999

Both Allison's and Flegal's studies presume that any increased rate of death in overweight or obese people is the result of their excess weight—a very unlikely assumption.

Those without a high school diploma are nearly twice as likely to be obese as those with a four-year degree. They are also much less likely to have health insurance and to receive quality health care. Other factors that could increase the risk of death among obese people include sedentary lifestyles, genetic ailments, and the negative effects of diet pills—including amphetamines, the weight loss drug of choice for much of the last half-century. A generation ago, 8 percent of all U.S. prescriptions were for weightloss amphetamines.

Allison and his co-authors acknowledge that their calculations assume "all excess mortality in obese people is due to obesity," and that this assumption had the effect of overestimating the total number of obesity-related deaths. They continue: "Our estimates may be biased toward higher numbers due to confounding by unknown variables."

Echoing that point, Flegal's team writes, "other factors associated with body weight, such as physical activity, body composition, visceral adiposity, physical fitness, or dietary intake, might be responsible for some or all of the apparent associations of weight with mortality."

Dr. David Williamson, who co-authored the study with Flegal, explained: "...we cannot truly say there is a causal relationship [between obesity and mortality]." The New England Journal of Medicine (NEJM) pointed out in a 1998 editorial that "mortality among obese people may be misleadingly high because overweight people are more likely to be sedentary and of low socio-economic status." In a letter amplifying their original editorial, the NEJM editors further note:

"Calculations of attributable risk are fraught with problems. They provide only an upper bound for the effect of a single variable, because many other factors, both recognized and unrecognized, may also be contributing to the outcome. When several known factors are taken into account, it is even possible to find that they account for more than 100 percent of deaths—a nonsensical result."<sup>76</sup>

Even the CDC has noted the inherent problems in measuring the risk attributed to poor diet and physical activity. In a paper on physical activity, the agency writes:

"[Mortality estimates] are generally derived by calculating the population attributable risk (PAR) ... Such estimates are inherently uncertain because they do not take into account the reality that some people have more than one risk factor for a disease; for these people, the elimination of a single risk factor (e.g., by becoming physically active) may not reduce mortality risk to the level attainable for people who initially have only that one risk factor. PAR methods thus overestimate the proportion of deaths avoidable by eliminating one modifiable risk factor, in this case physical inactivity."

The CDC's internal review committee's report notes: "Double counting [of deaths] is mentioned clearly in the Discussion section but not in the Introduction and not clearly in the Methods."

Dr. Jon Robison of Michigan State University explains the dubious logic behind the 400,000 number:

"Perhaps the most glaring absurdity about the 400,000 deaths due to obesity study resides in the pronouncement that 'all excess mortality in obese people is due to their obesity.' This is as preposterous as claiming that differences in mortality rates between blacks and whites are solely a result of the color of their skin!"78

University of Virginia Professor of Exercise Physiology Glenn Gaesser reinforces the point:

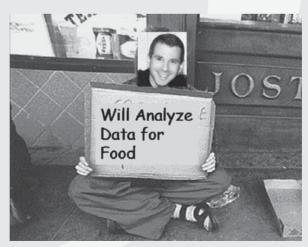
"The authors made no attempt to determine whether other factors, such as physical inactivity, low fitness levels, poor diet, risky weight loss practices, weight fluctuation, use of weight loss drugs, less than adequate access

to health care, etc. could have explained some or all of the excess mortality in large people."<sup>79</sup>

#### David Allison: The Man Behind the Numbers

Dr. Jerome Kassirer, former *New England Journal of Medicine* Editor-in-Chief, notes:

"On the question of obesity, physicians have been extensively involved with the pharmaceutical industry, especially opinion leaders and in the high ranks of academia. The involvement was in many instances quite deep. It involved consulting, service on speaker's bureaus, and service on advisory boards. And at the same time some of these financially conflicted individuals were producing biased obesity materials, biased obesity lectures, and biased obesity articles in major journals."80



A slide from a presentation by David Allison

Kassirer's comment describes, among others, prominent obesity researcher David Allison, who was the lead author of the 1999 JAMA study that concluded obesity was responsible for 300,000 deaths in 1990. Allison has accepted funding from virtually every major business in the weight-loss industry. That includes big drug companies that make weight-loss pills like Xenical and Meridia, popular diet companies like Jenny Craig, Weight Watchers, and Slim-Fast Foods, and the makers of the deadly "fen-phen" appetite suppressant combination—as well as the lawyers who defended those companies in court.

The CDC's now-discredited study upped the supposed obesity death toll to 400,000, noting: "We used the same procedure reported by Allison et al. to estimate annual overweight-attributable deaths." But *JAMA* noted when it published Allison's deeply flawed study that he "has received grants, honoraria, monetary and product donations, was a consultant to, and has contracts or other commitments with numerous organizations involving weight control products and services."

According to a financial disclosure he offered in a supplementary issue of *Obesity Research*,<sup>81</sup> Allison has received money or other support from an overwhelming number of companies hoping to profit from obesity. An article in *Scientific American* reports that he "discloses payments from 148 such companies."

#### Here is a partial list of Allison's supporters:

- Bristol Myers-Squibb (investigating compound SLV319 for use in anti-obesity drug)<sup>83</sup>
- Eon Labs Manufacturing, Inc. (made the phentermine portion of fen-phen)
- Fisons Corporation (produced the phentermine half of fen-phen combination)
- Glaxo (sells weight-loss drug Xenical in the United States)
- Hoffman-La Roche (produces Xenical)
- Interneuron (produced weight-loss drug Redux)
- Jenny Craig
- Johnson & Johnson (multiple weight-loss interests, including bariatric surgical staples)
- Knoll Pharmaceuticals (made weight-loss drug Meridia)
- Ligand Pharmaceuticals (works with Lilly Research labs on obesity products)<sup>84</sup>
- Lilly Research Labs (intracellular receptor technology to be used for anti-obesity drugs)
- McKenna & Cuneo LLP (fen-phen legal defense team)
- Medeva Pharmaceuticals (produced the phentermine half of fen-phen combination)
- Millennium Pharmaceuticals (investigated multiple anti-obesity compounds)
- NutriSystems (weight-loss plans)
- NutriPharma (ScanDiet)
- Ortho-McNeill Pharmaceuticals (sells Topamax, an epilepsy medication prescribed off-label for weight loss)

- Pfizer Central Research (currently has 24 novel compounds and 12 product enhancements in antiobesity drug development pipeline)<sup>85</sup>
- RW Johnson Pharmaceuticals Research Institute (sells Topamax)
- Schering-Plough (anti-obesity drug "ecopipam" in trials)
- Servier Amerique (produced dexfenfluramine portion of fen-phen)
- SlimFast Foods
- · Tanita (sells scales, body-fat monitors)
- Weight Watchers International
- Wellcome Trust (hormone PYY3-36 under investigation for weight loss)

#### Harvard's Straw Man

On May 25, 2005, researchers from the Harvard School of Public Health (HSPH) hosted a symposium to critique the Flegal study. Trying to maintain a state of public panic, they called her results "misleading" and her methodology "flawed," offering a number of theoretical arguments suggesting that Flegal had underestimated the true risk of obesity. They did not, however, acknowledge that Flegal anticipated and responded to their very critiques in her original paper, writing in *JAMA* that the HSPH arguments "did not have a major impact on our estimates of excess deaths."

The HSPH researchers argued that Flegal's study failed to account for the influence of smoking on obesity-related mortality. They suggested that smokers are on average thinner

than non-smokers, and at the same time at a much higher risk of premature death. Thus, according to their argument, by including smokers in her study, Flegal didn't incorporate the true health advantages of being thinner. The HSPH researchers suggested a similar line of reasoning for those with chronic diseases. These people tend to be thin, but also unhealthy. In their words:

"But determining the precise range of BMI associated with lowest mortality can be difficult, because the approach that researchers use to conduct their analyses can bias their findings. One such problem is a phenomenon that researchers call 'reverse causation': Low body weight often results from chronic disease, rather than being a cause of chronic disease. The weight loss may have been unintentional as a result of the underlying disease process; or the weight loss may have been intentional, because patients with serious conditions often become motivated for the first time to lose weight. Regardless, because of this phenomenon, people with a BMI below 25 are a mix of healthy individuals and those who are ill and have lost weight due to their disease. Leaner people are also more likely to smoke than their heavier counterparts. If researchers fail to account for both reverse causation and the adverse effects of smoking, they will find artificially inflated mortality rates among lean people, thus diminishing the harmful impact of overweight and obesity."87

To address these issues, the Harvard researchers offered three solutions. First, they suggested limiting the sample to "never smokers." Second, they wanted to exclude anyone with a pre-existing chronic disease. And third, they advocated excluding "early deaths" to further account for the effect of chronic

disease. Dr. Flegal's final figures did not incorporate these elements. In her original *JAMA* paper, Flegal explained why:

"To examine whether the increased relative risks at lower BMI levels might be related to possible weight loss associated with illness and increased mortality, which could also have decreased the relative risks associated with overweight and obesity, we repeated analyses excluding the first 3 or the first 5 years of deaths and found little change in the relative risk estimates (data not shown). We also repeated analyses including only individuals who never smoked and found that the elevated relative risks for the lowest BMI category persisted and that other relative risks were not systematically different."88

Flegal expanded on this point in an article published on the CDC's National Center for Health Statistics Web site:

"If these biases due to illness-induced weight loss or residual confounding by smoking or prevalent illness at baseline had been operating, one would expect to see a lower relative risk for underweight (closer to 1) and a higher relative risk for overweight and for obesity after controlling for baseline health status, smoking, and early deaths. However, the relative risks did not follow this pattern. Thus, these analyses of the effects of exclusions and of stratification by health status for the combined data set did not suggest that the results for the full data set were affected in any important or systematic way by residual confounding due to smoking or to prevalent illness at baseline. These analyses did not suggest that Flegal et al (2005) had overestimated the risks associated with underweight or underestimated the risks associated with overweight or obesity."89

In other words, Flegal crunched her data just as the HSPH folks would have liked, and found that it made no real difference. She still found that being technically "overweight" had a protective effect (relative risk below 1.0):

"For ages under 70, the relative risks for overweight varied from 0.40 to 0.91. For never-smokers ages 25–69 years in excellent or very good health at baseline, after excluding the first 3 years of deaths, the relative risk for overweight was 0.45 (significantly below 1.0). For grade 1 obesity for younger never-smokers, regardless of baseline health status and regardless of excluding the first 3 years of deaths, the relative risks were always below 1.0." <sup>90</sup>

In a follow-up letter published in *JAMA* responding to Harvard's critique, Flegal wrote:

"The relative risks were little affected by such exclusions, and changes were often in the direction opposite to those anticipated by Willett et al."91

Is Flegal's result the product of some "flaw," as the HSPH academics assert? Research from Loyola University backs Flegal up on smoking:

"Reanalysis of the Framingham Heart Study data does not support the hypothesis that there is an interaction between smoking and measures of obesity. Moreover, the estimated BMI or MRW at the minimum risk of death was similar for men and women smokers and non-smokers alike."92

Researchers from Johns Hopkins and the Obesity Research Center arrived at a similar conclusion: "Both models [smokers and never smokers] are virtually identical because of the negligible effect of smoking in terms of both magnitude and significance ... This [study] indicates that the relationship between BMI and mortality was not significantly different between never smokers and ever smokers." <sup>93</sup>

As for the claim that Flegal should have excluded early deaths, a frequently cited report surveying data from 29 other studies and more than 1.9 million subjects concluded:

"...either pre-existing disease does not confound the BMI-mortality association or eliminating early deaths [as Harvard suggests] is inefficient for reducing that confounding ... these results suggest that [excluding early deaths] may not be advisable because, to the extent that it has any effect at all, the magnitude of this effect is minimal, of questionable clinical significance, and of ambiguous meaning." 94

The debate between the HSPH and Flegal is not new. An HSPH letter responding to a Flegal study in the *American Journal of Public Health* (published months before her better known study from April 2005) read in part:

"One obvious logical problem is that, although most people die after 75 years of age, it is cumulative obesity exposure rather than weight at a specific older age that contributes the most to the higher mortality rates associated with obesity ... Thus, the relative risks calculated from the oldest age groups do not reflect the true long-term impact of obesity on mortality." 95

To which Flegal responded in her own letter:

"[The Harvard researchers] speculate that the number of deaths attributable to obesity in the United States may be underestimated when relative risks are calculated on the basis of current body mass index (BMI). They cite no data to support their speculations, but instead invoke the notion of 'reverse causality.' They hypothesize that relative risks are lowered by obese people who become ill, lose weight because of this illness to become normal weight, and die shortly thereafter of the underlying illness, surviving just long enough to be included in the study. However, this reverse-causation hypothesis is unlikely to be the correct explanation for the lower relative risks in the elderly for 2 reasons: first because data show that exclusion of preexisting illness has little effect on relative risk estimates, and second because weight loss from obesity to normal weight is relatively uncommon."96

An entirely separate argument made by the HSPH researchers is that data used in the Flegal study did not provide for a long enough follow-up time on individual subjects. They insist that a shorter follow-up period doesn't capture the full consequences of obesity. But once again Flegal anticipated and responded to this point in her original study. While suggesting that the issue requires further research, she wrote:

"To examine whether the higher relative risks in NHANES I might be due to the longer follow-up in NHANES I, we compared the relative risks from the first phase of NHANES I through the 1982-1984 follow-up with the relative risks from NHANES II and III. Thus, the follow-up period was similar for all surveys (10 years for NHANES I, 14 years for NHANES II, 9 years for NHANES III). The NHANES I relative risks over the first 10 years of follow-up were higher in almost every BMI-age subgroup

than were the relative risks from the other surveys (data not shown). Thus, even after controlling for length of follow-up, NHANES I tended to have higher relative risks than the other surveys ... [T]he relative risk for total mortality in weight-stable individuals in the latter part of the NHANES I follow-up were similar to relative risks in the earlier follow-up period."97

Flegal also pointed out that even in the Allison study, which predicted a much higher risk of death from obesity, "Across the 6 cohorts used by Allison et al, there was no relation between the length of follow-up in a cohort and the relative risk in the cohort."98

In sum, the HSPH critique is speculative at best, contradicted by many previous studies, and does not apply to Flegal's data. In her *JAMA* study she wrote, quite appropriately:

"We undertook additional analyses to examine whether our estimates of excess deaths might have been affected by factors such as length of follow-up, weight stability, weight loss caused by illness, or smoking status ... Taken together, these analyses suggest that differences in length of follow-up, weight loss because of underlying illness, or confounding by smoking status did not have a major impact on our estimates of excess deaths." <sup>99</sup>

#### Experts' Take on Obesity and Mortality

Experts across the country and around the world are skeptical of the link between obesity and mortality.

"The major problem with this 'obesity kills' statistic is the lack of compelling evidence to substantiate it." 100

"The data linking overweight and death, as well as the data showing the beneficial effects of weight loss, are limited, fragmentary, and often ambiguous. Most of the evidence is either indirect or derived from observational epidemiologic studies, many of which have serious methodologic flaws ... In this age of political correctness, it seems that obese people can be criticized with impunity, because the critics are merely trying to help them. Some doctors take part in this blurring of prejudice and altruism by overstating the dangers of obesity and the redemptive powers of weight loss." <sup>101</sup>

—Editorial published in *The New England Journal of Medicine*, 1998

"Studies concluding that obesity is harmful are embraced, despite potential flaws. Studies concluding that obesity is [not harmful] are rejected or simply ignored, regardless of merit." 102

—Journal of Obesity and Weight Regulation, 1987

"Someone needs to say the emperor has no clothes ... [the conventional wisdom on obesity] is cultural bias, not science." 103

—Dr. C. Wayne Callaway, Professor of Medicine, George Washington University, 1998

"These studies suggest that health problems frequently blamed on excess body weight are more likely caused by an unhealthy lifestyle rather than obesity itself." 104

—Letter published in the New England Journal of Medicine, 1998

"Evidence that it is more dangerous to be thin than fat is either ignored or minimized in analyses that shape public policy toward weight loss ... What evidence exists for an association between obesity and mortality or morbidity, is usually found not to apply to those with mild to moderate obesity."<sup>105</sup>

-Clinical Psychology Review, 1991

"Of all our convictions about health, the belief that obesity itself is a killer has no rival when it comes to the gap between conventional wisdom and scientific evidence ... [T]he health risks of moderate obesity have been greatly overstated." 106

—Dr. Glenn Gaesser, Professor of Exercise Physiology, University of Virginia, 1997

"The idea has been greatly oversold that the risk of dying prematurely or of having a heart attack is directly related to relative body weight." <sup>107</sup>

—University of Minnesota Professor Emeritus Ancel Keys, W.O. Atwater Memorial Lecture, 1980

"The establishment clings to the belief that weight causes disease and death just as people once insisted that the world was flat." 108

—Dr. Susan Wooley, Professor Emerita, the University of Cincinnati, 1998

"The major studies of obesity and mortality fail to show that overall obesity leads to greater risk." 109

-Dr. Reubin Andres, National Institutes of Health, 1980

"[M]ost epidemiological studies reveal that aside from the extremes, BMI is not that strong a predictor of death rates."<sup>110</sup>

—QUEST, the official journal of the National Association for Kinesiology and Physical Education in Higher Education, 2004

"Many longitudinal cohort studies reported no direct relationship between bodyweight and mortality; in others a negative relationship was observed."

—International Journal of Obesity and Related Metabolic Disorders, 1996

"Increased body mass index was marginally associated with reduced risk of mortality ... In many studies overall obesity—often expressed as an elevated body mass index—has not been significantly related to myocardial infarction."

-British Medical Journal, 1993

"Studies on the relation between body weight and mortality have shown inconsistent results ... [W]e did not find an increased mortality at the upper end of the BMI distribution." <sup>113</sup>

—Journal of Clinical Epidemiology, 1997

"A report from the WHO-MONICA study that examined the correlation between changes in risk factors and coronary heart disease (CHD) incidence rates from 38 separate international populations found that increasing BMI trends were actually associated with declining CHD rates among men; among women, there was no association between changes in BMI and CHD." 114

—JAMA, 2005

"These results suggest that high levels of obesity indicators are only slightly associated with an excess mortality and that overweight and obesity are health hazards only if they are accompanied by an elevation of other risk factors, mainly of blood pressure ... Everything else being equal, the contribution of elevated levels of BMI to the risk of

dying in the next 10 years is limited ... The limited role of elevated BMI in general mortality when other risk factors, mainly [blood pressure], do not increase together with BMI is confirmed also by the simple analyses reported."<sup>115</sup>

—Preventative Medicine, 1993

"...increased BMI (i.e., overweight and obesity) was not an independent predictor of cardiovascular risk ... overweight and obese women with normal metabolism have a relatively low cardiovascular risk."

-Circulation, 2004

"Many studies have reported no association between body weight and mortality. [Dr. Ancel] Keys' review of 13 prospective studies found that only one showed a definite univariate relationship between overweight and CHD. Similarly, review of 16 prospective studies of obesity and mortality led Andres to conclude that obesity does not influence total mortality the way one would expect."

—American Journal of Public Health, 1989

"The resulting empirical findings from each of four race/sex groups, which are representative of the US population, demonstrate a wide range of BMIs consistent with minimum mortality and do not suggest that the optimal BMI is at the lower end of the distribution for any subgroup." <sup>118</sup>

— American Journal of Epidemiology, 1998

"The levels of BMI carrying the minimum risk of death are higher than expected—that is, about 29 units of BMI for middle aged men, 27 to 29 units for young women, and nearly 32 units for middle aged women."

—Journal of Epidemiology and Community Health, 1998

"Neither coronary heart disease nor cancer, the two leading causes of death, was significantly associated with BML"<sup>120</sup>

—Journal of Clinical Epidemiology, 1990

"The minimum mortality [for women over 50] occurred at a BMI of approximately 34."<sup>121</sup>

—Journal of Women's Health, 1998

"Preventing overweight would have had only a negligible effect on mortality in the present study population; this confirms the results of several studies that document only a weak association between high body weight and mortality." <sup>122</sup>

-British Medical Journal, 1990

"...nine-year mortality data from NHANES I were analyzed ... mortality for all women combined did not vary according to BMI. For men, a small positive effect was seen only in the highest BMI category." <sup>123</sup>

-Nutrition Reviews, 1993

#### From a 2005 Study in the British Medical Journal...

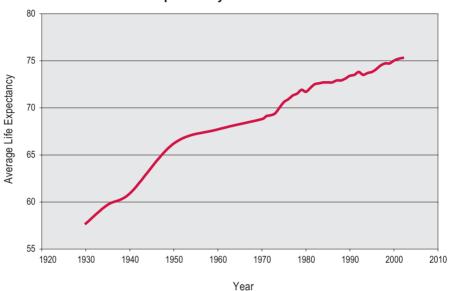
"No excess adult health risk from childhood or teenage overweight was found. Being thin in childhood offered no protection against adult fatness, and the thinnest children tended to have the highest adult risk at every level of adult obesity ...

"The absence of an association between body mass index at age 9 and percentage body fat at age 50 suggests that the association between childhood and adult body mass index, seen in this and previous studies, may mainly reflect tracking of build rather than fatness. Muscle mass and the size of the bony frame also contribute to body mass index. This is particularly relevant in children, in whom obesity is rare and lean mass makes a substantial contribution to body mass index. This may explain why raised childhood and teenage body mass index showed no positive association with risk of adult disease. In fact, the trend was consistently negative, suggesting that those thinnest in childhood have the highest overall risk of adult disease ... Another large early study that measured a similar range of risk factors to ours, also found no overall excess adult disease risk from high childhood body mass index and that men thinnest in childhood were at greatest risk after adjustment for adult body mass index ...

"Current concerns about rising rates of overweight in children also hinge on the assumption that fat children are more likely to become fat adults. Our data suggest a much less deterministic situation. There was a high degree of variation between childhood and midlife in degrees of fatness and no net increase in adult disease risk for overweight children or teenagers ..."124

## Myth: Obesity Will Significantly Shorten Life Expectancy

#### Life Expectancy in the United States



"Olshansky now says ... his life expectancy forecasts might be inaccurate."

—Science, 2005

In 2002, Dr. William Klish of Texas Children's Hospital told *The Houston Chronicle*: "If we don't get this epidemic [of childhood obesity] in check, for the first time in a century children will be looking forward to a shorter life expectancy than their parents." Since then, Klish's statement has entered the lexicon of obesity scaremongers, making its way into countless articles, editorials, and even Congressional testimony—all without so much as a shred of credible research to back it up. Klish himself told the Center for Consumer Freedom that while he is the source of this pessimistic prognostication, his claim does not come from "evidence-based research." Rather, he explained: "It's based on intuition."

On March 17, 2005, more than three years after Klish first suggested the theory, *The New England Journal of Medicine* released a deeply flawed but highly publicized study that appeared to justify Klish's assertion. It claimed that because of obesity, the "youth of today may, on average, live less healthy and possibly even shorter lives than their parents." But like Klish, Dr. S. Jay Olshansky and his co-authors admitted that their dire prediction relied on their "collective judgment" rather than empirical, scientific evidence.

In May 2005, *Science* magazine published an article on the controversy over obesity deaths following the publication of a paper by Dr. Katherine Flegal and co-authors that said the number of deaths from excess weight was just one-fifteenth what the CDC said it had been. In the article, Olshansky appeared to back off his conclusions about life expectancy.<sup>6</sup> According to *Science*:

"Olshansky now says that in light of Flegal's recent paper on obesity deaths and a companion paper that she, Williamson, and other CDC scientists authored in the same issues of *JAMA*, his life expectancy forecasts might be inaccurate."

Even before the Flegal study, Olshansky had more than his share of critics. "The Olshansky piece is seriously flawed," explained Dr. James Vaupel, director of the Max Planck Institute for Demographic Research in Germany. "His perspective is that of an advocate making a case rather than a scientist evaluating the body of conflicting evidence."

Vaupel isn't alone in questioning Olshansky's original prediction. Dr. Robert N. Anderson, the lead author of the CDC's National Vital Statistics Report on life expectancy,

explained that he was extremely skeptical of Klish's and Olshansky's claim about obesity's effect on life expectancy. He told the Center for Consumer Freedom: "I really would be shocked if we got a generation down the road and life expectancy was lower than the previous generation. I really would be surprised ... We've never seen anything like that. Life expectancy has gone up pretty steadily."8

Even noted obesity scaremonger JoAnn Manson, who is profiled later in this report and is one of the few scientists to criticize the Flegal study, told the Associated Press: "the calculations that were made may not be perfect."

So what went wrong with Olshansky's study? Although he purports to show that if the entire nation were an "ideal" weight we might live, on average, a few months longer, he provides no empirical research to back up his foreboding forecast about life expectancy actually decreasing. Instead, without so much as a footnote (except to their own work), he and his co-authors muse that the "trends" in the data suggest the possibility of life expectancy declining.

"These are just back-of-the-envelope, plausible scenarios. We never meant for them to be portrayed as precise." 10

—Study co-author David Allison in Scientific American, June 2005

#### The Authors

No one familiar with the study's authors would be surprised by their conclusions. Olshansky tops the list of the nation's life-expectancy naysayers. Dr. Richard Suzman, associate director of the Behavioral and Social Research Program at the National Institute on Aging, told the Knight-Ridder newswire: "Olshansky's position [on decreasing life expectancy] is a minority perspective in demography."<sup>11</sup>

Dr. Vaupel added, "There is a small chance—less than one in 100—that Olshansky's prediction of declining life expectancy might possibly prove correct." <sup>12</sup>

#### Medical Technology Improvement

Like the 400,000-deaths study, Olshansky's work essentially ignores the influence of medical progress in increasing life expectancy. Despite the enormous gains we've seen (more than six years of life expectancy since 1970), <sup>13</sup> Olshansky and his co-authors write: "We believe that potential forms of technology do not justify developing or revising forecasts for life expectancy." Olshansky's theory is questionable, to say the least. Discussing their aforementioned study that found a dramatic decline in the number of deaths attributed to obesity, Flegal and her co-authors write:

"...the largest difference is due to the inclusion of the mortality data from NHANES II and NHANES III, which decreased estimates by 63% or more relative to NHANES I mortality data alone ... Relative to NHANES I, the more recent data from NHANES II and NHANES III suggest the possibility that improvements in medical care, particularly for cardiovascular disease, the leading cause of death among the obese, and its risk factors may have led to a decreased association of obesity with total mortality. Cardiovascular risk factors have declined at all BMI levels in the US population, but,

except for diabetes, the decline appears to be greater at higher BMI levels. These findings are consistent with the increases in life expectancy in the United States and with the declining mortality rates from ischemic heart disease. Life expectancy increased from 73.7 years in 1980 to 75.4 years in 1990 to 77.0 years in 2000 and continues to increase. Age-adjusted death rates (per 100 000 population) for ischemic heart disease declined from 345.2 in 1980 to 249.6 in 1990 to 186.6 in 2000 and continue to decline."<sup>14</sup>

A second JAMA paper published in April 2005 found:

"Among obese persons today, prevalence of high cholesterol, high blood pressure, and smoking are now 21, 18 and 12 percentage points lower respectively, than among obese person 30 to 40 years ago ... Thus, obese and overweight persons may be at lower risk of [cardiovascular disease] now than in previous eras." 15

An article in *Scientific American* reports:

"The new findings reinforce those published in 2001 by a 10-year WHO [World Health Organization] study that examined 140,000 people in 38 cities on four continents. The investigators, led by Alun Evans of the Queen's University of Belfast, saw broad increases in BMI and equally broad declines in high blood pressure and high cholesterol. 'These facts are hard to reconcile,' they wrote."

Olshansky co-authored the study with longtime obesity doomsayer David Ludwig, who has compared the problem to a SARS outbreak that affects 60 million people.<sup>17</sup> Co-author David Allison presents a number of troubling financial conflicts of interest—so many, in fact, that *The New England Journal of Medicine* published a three-page financial disclosure, listing more than 100 organizations (largely weight-loss companies) from which he has received money.<sup>18</sup>

Despite the controversy surrounding Allison's method of determining the number of deaths attributable to obesity, the authors of the *NEJM* study explain that because they only wanted "plausible estimates rather than precise numbers," they chose to rely on Allison's "simpler approach." Not surprisingly, that "simpler approach" tends to exaggerate the problem.

#### From Science to Activism

Before Olshansky's article was published, the Center for Consumer Freedom set out to determine the veracity of Dr. Klish's initial claim about this generation of children living shorter lifespans than their parents. At that point, dozens of activists, politicians, researchers, and even respected public health officials had already taken Klish's statement and run with it. In March of 2004, Surgeon General Richard Carmona told Congress: "Because of the increasing rates of obesity, unhealthy eating habits, and physical inactivity, we may see the first generation that will be less healthy and have a shorter life expectancy than their parents." 19

But Carmona's spokesman told the Center for Consumer Freedom: "I don't think that there is a study somewhere that life expectancy will shrink if we don't do this. I

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**Excerpted** 

#### **Obesity: An Overblown Epidemic?**

A growing number of dissenting researchers accuse government and medical authorities—as well as the media—of misleading the public about the health consequences of rising body weights.

By: W. Wayt Gibbs

But what about the warning by Olshansky and Allison that the toll from obesity is yet to be paid, in the form of two to five years of life lost? "These are just back-of-the-envelope, plausible scenarios," Allison hedges, when pressed. "We never meant for them to be portrayed as precise." Although most media reports jumped on the "two to five years" quote, very few mentioned that the paper offered no statistical analysis to back it up.

The life expectancy costs of obesity that Olshansky and his colleagues actually calculated were based on a handful of convenient, but false, presuppositions. First, they assumed that every obese American adult currently has a BMI of 30, or alternatively of 35—the upper and lower limits of the "mild obesity" range. They then compared that simplified picture of the U.S. with an imagined nation in which no adult has a BMI of more than 24—the upper limit of "healthy weight"—and in which underweight causes zero excess deaths.

To project death rates resulting from obesity, the study used risk data that are

more than a decade old rather than the newer ratios Flegal included, which better reflect dramatically improved treatments for cardiovascular disease and diabetes. The authors further assumed not only that the old mortality risks have remained constant but also that future advances in medicine will have no effect whatsoever on the health risks of obesity.

simplifications all these reasonable, the March paper concluded, then the estimated hit to the average life expectancy of the U.S. population from its world-leading levels of obesity is four to nine months. ("Two to five years" was simply a gloomy guess of what could happen in "coming decades" if an increase in overweight children were to fuel additional spikes in adult obesity.) The study did not attempt to determine whether, given its many uncertainties, the number of months lost was reliably different from zero. Yet in multiple television and newspaper interviews about the study, coauthor David S. Ludwig evinced full confidence as he compared the effect of rising obesity rates to "a massive tsunami headed toward the United States."20

think that it was just based on some literature that he had read ... It was an amalgamation of the information he has been reading."<sup>21</sup>

In the fall of 2004, the Department of Agriculture's Undersecretary for Food, Nutrition, and Consumer Services told a Congressional subcommittee that "this may be the first generation of children not to live as long as their parents as a direct result of [childhood obesity]."<sup>22</sup> His spokesman did not return follow-up calls after telling the Center for Consumer Freedom in an initial conversation that he could not find any research to substantiate this claim.<sup>23</sup>

In the summer of 2004, when *TIME* magazine and ABC News co-hosted a highly publicized and decidedly one-sided conference on obesity, the head of the Robert Wood Johnson Foundation (RWJF) began the proceedings by saying: "If we don't do something to reverse these trends, we will raise the first generation of Americans to live sicker and die younger than their parents." Announcing an initiative to fight childhood obesity, President Bill Clinton said: "For the first time in American history, our current generation of children could live shorter lives than their parents." Similarly, National Governors Association chairman Mike Huckabee announced his "Healthy America" initiative citing the study.

A similar statement showed up in a report from the RWJF-funded Trust for America's Health, titled "F as in Fat: How Obesity Policies Are Failing in America." The first page of the proposal reads: "many experts ... predict that the nation's younger generation may be the first in American history to live sicker and shorter lives than their parents." When asked

if they could name their "many experts," the group cited three: the Surgeon General, Klish, and "someone" at the CDC. (After a day of searching all the CDC could produce was an editorial quoting a doctor affiliated with the agency's VERB program.)<sup>27</sup>

The Trust's spokesperson added: "The reason that we use these kinds of facts is because it does draw press attention to the problem ... A lot of policy organizations [use sound-bites that do not rely on scientific literature], because they draw attention, quite honestly."28

Preventive Medicine Research Institute founder Dean Ornish offered a similar explanation for his (and others') regurgitation of Klish's and Olshansky's false claim: "I think this gets quoted because it gets people's attention to what is a real problem that only seems to be getting worse. To that extent, it can be useful." <sup>29</sup>

Altogether, the Center for Consumer Freedom contacted more than a dozen people who had stated publicly that child-hood obesity would make this the first generation of children to have a shorter lifespan than their parents. And time after time, they failed to provide a single source to back up their claim. The only exception was Yale professor David Katz, who cited two studies that supposedly prove his point that obesity is shortening life expectancy.<sup>30, 31</sup> Neither study substantiates this claim.

Although both studies indicate that the severely obese may suffer health complications due in part to their weight, they don't come close to suggesting that obesity could change the CDC's estimate that children born in 2004 are expected to live more than six years longer than their parents.<sup>32</sup>

Neither does the research of Olshansky, Ludwig, Allison, and their colleagues.

## Myth: You Can't Be Overweight and Healthy

"Groundbreaking work on fitness and weight has been done by [epidemiologist Steven] Blair and colleagues at the Cooper Institute. They have shown that the advantages of being fit are striking and that people can be fit even if they are fat ... and thus have lowered risk of disease. A remarkable finding is that heavy people who are fit have lower risk than thin people who are unfit."

—Dr. Kelly Brownell, Director of the Yale Center for Eating and Weight Disorders, 2003

"Consistently, physical inactivity was a better predictor of all-cause mortality than being overweight or obese."<sup>2</sup>

—Annals of Epidemiology, 2002

"There was a steep inverse gradient between fitness and mortality in this cohort of men with documented diabetes, and this association was independent of BMI ... Obese men with fitness levels greater than the lowest quartile were at no increased risk for mortality when compared with men in the reference group."

-Diabetes Care, 2004

"[A] fit man carrying 50 pounds of body fat had a death rate less than one-half that of an unfit man with only 25 pounds of body fat."

—Harvard Health Policy Review, 2003

"We've studied this from many perspectives in women and in men and we get the same answer: It's not the obesity—it's the fitness." 5

-Steven Blair, P.E.D., Cooper Institute for Aerobics Research, 2004

"In Greek schoolchildren, primary CHD [coronary heart disease] risk factors are mainly associated with physical

activity levels, independently of fitness, fatness, and/or fat intake... It is noteworthy that the present data contradict recent reports citing obesity as the single most important contributor in the pathogenesis of CHD during childhood ... Confirming a previous report in Greek children, we found that the CHD risk factors studied were not substantially affected by qualitative aspects of diet."<sup>6</sup>

-Archives of Disease in Childhood, 2004

"Active obese individuals actually have lower morbidity and mortality than normal weight individuals who are sedentary ... the health risks of obesity are largely controlled if a person is physically active and physically fit."

—The President's Council on Physical Fitness and Sports, 2000

"Compared with normal weight, overweight and obesity did not significantly increase all-cause mortality risk. Compared with low CRF [cardiorespiratory fitness], moderate and high CRF were associated significantly with lower mortality risk."8

-Obesity Research, 2002

"Obese individuals with at least moderate CRF [cardiorespiratory fitness] have lower rates of cardiovascular disease (CVD) or all-cause mortality than their normal-weight but unfit peers. In fact, death rates in the former group are about one half those of the latter."

-Editorial, JAMA, 2004

"Unfit, lean men had twice the risk of all-cause mortality as did fit, lean men and also had higher risk of all-cause mortality when compared with fit, obese men. The all-cause mortality rate of fit, obese men was not signifi-

cantly different from that of fit, lean men ... In summary, we found that obesity did not appear to increase mortality risk in fit men. For long-term health benefits we should focus on improving fitness by increasing physical activity rather than relying only on diet for weight control."<sup>10</sup>

—American Journal of Clinical Nutrition, 1999

"The report from the Aerobics Center Longitudinal Study presents convincing evidence that fitness is a more potent risk factor for mortality than is fatness ... an effect of fitness that was statistically independent of the level of fatness was confirmed. The effect of fatness independent of fitness was less clear."

11

—American Journal of Epidemiology, 2002

"If the height/weight charts say you are 5 pounds too heavy, or even 50 pounds or more too heavy, it is of little or no consequence healthwise—as long as you are physically fit. On the other hand, if you are a couch potato, being thin provides absolutely no assurance of good health, and does nothing to increase your chances of living a long life."<sup>12</sup>

—Steven Blair, P.E.D., Cooper Institute for Aerobics Research, 1997

"This prospective follow-up study among middle-aged and elderly men and women indicates that obesity (as assessed by increased BMI) is not related to an increased risk of all-cause and CVD mortality, but low-level LTPA [leisure time physical activity] and a low level of perceived physical fitness and functional capability are ... In conclusion, in contrast with our initial hypothesis, obesity was not found to be an independent predictor of mortality among

middle-aged and elderly men and women. However, low-level LTPA seemed to predict and a low level of perceived physical fitness and functional capability predicted an increased risk of all-cause and CVD mortality among both men and women."<sup>13</sup>

—International Journal of Obesity Related Metabolic Disorders, 2000

"An interesting finding of this study is that overweight, but fit men were at low risk of all-cause mortality." <sup>14</sup>

-International Journal of Obesity Related Metabolic Disorders, 1998

"Most studies of BMI and other measures of obesity have not adequately accounted for physical fitness, a known modifier of weight status and a potential mediator of the effects of obesity on CAD [Coronary Artery Disease] and adverse CV outcomes ... Our data support previous studies showing that functional capacity appears to be more important than BMI for all-cause and CV mortality, especially in women." 15

—JAMA, 2004

Fitness vs. Fatness: Relative Risk of All-Cause Mortality			
Normal weight and fit 1			
Normal weight and unfit		2.2	
Overweight and fit 1.1			
Overweight and unfit		2.5	
Obese and fit 1.1		_	
Obese and unfit			3.1

(Source: Wei et al. "Relationship Between Low Cardiorespiratory Fitness and Mortality in Normal-Weight, Overweight, and Obese Men." *JAMA*. 1999;282: 1547-1553.)

#### -Excerpted-

# Obesity Epidemic That Isn't: Get Moving, Get Healthy

By Dr. Howard Brody, Michigan State University Professor of Medical Ethics

My colleague, Dr. Henry Barry, runs a session for physicians attending a special fellowship program at the College of Human Medicine at Michigan State University. The goal is to teach them research skills that they can apply to a quality-improvement project in their own offices.

Barry suggested asthma as a good focus for the project, but these docs knew better. They had heard all about the huge obesity epidemic sweeping the nation, and they wanted to get their practices geared up to fight this foe.

So Barry gave them their marching orders. They had to carefully review the medical journals for scientific studies that showed, first, what sort of problem obesity was, and next, what truly worked to fix it.

The physicians were a bit sheepish when they came back after doing their

homework. To oversimplify a bit in the name of bluntness, what they found in the scientific data was first, there's no evidence that obesity itself is a health problem; and second, there's no evidence that if it were, we does have a clue as to what to do about it.

Now that sounds like heresy in today's world, so let me explain.

There are a lot of studies, all of which show obese people have worse health and die sooner. The trouble is that few of the studies carefully separate out two factors—obesity and inactivity. The obese folks also are inactive, as a rule, so which one actually causes the harm?

Some suggestive evidence would cause us to think that it may well be the inactivity, not the obesity. When you can get fat folks moving around, they tend to get healthier, even if they don't lose any weight. So maybe our problem is we have an inactivity epidemic, not an obesity epidemic.<sup>16</sup>

#### What About That Harvard Study?

In 2004, a study conducted by researchers from the Harvard School of Public Health claimed that physical activity does not negate the adverse health effects associated with obesity. Of this study's many flaws, one stands out: its measurement of exercise. The authors accounted only for running, jogging, walking (outside, but not on a treadmill), biking, swimming laps (but not swimming in a lake or the ocean), calisthenics (rowing counts, but not yoga), tennis, and squash and racquetball.

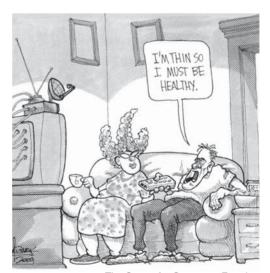
Perhaps they had never heard of basketball or other team sports, not to mention yard work, work-related exercise, or any of the other physical activities that are part of our daily lives. And considering that the study's data were collected from more than 116,000 nurses, you might think the authors would have included the often strenuous activities associated with the nursing profession.

According to the American Cancer Society, "[s]urveys that ignore occupational activity may underestimate activity for some population groups that report little or no leisure-time activity." <sup>18</sup>

#### The Cost of Physical Inactivity

Physical inactivity causes a tremendous burden of disease and death. Researchers commissioned by the President's Council on Physical Fitness and Sports coined the phrase "Sedentary Death Syndrome." And no wonder. In 2000, *The Journal of Applied Physiology* reported that approximately "250,000"

deaths per year in the United States are premature due to physical inactivity."<sup>20</sup> The Active Living by Design program indicates that "34% of coronary heart disease deaths can be attributed to physical inactivity; physically inactive adults are nearly twice as likely than those who are active to have coronary heart disease."<sup>21</sup> A study in the journal *Medicine and Science in Sports and Exercise* reports: "Sedentary living is responsible for about one-third of deaths due to coronary heart disease, colon cancer, and diabetes."<sup>22</sup> And according to an article in *The New England Journal of Medicine*, the risk of death among the least fit is four times greater than it is among the most fit.<sup>23</sup>



—The Center for Consumer Freedom

#### Fat People and Exercise

"If fat people get fit, they accrue the health benefits of increased physical activity regardless of whether or not they lose body fat in the process."<sup>24</sup>

—Professor Chris Riddoch, Department of Exercise & Health Sciences, University of Bristol, 2004

- "...an overweight or obese person can have good cardiovascular health as long as he/she remains active and possesses a reasonable level of fitness."25
  - —The President's Council on Physical Fitness and Sports, 2000
- "Adiposity [fatness] does not hinder the fitness response to exercise training in obese women." <sup>26</sup>
  - —Journal of Sports Medicine and Physical Fitness, 2000

## Myth: Overeating Is the Primary Cause of Obesity



—Tom Toles

"So it's perhaps surprising that, in a debate that has often focused on foods alone, actual levels of caloric intake among the young haven't appreciably changed over the last twenty years."

> —Then-FDA Commissioner Dr. Mark McClellan, 2003

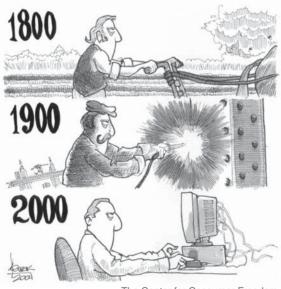
"Television. Cars. Computers. Remote controls. Elevators. Escalators. E-mail. Leaf-blowers. Golf carts. Automatic doors. Automatic windows. Automatic toilet-flushers. It all adds up. Little by little, we're turning into a nation of couch potatoes. And we're paying a price for it. Inactive people have a higher risk of heart disease, diabetes, colon cancer, obesity, and osteoporosis ... Getting off the couch doesn't just ward off life-threatening illness. It may also

help you function like you're 20 years younger, cut your odds of ending up in a nursing home, help you sleep better, ward off colds, and improve your outlook on life."<sup>2</sup>

—Nutrition Action HealthLetter, newsletter of the Center for Science in the Public Interest. 1999

"The lack of evidence of a general increase in energy [food] intake among youths despite an increase in the prevalence of overweight suggests that physical inactivity is a major public health challenge in this age group."<sup>3</sup>

—American Journal of Clinical Nutrition, 2000



—The Center for Consumer Freedom

"These results suggest that habitual activity plays an important role in weight gain, with no parallel evidence that energy intake had a similar role ... The composite findings from NGHS so far indicate that the drastic decline in habitual activity during adolescence might be a major factor in the doubling of the rate of obesity development in the USA in the past two decades, since no concomitant increase in energy intake was apparent."<sup>4</sup>

—Lancet, 2005

"The obesity epidemic is driven, in my view, more by decreases in average daily energy expenditure than by increases in average daily energy intake. Unfortunately we do not have data on average daily energy expenditure or on changes in this variable, and the data we have on average daily energy intake are questionable. Therefore the fundamental cause of the increases in obesity prevalence observed over the past several years cannot be determined."

—Steven Blair, P.E.D., Cooper Institute for Aerobics Research, 2005

"Of the 7 dietary and physical activity variables examined in this cross-sectional study, insufficient vigorous physical activity was the only risk factor for higher body mass index for adolescent boys and girls ... Interestingly, in this group of adolescents, increased energy intake (higher kilojoules) was related to decreased overweight status. At first, this finding appears contradictory. However, given the increasing levels of vigorous activity among this group, it is likely that they expend greater amounts of energy, creating a favorable energy balance."

—Archives of Pediatric & Adolescent Medicine, 2004

"Contrary to hypotheses, elevated intake of highfat foods, binge eating, and exercise did not predict obesity onset."

—Journal of Consulting and Clinical Psychology, 2005

"A reduction in energy expenditure must be the main determinant of the current epidemic of obesity." [Note: this study also found that people who exercise the most had a 57 percent lower chance of being obese.]

-International Journal of Obesity, 1995

"Inactivity is a major cause of obesity in the United States. In fact, inactivity might be a far more significant factor in the development of obesity than overeating." 9

—The President's Council on Physical Fitness and Sports, 2004

"It is often assumed that the increase in pediatric obesity has occurred because of an increase in caloric intake. However, the data do not substantiate this." <sup>10</sup>

—Journal of Clinical Endocrinology & Metabolism, 2004

"In fact, several investigators report that the calorie intake (defined in absolute or weight-adjusted units) of obese persons is not greater and may be less than the intake of nonobese persons. Body weight, body fat, and lean body mass were also not associated with caloric intake in our study of obese men ... [W]e conclude that the nonsignificant correlations between obesity measures and total caloric intake suggests that variations in the level of obesity among these sedentary overweight men cannot be directly related to caloric consumption and may reflect sedentary lifestyle."

—American Journal of Clinical Nutrition, 1988

"... there has been no relationship between either total energy intake or fat consumption and the prevalence of clinical obesity over the last 60 years, whilst proxy measures of physical inactivity (TV viewing and car ownership) are closely related."<sup>12</sup>

—British Medical Bulletin, 1997

"Evidence suggests that modern inactive lifestyles are at least as important as diet in the aetiology [origin] of obesity and possibly represents the dominant factor." <sup>13</sup>

-British Medical Journal, 1995

"... those who were obese and reported the least physical activity had the lowest caloric intake." <sup>14</sup>

—American Journal of Preventative Medicine, 2003

"Results from this study show that adiposity was not related to either absolute or relative energy intake for males and only to absolute energy intake for females; this relationship disappeared when consumption was expressed relative to body weight or lean body mass. Drean *et al.* similarly found no relationship between energy intake and body fat in middle-aged men. Studies in the German Democratic Republic and from the National Health and Nutrition Examination Survey that used large databases, indicate that normal-weight and overweight persons ingest about the same number of joules." <sup>15</sup>

—American Journal of Clinical Nutrition, 1990

"Energy intakes per person were [about] 7% lower in 1994 than in 1977–78." <sup>16</sup>

—American Journal of Clinical Nutrition, 2000

"Dietary factors were not associated with BMI across the three study years ... Moreover, there was no significant correlation between time spent watching television and the percentage of calories consumed from fat in any of the three observation years."17

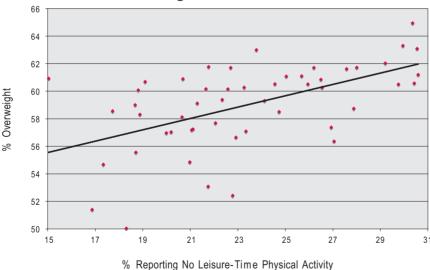
—International Journal of Obesity, 2005

"... from 1980 through 2000, obesity increased 10 percent, physical activity decreased 13 percent and caloric intake rose 1 percent among U.S. adolescents."18

-Dr. Lisa Sutherland, University of North Carolina, 2003

"... about 40 percent of the recent growth in weight seems to be due to agricultural innovations that have lowered food prices, while 60 percent may be due to demand fac-

#### Leisure-Time Physical Activity and Overweight Levels in the 50 States



States with a higher percentage of citizens reporting no leisure-time physical activity report higher rates of overweight and obesity.

(Source: Behavioral Risk Factor Surveillance System 2003 and the American Cancer Society)

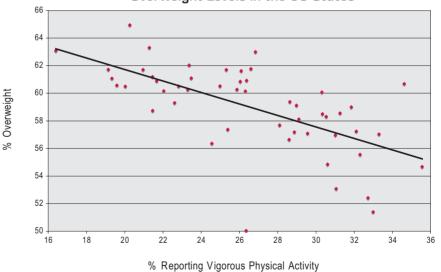
tors such as declining physical activity from technological changes in home and market production ... [T]his secular growth in weight has been accompanied by only modest gains in calorie consumption. Indeed, the immediate postwar period witnessed substantial growth in weight and *declining* consumption of calories."<sup>19</sup>

-National Bureau of Economic Research, 2004

"After 14 years of working, those in the least sedentary occupations have about 3.5 units of BMI less than those in the most sedentary ones."<sup>20</sup>

—Harvard Institute of Economic Research, 2003

#### Vigorous Physical Activity and Overweight Levels in the 50 States



States with a high percentage of citizens participating in vigorous physical activity report lower rates of overweight and obesity.

(Source: Behavioral Risk Factor Surveillance System 2003 and the American Cancer Society)

#### The State of Physical Activity

- "Only about one-half of U.S. young people (ages 12-21 years) regularly participate in vigorous physical activity. One-fourth report no vigorous physical activity."<sup>21</sup>
- Only 15 percent of U.S. adults engage regularly (three times a week for at least 20 minutes) in vigorous physical activity during leisure time.<sup>22</sup>
- "According to annual tracking surveys initiated in 1987 by American Sports Data, Inc., the fitness revolution reached its apogee in 1990. Since that time, the number of frequent fitness participants in the U.S. has fallen imperceptibly from 51 million in 1990, to 50.9 million in 2002. But factoring out population growth, there has been a per capita decline of 15% in frequent fitness participation (100+ days per year in any one activity). Among children 12-17, the plunge is 41%—hard evidence of a monumental neglect that mirrors the dilapidated state of physical education in U.S. public schools."<sup>23</sup>
- More than 60 percent of American adults are not regularly physically active.<sup>24</sup>
- "More than a third of young people in grades 9-12 do not regularly engage in vigorous physical activity. Daily participation in high school physical education classes dropped from 42 percent in 1991 to 29 percent in 1999."25
- About 25 percent of adults report no physical activity at all in their leisure time. 26

- From 1977 to 1995, the number of walking and biking trips made by children declined by 61 percent.<sup>27</sup> The National Sporting Goods Association's Youth Participation in Selected Sports survey reports that bicycle riding among adolescents dropped more than 25 percent between 1996 and 2002.<sup>28</sup> And according to the Kaiser Family Foundation, a child is six times more likely to play a video game than ride a bicycle in a typical day.<sup>29</sup>
- 75 percent of all trips less than a mile are taken by car.30
- "With Americans using cars for 89 percent of all their trips, it is not surprising that the number of trips the average American adult takes on foot each year dropped 42 percent between 1975 and 1995."<sup>31</sup>
- Yale professor Kelly Brownell reports: "There's only one state in the country that mandates daily physical education in schools, and that happens to be Illinois. In the rest of the country it's district by district and highly variable. In some places children get almost no physical education in high school. In other places they might get one or two days a week. But even then, studies have shown that out of a typical gym period, only six minutes are spent being physically active! The rest of the times it's standing in line, visiting with your friends, standing around waiting for the ball to come to you, things like that. So the amount of physical education students get is actually very small—it can be measured in minutes per week. It's hard to imagine that we're going to have a fit nation if that's what we're teaching our kids in school."32

- According to the journal *Pediatrics*, "only 21.3% of all adolescents participated in 1 or more days per week of PE in their schools."<sup>33</sup>
- The Urban Institute reports: "Using Labor Department data, we estimate that the percentage of workers in physically demanding jobs has dropped substantially—from about 20 percent in 1950 to almost 8 percent in 1996 (figure 1). (Physically demanding jobs are defined as requiring frequent lifting or carrying of objects weighing more than 25 pounds.) Our estimate probably understates the decline because it does not take into account the possibility that even jobs classified as physically demanding today are less strenuous than jobs in the past. In addition, the drop in the number of workers in physically demanding jobs was most dramatic among older age groups."<sup>34</sup>

#### Other Causes of Obesity: Little Things That Can Add Up Over Time

**Yo-Yo Dieting:** "Despite the increased prevalence of intentional weight loss, weight cyclers ["yo-yo dieters"] gained more weight than noncyclers between 1993 and 2001." <sup>35</sup>

—Harvard researchers writing in the International Journal of Obesity, 2004

**Video Games:** "This study provides the strongest evidence for an independent association between time spent playing electronic games and childhood obesity."<sup>36</sup>

—Obesity Research, 2004

**Depression:** "We also found support for the hypothesis that depressive symptoms would predict obesity onset ... for each additional depressive symptom reported by an adolescent,

there was more than a fourfold increase in risk for obesity onset, which suggests that this effect is clinically meaningful in magnitude." <sup>37</sup>

—Journal of Consulting and Clinical Psychology, 2005

**Sleep Deprivation:** "For participants who sleep less than eight hours a night—74 percent of the group—BMI was inversely proportional to sleep duration. That is, the less sleep a subject got, the greater the person's BMI and thus the more overweight." <sup>38</sup>

—Tufts University Health & Nutrition Letter, 2005

"In young men allowed to sleep only 4 hours/night for 2 days, leptin decreased and ghrelin increased relative to the pattern seen with 10 hours of sleep on each of two nights. Thus, our epidemic of obesity may reflect one response to less sleep." <sup>39</sup>

—Journal of the American Dietetic Association, 2005

**Birth Control:** "Quasi-experimental studies of [birth control] implants do show a significant association [with weight gain]. Norplant use is associated with an average weight gain of 2.2 lbs per year. Six quasi-experimental and non-experimental studies examined the association between use of the injectable, Depo Provera, and weight gain. Results indicate that women using Depo Provera do gain weight in the first year (2.5 –12 lbs) and in subsequent years."<sup>40</sup>

—Oregon Department of Human Services, 2004

**Infant Formula:** "The main finding of the present study was that weight gain during the first week of life in healthy, European American, formula-fed infants was associated with overweight status 2 to 3 decades later."<sup>41</sup>

—Circulation, 2005

#### **Smoking Cessation and Weight Gain**

"For men, about a quarter and for women, about a sixth of the increase in the prevalence of overweight could be attributed to smoking cessation within the past 10 years."42

-The New England Journal of Medicine, 1995

"There is no question that smoking affects the epidemic of obesity," said Dr. Neil Grunberg, a psychologist and neuroscientist at the Uniformed Services University in Bethesda, Md. Smokers who quit, he noted, gain about 10 to 12 pounds on average, in part because they crave sweet foods and carbohydrates. In addition, Dr. Grunberg said, smokers' metabolism slows down after they quit ... 'I sure would like for people not to be obese,' [CDC researcher] Dr. Williamson said. But, he added, if they got that way because they don't smoke, then 'maybe the sky isn't falling quite as much as we think it is.' "43

-The New York Times, December 19, 2004

"Rising cigarette prices account for as much as 20 percent of increasing BMI."44

-National Bureau of Economic Research, 2001

#### Myth: Food Marketing Is Making Kids Fat

"While it might seem obvious that bombarding kids with sales pitches for cartoon-character cereal and snacks contributes to the obesity epidemic among U.S. children, scientists say the hard evidence is thin."45

—Reporter Betsy McKay in The Wall Street Journal, 2005

"There is only circumstantial evidence that the ads cause poor eating." 46

 —Center for Science in the Public Interest Scientific Advisory Board member and Yale University professor Kelly D. Brownell

"Despite media claims to the contrary, there is no good evidence that advertising has a substantial influence on children's food consumption and, consequently, no reason to believe that a complete ban on advertising would have any useful impact on childhood obesity rates." 47

—Imperial College School of Medicine Epidemiology Professor David Ashton in the Journal of the Royal Society of Medicine, 2004

"...the data seems to suggest that kids are seeing probably less advertising than they've ever seen before. Kids are watching less television and probably are exposed to less advertising than they ever have before. Certainly they are watching more DVDs and videos and certainly playing more video games. But it's not clear the extent to which food advertising is prevalent in those media. Kids are spending unquestionably more sedentary time in front of screens, like computers, DVDs, and the like, but they seem to be watching television less and being exposed to less advertising than ever before." 48

—Former Director of the Federal Trade Commission's Office of Policy Planning and George Mason University law professor Todd Zywicki, 2005

### Myth: Mandatory Nutritional Information on Restaurant Menus Will Reduce Obesity

"What we did in making nutrition labeling mandatory did not help obesity. In fact, some people would say it hurt ... The first thing we notice is this contradiction about the fact that we had mandatory nutrition labeling for ten years, and the situation got steadily worse during that time."<sup>49</sup>

—Former Food and Drug Administration Commissioner Lester Crawford at the World Obesity Congress and Expo, 2004



—The Center for Consumer Freedom

"Recent consumer choice studies suggest that the effect of nutritional information on diet in [restaurant] settings may be modest. For example, a Pennsylvania State University study of food intake among normal-weight women found that explaining the concept of energy density (number of calories per gram of food) and providing nutrition information on labels during meals in a laboratory setting had no impact on subjects' energy intakes. A restaurant study in England found that providing nutrition information had no effect on overall energy and fat intake of patrons. In fact, the presence of 'lower-fat' information was associated with fewer restaurant patrons' selecting the target dish.

Another study in an Army cafeteria found no significant difference between sales before and after nutrition labeling for either average "healthy" (labeled, containing less than 15 grams of fat and 100 milligrams of cholesterol per serving) entrée sales or the proportion of healthy entrées to total entrée sales."<sup>50</sup>

—Amber Waves, 2005

"The pattern of food intake across the different levels of energy density was similar when nutritional information was provided and when it was not. In this population, explaining the concept of energy density and providing nutritional information during meals had no overall impact on the weight of food consumed." 51

—*Appetite*, 2002

"The presence of factual 'lower fat' information did not substantially affect expectations of sensory quality and acceptance, or overall energy and fat intake, though it was associated with a trend toward a decreased proportion of restaurant patrons selecting the target dish." <sup>52</sup>

—Public Health Nutrition, 1999

"A recent laboratory study of food intake among normal-weight women found that explaining the concept of energy density and providing nutrition information on labels during meals had no impact on energy intake. Similarly, a controlled experiment in a restaurant setting in England found that provision of nutrition information had no effect on overall energy and fat intake." 53

—American Journal of Preventative Medicine, 2004

#### The "Toxic Food Environment" Causes Obesity

"Our data suggest that public health policy targeting takeaway food and eating out are likely to have little impact."54

—International Journal of Obesity, 2005

The so-called "toxic food environment" is often blamed for contributing to American obesity. Activists and academics claim that the number of convenient, inexpensive food options makes it too easy to eat. But leading research published in The International Journal of Obesity in 2005 determined that "there was no relationship between availability of eating places and prevalence of obesity." The study found:

"Takeaway and fast foods are increasingly being blamed for the obesity epidemic; however, this linkage has not been convincing. ... In these disparate towns no relationship between availability of takeaway foods and the prevalence of obesity was found. We also found no correlation between increasing takeaway consumption and obesity measured by either BMI or waist circumference ... This study provided an excellent opportunity to test whether towns with greater availability of takeaway foods and restaurants have a higher prevalence of obesity. No such association was found: fast food consumption was not associated with greater obesity, although those consuming no takeaways had a lower waist circumference. The only major identifiable risk factor for the alarmingly high prevalence of obesity was physical activity. While debate on influencing the food supply and dietary intake continues, implementation of strategies which increase physical activity are urgently required."55

The United States Department of Agriculture (USDA) adds that overall consumption of "good" foods, such as fresh fruits, is up:

"Total fruit consumption in 2000 was 12 percent above average annual fruit consumption in the 1970s. Fresh fruit consumption (up 28 percent during the same period) outpaced processed fruit consumption (up 2 percent). Noncitrus fruits accounted for all of the growth in fresh fruit consumption. Total vegetable consumption in 2000 was 23 percent above average annual vegetable consumption in the 1970s. As in the case of fruit, fresh vegetable use (up 26 percent during the same period) outpaced processed vegetable use (up 21 percent)."56

#### Roland Sturm from the RAND Institute reports:

"There were no significant effects for dairy or fast-food prices, nor for outlet density ... We initially expected food outlets to play an important role, but no association was found ... [T]he absence of an effect on weight change in our data could also be an indication that density, or at least the variation in density, of food outlets has a smaller impact on diet than commonly assumed."57

#### Myth: Healthy Food Is Too Expensive

According to the USDA:

"Among the 69 forms of fruits and 85 forms of vegetables included in the analysis, more than half were estimated to cost 25 cents or less per serving in 1999, and 86 percent of all vegetables and 78 percent of all fruit cost less than 50 cents a serving. That's 127 different ways to eat a serving

of fruits and vegetables for less than the price of a 3-ounce candy bar. In fact, consumers can meet the [Food Guide Pyramid | recommendations of three servings of fruits and four servings of vegetables daily for as little as 64 cents. Consumers trying to meet the 5-a-day challenge could do so for even less."58

In 2005, Washington Post food columnist Sally Squires asked: "What about eating according to the new U.S. Dietary Guidelines? Can you do it without taking a big bite out of your wallet?"59 Her answer:

"A little more than \$5 for a full day's worth of modestly priced nutritious food (including oatmeal, milk, fresh fruit; beans and rice; whole grain and white bread, a hearty salad and a cup of peas). That's about the cost of one average fast-food meal."

When asked whether eating a sound diet costs less, Center for Science in the Public Interest Executive Director Michael Jacobson acknowledged: "Unprocessed, basic foods are frequently dirt cheap. Potatoes sometimes go for as little as a nickel or dime a pound in many places, and they're one of the very most nutritious foods. Beans and rice are very inexpensive."60

## Myth: Soda Causes Childhood Obesity



—Jeff Parker

"...the inclusion of sugar-sweetened beverages in the snack food category did not meaningfully change the results. Regardless of the definition of snack food, there was not a strong association between intake of snack foods and weight gain ... Our data did not offer support for the hypothesis that snacking promotes weight gain."

—Harvard researchers writing in the International Journal of Obesity and Related Metabolic Disorders, 2004

"These data indicate that snacking [including soda]—in and of itself—is not associated with an increased prevalence of obesity. Contrary to our expectations, our findings did not indicate any association between snacking patterns and BMI, nor did we find great differences in dietary intake patterns based on snacking habits."<sup>2</sup>

—Journal of Human Nutrition, 2003

"There was no relationship between RCSD consumption from all sources and BMI in either the CSFII or the

NHANES data. The risk assessment showed no impact on BMI by removing RCSD consumption in school. These findings suggest that focusing adolescent overweight prevention programs on RCSD in schools will not have a significant impact on BMI."3

-Risk Analysis, 2005

"BMI was not associated with consumption of milk, regular carbonated beverages, regular or diet drinks/ades, or noncitrus juices."4

—International Journal of Food Sciences and Nutrition, 2003

"Total daily energy intake from the sum of calories from chips, candy, soda, baked goods, and ice cream was significantly higher in the non-obese than in the obese group."5

—Obesity Research, 1999

"Despite concerns about the adverse effects of sugar on body weight levels, the majority of epidemiological studies have demonstrated no positive correlations between sugar consumption and obesity."6

-European Journal of Clinical Nutrition, 1999

"Children from schools with and without sales of soft drinks consumed an average of 33.5 and 32.5 g of sucrose per day respectively. Availability of soft drinks at schools was not associated with significantly increased risks of overweight. Children attending schools with more frequent physical education classes were increasingly more likely to have normal body weight ..."7

#### Debunked

Four published studies claim to show a connection between childhood obesity and soda consumption. All of them have significant limitations.

#### Study 1 - Journal of Pediatrics, 2003

The authors readily admit: "Unfortunately, the sample size was too small to provide sufficient power for the observed difference in weight gain to be statistically significant." That's because their study was based on a sample of only 21 children. They also note: "Similar trends in weight gain, just stronger, was [sic] observed with excessive consumption of fruit juice." In fact, the study found that children who drank more than 12 ounces of fruit juice each day gained three times as much weight as kids who consumed more than 16 ounces of soda.8

#### Study 2 - British Medical Journal, 2004

Children in England were given anti-soda lessons and compared with children who did not receive the lessons. In the first group, the number of obese kids dropped from 16 to 14. But obesity also declined—from 15 to 14 among kids who did not receive the lessons. Moreover, the difference in BMI between the two groups was not statistically significant.9

#### Study 3 - Obesity Research, 2004

While claiming to show that soda consumption was linked to childhood weight gain, this study found that diet soda consumption was more closely linked to

obesity than sugar-added beverages. At the same time, it determined that fruit juice outpaced sugar-added beverages in contributing to weight gain. It also found that children consumed three times more milk than sugar-sweetened beverages.10

#### Study 4 - Lancet, 2001

The authors admit: "There was no independent, significant association between baseline consumption [of sugar sweetened drinks, including soda] and obesity ... The study has limited statistical power, with 548 children (the entire cohort) in analyses of BMI, but only 37 in estimates of incident obesity."11 This compares with the aforementioned study of 14,000 children by Harvard researchers,12 which concluded soda and snack consumption were not linked to obesity.

#### Myth: High-Fructose Corn Syrup Is **Especially Fattening**

In 2004, researchers George Bray and Barry Popkin published a study blaming high-fructose corn syrup for contributing to obesity in America.<sup>13</sup> The study caused enormous controversy. Even Michael Jacobson of the Center for Science in the Public Interest told the Associated Press that "the authors of this paper misunderstand chemistry, draw erroneous conclusions and have done a disservice to the public in generating this controversy."14

Meanwhile, New York University nutrition professor Marion Nestle explained: "It's basically no different from table sugar. Table sugar is glucose and fructose stuck together.

Corn sweeteners are glucose and fructose separated. The body really can't tell them apart."15



—The Center for Consumer Freedom

"Evidence for the association between sugarsweetened drink consumption and obesity is inconclusive ... [N]ational data showed no association between sugar-sweetened beverage consumption and BMI [body mass index] calculated from self-reported height and weights of children and adolescents."16

> —CDC research published in the International Journal of Obesity, 2005

## Myth: Obesity Costs \$117 Billion Annually



—The Center for Consumer Freedom

### The authors used an incorrect definition of obesity.

In 2004, the major media reported in more than 450 stories that obesity costs the U.S. economy \$117 billion every year. Where did this figure come from? In March 1998, the journal *Obesity Research* published a study that arrived at this estimate for the costs of both direct medical expenses and indirect losses, including diminished productivity. In December 2001, "The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity" cited that figure, and the myth was born.

The study that originated the \$117 billion figure had serious limitations, as the authors themselves admitted. "We are still uncertain about the actual amount of health utilization associated with overweight and obesity," they wrote.

"Height and weight are not included in many of the primary data sources"

The authors also acknowledged that their methodology allowed for the "double-counting of costs," which "would inflate the cost estimate." If, for example, an obese man were hospitalized with hypertension, cancer, and diabetes, his expenses would have been counted three times.

Finally, the authors used an incorrect definition of obesity. A BMI of 30 or higher makes you obese, but the authors decided to set their threshold at 29. A small error? Not at all. They wrongly included the healthcare costs of more than 10 million non-obese Americans, including Bruce Willis, Harrison Ford, and George Clooney, each of whom has a BMI of 29.4

In 2000, a team of CDC experts concluded that increased rates of moderate exercise "among the more than 88 million inactive Americans over the age of 15" could reduce medical costs by more than \$75 billion annually. When they included indirect expenses, these researchers concluded that physical

#### **Graham Colditz's Costly Study**

Graham Colditz—co-author of the study that mistakenly blamed obesity for an annual \$117 billion hit to the U.S. economy-has received funding from Roche, maker of the weight-loss pill Xenical. He also co-authored a 1999 study on the economic benefits of weight loss among obese people. That study was funded by Knoll, maker of the weight-loss pill Meridia.

inactivity alone costs \$150 billion each year. That's nearly 30 percent more than the (exaggerated) \$117 billion estimate of direct and indirect costs of obesity.

Commenting on papers describing the mortality, morbidity, and cost of obesity in Switzerland, the CDC's Dr. Katherine Flegal describes some common pitfalls. These same comments can apply to nearly all estimates of the costs of obesity:

"These two papers continue several unfortunate trends in the obesity literature ... Using the incorrect formula and calculating attributable fractions without adjusting for confounding could give rise to an overestimation of the impact of obesity ... Assuming that age-adjusted relative risks are the same for all ages can lead to additional overestimation if the true relative risks are lower in the elderly."8

#### Is Obesity Really the Cause?

"...there was no statistically significant relationship between obesity and medical expenditures."

Studies that attempt to calculate the cost of obesity generally do not control for potentially confounding factors. A 2005 study published in Obesity Research attempted to correct this failing, and concluded that after controlling for health status and socioeconomic factors, "there was no statistically significant relationship between obesity and medical expenditures."9 The article hypothesized:

"Obese patients may believe that they are at increased risk for health problems that may be prevented or attenuated by more frequent visits to their primary providers. In addition, physicians cognizant of the increased risks associated with obesity, may request more follow-up appointments with interval diagnostic testing and monitoring for their obese patients. This differential care and testing may take place in the absence of actual health status differences. because it is motivated by perceived risk for potential health problems. The difference in the associated costs for this 'extra' care for obese patients may not be of a magnitude high enough to achieve statistical significance."



"...the prevalence of diabetes ... did not appear to increase substantially during the 1990s."

—CDC's Morbidity and Mortality Weekly Report, 2003

Diabetes "epidemic" amounts to 0.4% increase	
Adjusted percentage of adults aged ≥ 20 with fasting blood glucose levels above 126 mg/dL	
NHANES III (1988–1994)	NHANES (1999–2000)
8.2	8.6

(Source: Morbidity and Mortality Weekly Report, September 5, 2003)

#### According to the CDC:

"The twin epidemics of diabetes and obesity continue. From 1991 to 2001, a recent CDC study found a 61 percent increase in diagnosed diabetes (including gestational) in Americans and a 74 percent increase in obesity, reflecting the strong correlation between obesity and the development of diabetes."<sup>2</sup>

But epidemiological research gathered, analyzed, and published by the CDC tells a very different story. According to the agency, data from its NHANES survey collected between 1988 and 2000 "indicate that the prevalence of diabetes, either diagnosed or undiagnosed, and impaired fasting glucose did not appear to increase substantially during the 1990s."<sup>3</sup>

So what explains the discrepancy in the CDC's data?

The CDC employs two different methods of measuring the prevalence of diabetes. The first counts the number of self-reported cases of diabetes. The second uses data gathered from laboratory blood samples to count patients whose fasting glucose levels exceed 126 milligrams per deciliter (mg/dL) of blood—the diagnostic standard for epidemiological research. The CDC's 61-percent-increase estimate comes from the Behavioral Risk Factor Surveillance System and relies on the first method. The NHANES data—which show almost no increase in the prevalence of diabetes come from the latter. According to CDC researchers:

"We are also reminded that, although several studies have reported higher rates of diagnosed diabetes in recent decades, the NHANES data are the only national data examining changes in total diabetes prevalence."4

When determining which data to trust, it is important to keep in mind two factors that might make the NHANES estimate superior. First, NHANES accounts for a change in the standard by which diabetes is diagnosed. Second, it is not subject to bias based on increased awareness, and therefore increased diagnosis, of diabetes.

#### **Wrong Before**

A 2002 article by CDC researchers published in The American Journal of Public Health reported that "diabetes prevalence among the U.S. general population younger than 45 years increased by 14% between 1990 and 1996."5 Two months later, the team of researchers published a correction, noting that the increased prevalence among the population younger than 45 was just 3 percent.6

#### **Changing Standards for Diagnosis**

In 1997, the American Diabetes Association (ADA) and the federal government lowered the *per se* standard for diagnosing diabetes from a fasting blood glucose level of 140 mg/dL to 126 mg/dL.<sup>7</sup> The CDC's *Morbidity and Mortality Weekly Report* notes that "the potential impact on the prevalence estimates of the change in diagnosis of diabetes adopted by the ADA in 1997 should be accounted for." However, the CDC's estimate of a 61 percent increase fails to account for changes in how diabetes is diagnosed.

The ADA's "Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus" notes:

"Widespread adoption of the new criteria may, however, have a large impact on the number of people actually diagnosed with diabetes. Presently, about half the adults with diabetes in the U.S. are undiagnosed, but many might now be diagnosed if the simpler FPG [Fasting Plasma Glucose] test were always used."

Doctors Steven Woolf and Stephen Rothemich from Virginia Commonwealth University report in the journal *American Family Physician* that among American adults this redefinition increased the number of diabetics by nearly 50 percent:

"Lowering the diagnostic threshold shifts the definition of diabetes into the central bulge of the bell curve where the glucose level of most Americans falls. Among U.S. adults 40 to 74 years of age who have not been diagnosed with diabetes, 1.9 million have fasting plasma glucose levels of

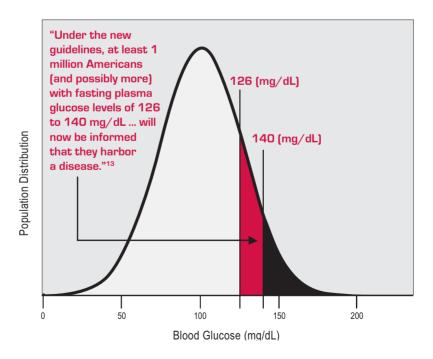
126 to 140 mg per dL (7.0 to 7.8 mmol per L), which is almost as many as the 2.2 million who have levels over 140 mg per dL (7.8 mmol per L). Under the new guidelines, at least 1 million Americans (and possibly more) with fasting plasma glucose levels of 126 to 140 mg per dL (7.0 to 7.8 mmol per L), who previously would have been told that they had normal (or impaired) glucose tolerance, will now be informed that they harbor a disease ... The evidence used for the new diagnostic criteria is from epidemiologic studies cited by Mayfield that show a progressive increase in the risk of complications beginning with fasting plasma glucose levels as low as 110 to 120 mg per dL (6.1 to 6.7) mmol per L). There are three problems with basing the new policy on these data. First, other studies show no increase in risk at these low levels. Second, even if risk is increased, the new policy argues that having a risk factor (a mildly elevated fasting plasma glucose level) is tantamount to having a disease ... Third, and most important, there is no prospective evidence that correcting these mild elevations improves health ... Whether normalizing fasting plasma glucose levels in the range of 126 to 140 mg per dL (7.0 to 7.8 mmol per L) has a meaningful impact on patient outcomes is unknown."10

Case Western Reserve University professor Paul Ernsberger explains the implications of the ADA's 1997 redefinition:

"Is the overall incidence of diabetes rising? It is difficult to say. This is because the standards for diagnosing diabetes have changed radically over the last 30 years. We have gone from measuring glucose in the urine to carrying out an elaborate procedure known as the oral glucose tolerance test and finally to relying solely on fasting blood glucose.

The level defining diabetes was dropped from 140 to 126 mg/dL in the 1990s. Loosening the diagnostic standards greatly increased the number of people classified as diabetic. Also, screening for diabetes has been stepped up, and now most people over age 45 are supposed to be checked every 3 years. In contrast, the average fasting blood glucose level in the adult population is about 85 mg/dL, and this value has not changed in decades. If there truly were an epidemic of diabetes, the average blood glucose level would rise, just as the average body weight has risen."

"Lowering the diagnostic threshold shifts the definition of diabetes into the central bulge of the bell curve where the glucose level of most Americans falls."<sup>12</sup>



(Source: National Health and Nutrition Examination Survey, 2001-2002)

#### Pre-Diabetes and Impaired Fasting Glucose

In a move similar to the redefinion of "overweight" from a BMI of 27 to 25, the American Diabetes Association's "Expert Committee" redefined the condition commonly known as "pre-diabetes" from a fasting plasma glucose of 110 mg/dL to 100 mg/dL.14 The resulting change dramatically increased the number of Americans considered to have pre-diabetes, also know as impaired fasting glucose (IFG) or impaired glucose tolerance (IGT). Commenting on the decision, Doctors David L. Schringer and Brett Lorber wrote:

"The important point is that the Expert Committee's recommendation is not based on the logical analysis of good quality evidence regarding patient outcomes. It is not 'evidence-based.' It is conjecture and opinion."15

A "position statement" from the American Diabetes Association concurs that "pre-diabetes" not a disease:

"Patients with IFG and/or IGT are now referred to as having 'pre-diabetes' indicating the relatively high risk of development of diabetes in these patients. In the absence of pregnancy, IFG and IGT are not clinical entities in their own right but rather risk factors for future diabetes as well as cardiovascular disease."16

#### Case Western's Ernsberger adds:

"A fasting glucose between 100 and 125 mg/dL or a postmeal glucose between 140 and 199 mg/dL is called 'prediabetes.' This predisease description is not meaningful and is not harmful by itself. It does not mean that one is fated to become diabetic, just that one is at higher risk. This description is the source of a lot of confusion, and many people are convinced that they have diabetes when they are only in this borderline area. This is important because most of the studies of diabetes incidence and risk factors are based on people's own report that they are diabetic rather than actual blood glucose numbers."<sup>17</sup>

"The definitional changes for diabetes and for being overweight are not based on trials but solely on extrapolations from the experiences of patients with more advanced disease." 18

—Effective Clinical Practice, 1999

According to an article in *Effective Clinical Practice* by Dartmouth Medical School's Lisa Schwartz and Steven Woloshin, the new definitions for both diabetes and overweight not only artificially inflate the diseases' prevalence, but also pose new problems for clinicians:

"Adopting the new definitions would dramatically inflate disease prevalence. Changing the threshold for diabetes from a fasting glucose level of >140 mg/dL to >126 mg/dL would result in 1.7 million new cases ... For hypercholesterolemia and being overweight, the number of new cases would be 42 million and 29 million, respectively ... The impact of such ubiquitous labeling is difficult to quantify

but is probably substantial. In a nation already obsessed with weight and body image and in which eating disorders (e.g., anorexia nervosa and bulimia) are prevalent, labeling half of the population 'overweight,' for example, may be traumatic.

"Treatment side effects represent another potential harm. Even if serious side effects are rare, the enormous increase in the number of people exposed to treatment means that more will occur. The cardiovascular abnormalities related to the use of dexfenfluramine and fenfluramine (i.e., Phen-Fen) to treat obesity are a recent salient example."19

#### Increased Awareness

Increasing awareness of diabetes—and not an actual increase in prevalence—helps account for the CDC's bloated numbers. CDC researchers writing in Diabetes Care found:

"...increasing attention to obesity and diabetes in both the lay and professional media may have conditioned health care providers to associate extreme obesity with a high risk of undiagnosed diabetes, making them more likely to question obese patients about symptoms and then to perform more testing ... A third implication of our findings is that because much diabetes surveillance is based on self-report of diabetes, a simultaneous increase in obesity prevalence and the detection of diabetes among the most obese could complicate our interpretation of historical trend data. In light of these observations, it is possible that the observed increases in self-reported diagnosed diabetes have slightly overestimated the true increase in total diabetes prevalence."20

A separate team of CDC researchers writes: "The change in prevalence demonstrated by [the BRFSS and NHIS] might reflect other factors such as enhanced detection rather than true increases."21 The data help substantiate this point. The number of undiagnosed cases of diabetes among obese individuals has decreased from 12.5% in 1980 to just 3.2% in 1999.22 Writing in Morbidity and Mortality Weekly Report, a group of CDC researchers note:

"Data from the National Health Interview Survey (NHIS) and the Behavioral Risk Factor Surveillance System (BRFSS) have documented steady increases in the prevalence of diabetes. However, these surveys rely only on self-reports of previously diagnosed diabetes and cannot measure the prevalence of undiagnosed diabetes."23

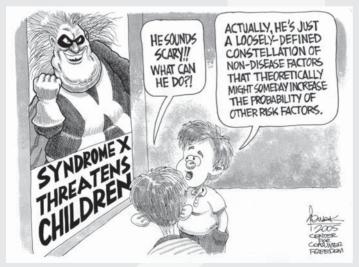
Fewer undiagnosed cases means that more people in the BRFSS study will report they have diabetes. But the shift from undiagnosed cases to diagnosed cases doesn't indicate any actual increase in the prevalence of the disease. Only the NHANES data—which show a much lower increase—can control for this problem.

#### Syndrome X

In the last decade, obesity researchers have raised the sinisterspecterof"SyndromeX"-alsoknownasmetabolic syndrome. But this "syndrome" isn't a syndrome at all. It is simply a loosely defined constellation of "risk factors" that can be associated with obesity. In 2005, a joint statement issued by the American Diabetes Association and European Association for the Study of Diabetes in the journal Diabetes Care questioned the so-called syndrome.

#### It read:

"...we found that the metabolic syndrome has been imprecisely defined, there is a lack of certainty regarding its pathogenesis, and there is considerable doubt regarding its value as a CVD risk marker. Our analysis indicates that too much critically important information is missing to warrant its designation as a 'syndrome.' Until much needed research is completed, clinicians should evaluate and treat all CVD risk factors without regard to whether a patient meets the criteria for diagnosis of the 'metabolic syndrome.'"24



The Center for Consumer Freedom

They went on to summarize their concerns about Syndrome X:

- "Criteria are ambiguous or incomplete. Rationale for thresholds are ill defined."
- "Value of including diabetes in the definition is questionable."
- "Insulin resistance as the unifying etiology is uncertain "
- "No clear basis for including/excluding other CVD risk factors."
- "CVD risk value is variable and dependent on the specific risk factors present."
- "The CVD risk associated with the 'syndrome' appears to be no greater than the sum of its parts."
- "Treatment of the syndrome is no different than the treatment for each of its components."
- "The medical value of diagnosing the syndrome is unclear "

#### Myth: Childhood Type-2 Diabetes Is an Epidemic

"Type 2 diabetes is still a rare condition [in children]."25

—Center for Disease Control, 2005

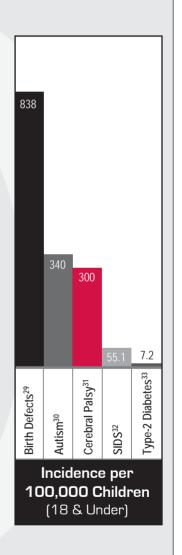
To date there are no nationally representative data on the prevalence of type-2 diabetes in children. The best information the CDC offers is: "Health care providers are finding more and more children with type-2 diabetes,

a disease usually diagnosed in adults aged 40 years or older."26 While there may be an increase in diagnosis, that does not necessarily imply that the absolute number of cases is high. Essentially, every study attempting to measure the prevalence of childhood type-2 diabetes has looked only at specific minority populations. The closest thing to a representative sample comes from a study based in Cincinnati, which found that 7.2 of every 100,000 children have type-2 diabetes.27

#### A Misdiagnosed "Epidemic"

Hype about the so-called "epidemic of childhood type-2 diabetes" has had unexpected and troubling consequences. A study of 2,868 children presented at the American Diabetes Association's 2005 annual conference and funded by the CDC found that many cases of type-2 diabetes in children are misdiagnosed. The Associated Press reported:

"...doctors may be missing opportunities to diagnose and treat kids with Type 1 diabetes, who need insulin to survive. Many children were misclassified as Type 2. the diabetes linked to obesity, possibly because their weight problems are throwing doctors off track ... [R]esearchers found that one out of three children diagnosed with Type diabetes were found to be Type 1 after they were given



a more sensitive test that is not commonly used in doctors' offices."28

# The Myth Makers:

**Financially Conflicted Obesity Research** 



"Many, if not most, high-profile obesity researchers are either consultants to the diet, food, or pharmaceutical industry, or conduct research for those industries. Many do both."

-Ellen Ruppel Shell, author of The Hungry Gene

In July 2004, the decades-long effort to have obesity declared a "disease" scored a major victory when a government rule change allowed Medicare to pay for prescription diet pills, bariatric surgery, and weight-loss plans such as Weight Watchers and Jenny Craig. That decision followed a similar policy change by the Internal Revenue Service to allow certain weight-loss products to be tax deductible.

This shift to treat obesity as a "disease" was the result of a long-term lobbying and public relations campaign waged by the \$46 billion-per-year weight-loss industry to hype the costs and risks of being overweight.

Since the 1980s, public opinion about obesity has been skillfully molded by the pronouncements of financially conflicted researchers and the companies that fund them. A small group of influential scientists—shaping public and professional notions of obesity—continually exaggerate the consequences of overweight and obesity. At the same time, they receive substantial monetary gifts, honoraria, and research money from the companies that stand to profit directly from their activities.

As author Ellen Ruppel Shell notes in her book *The Hungry Gene*, "[m]any, if not most, high-profile obesity researchers are either consultants to the diet, food, or pharmaceutical industry, or conduct research for those industries. Many do both."<sup>2</sup> She continues:

"It is no secret in the scientific community that purveyors of weight-loss drugs and diet plans feather the nests of the specialists who vouch for them. Nor is it news that corporate patrons expect to get what they pay for: that scientists who find benefit in weight-loss products are more likely to enjoy the continued support of the makers of those products."3

A July 2005 report in the Seattle Times noted:

"Some of the world's most prominent obesity experts, with backing from the drug industry and medical societies, defined obesity as a stand-alone "disease" that caused premature death and needed to be treated with drugs. In making obesity a disease, these experts helped create a billion-dollar market for the drugs."4

Former New England Journal of Medicine editor Jerome Kassirer fears the corrupting influence of such an arrangement:

"Physicians are involved in a major way with the pharmaceutical and diet industry with respect to the recent emphasis on obesity. There is reason to believe that some of the major figures in the obesity field are influenced by this involvement."5

In his book, On the Take, Kassirer describes how opinion leaders become involved with pharmaceutical companies:

"Trinkets bloom into meals at fine restaurants; meals grow into speaking fees; speaking fees morph into ongoing consultations and memberships on drug company advisory boards—positions that command up to six figures a year."6

#### A Weight Loss Goldmine

A brochure promoting the first World Obesity Congress and Expo noted with emphasis: "Within 10 years, the market for obesity drugs is projected to be \$50 BILLION, more than outselling today's top three "blockbuster" categories—cholesterol-lowering, anti-depressants, and heartburn—COMBINED!" The document further exclaimed: "The worldwide Bio-pharma industries are in a race for what is almost certainly the biggest windfall in the history of modern pharmaceuticals! ... An effective therapeutic is indeed the pharmaceutical 'Holy Grail.'" The brochure went on to note that a discussion topic would be: "What kind of obesity outcomes research is needed to make a compelling case for the 'value' of a therapeutic?"

Author Ellen Ruppel Shell reports in her book *The Hungry Gene* that the "chief business officer of one of the fastest-growing biotechnology companies in the world" says, "Obesity is the trillion-dollar disease."<sup>10</sup>

In April 2005 The New York Times reported:

"From pharmaceutical giants to tiny start-ups, the industry is spending billions of dollars developing obesity drugs. An estimated 200 possibilities are now in the research pipeline or under test among patients at dozens of clinics ... "Everybody is just foaming at the mouth to make money" from obesity drugs, said Dr. Donna Ryan, an obesity researcher affiliated with Louisiana State University, which has received millions of dollars in government and drug-industry grants." 1

## Myth Makers: Professional Organizations

The three most significant organizations in shaping medical and public perceptions about obesity are the American Obesity Association (AOA), the North American Association for the Study of Obesity (NAASO), and the Centers for Obesity Research and Education (CORE). As these nonprofit groups hype the problem of obesity, most people remain unaware of the extremely close ties they maintain with their for-profit sponsors in the weight-loss industry.

#### **American Obesity Association**

"[Our] fundamental mission is to have obesity regarded as a disease of epidemic proportions."

—American Obesity Association website

"Drug companies make no secret of trading on the good name—and the goodwill—of the academics whose research they support. For example, many of the members of the respected International Obesity Task Force and National Task Force on the Prevention of Obesity also serve on the advisory council of the American Obesity Association (AOA). The main function of the AOA council is to lobby for legislation mandating insurance coverage for weight loss drugs. Its main support comes from drug makers, including Interneuron, American Home Products, Roche Laboratories, Servier, and, of course, Knoll Pharmaceuticals Ltd."<sup>2</sup>

-Ellen Ruppel Shell, The Hungry Gene

Is the American Obesity Association the lobbying arm of the weight-loss industry? It claimed credit for convincing the Internal Revenue Service to allow tax deductions for weight-loss programs<sup>3</sup> such as those provided by Weight

#### AOA's donors have included the following companies, all involved in the weight-loss industry: 4,5

- Abbott Laboratories
- American Home Products
- Eli Lilly and Company
- Ethicon Endo-Surgery, Inc.
- GlaxoSmithKline
- Health Management Resources
- Hoffman LaRoche
- Interneuron Pharmaceuticals
- Jenny Craig International
- Johnson & Johnson
- Knoll
- Medeva Pharmaceuticals
- Merck
- Novartis Nutrition Corporation
- Ortho-McNeil Pharmaceutical
- Pfizer
- Regeneron Pharmaceuticals, Inc.
- Roche
- Sanofi-Aventis
- Slim-Fast Foods Company
- Tanita
- · Weight Watchers International
- Wyeth-Ayerst

AOA has received significant funding from the makers of "fen-phen" ingredients (Wyeth-Ayerst, Interneuron Pharmaceuticals, and Medeva Pharmaceuticals), which primarily supported the organization when it was started in the mid-1990s.6

Watchers and Jenny Craig—two of the organization's sponsors. It also led the charge to win Medicare coverage of obesity treatments.7 AOA co-founder Judith Stern has even advocated having the government pay for Weight Watchers fees incurred by food-stamp recipients.8

When the government announced in 2003 that it would reconsider the language for Food and Drug Administration (FDA) guidance on obesity treatments, AOA convened meetings of pharmaceutical companies to craft language that was later suggested for government adoption. Among the participating companies were Abbott Laboratories, Amylin Pharmaceuticals, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Merck, Millennium, Novartis, Pfizer, Regeneron, Roche Laboratories, and Sanofi-Synthelabo. They described themselves, appropriately enough, as "the AOA-industry group."9

The group wanted the BMI threshold for weight-loss treatment shifted from 27 (with one or more comorbidities) to 25 (with one or more comorbidities). In other words, they recommended that a 5 foot 10 inch man who weighs 171 pounds and has hypertension should be given weight-loss pills. "The AOA-industry group" also called for obesity to be termed a "disease."

AOA's board includes the chief scientific officer of Weight Watchers, a former senior medical director of Knoll, 10 and the vice president of Novartis.11 The group's Secretary is the Executive Medical Director of a chain of weight-loss centers in California.12

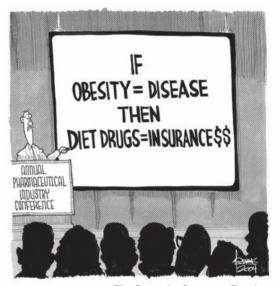
AOA proclaims "it is organized as a 501(c)(4) tax-exempt organization for the purpose of advocating on behalf of persons with obesity."13 According to a 1998 report in the Wall Street Iournal:

"At the advisory panel hearing on Meridia, [AOA president Richard Atkinson, the first speaker, described the association as 'a lay advocacy group representing the interests of the 70 to 80 million obese American women and children and adults afflicted with the disease of obesity.'

"The association charges individuals \$25 for membership. [AOA co-founder Judith] Stern says she and Dr. Atkinson belong but she has 'absolutely no idea' how many others are members. Asked for a member count, Morgan Downey, the group's executive director, produced a single, completed application and check and said it was from the only paid member he had seen.

"Dr. Atkinson says the group receives most of its funding—several hundred thousand dollars in all—from the pharmaceuticals industry, including Interneuron, American Home Products, Roche Laboratories, Knoll Pharmaceuticals Ltd. and Servier—all of which market or develop diet pills."14

AOA says its "fundamental mission is to have obesity regarded as a disease of epidemic proportions."15 To achieve this goal, the group regularly engages in rhetorical excess. AOA's Executive Director, Morgan Downey, repeatedly states that obesity is the "most prevalent, fatal, chronic disease of the 21st century."16 Stern once claimed: "If we don't try something new, in about 10 years everyone in the country will be overweight or obese."17 Atkinson has even made the absurd assertion that "medicine has never seen an epidemic of this proportion." <sup>18</sup>



—The Center for Consumer Freedom

Another AOA strategy is to trumpet questionable statistics about the risks and costs of obesity. The group greatly surpassed other existing estimates of obesity's annual price tag, concluding in a 1999 report that it costs the United States \$238 billion each year. 19 That's more than double the \$117 billion figure produced by Graham Colditz's study, which admitted to a "double-counting of costs" that would "inflate the cost estimate."

AOA has also defended flawed figures on obesity-related mortality. Downey wrote a 2002 essay attempting to rebut now-confirmed doubts about whether obesity kills 300,000 Americans every year. He argued for the flawed figure because it meant millions of dollars for obesity researchers and perhaps billions in profits for AOA's corporate sponsors:

"If it is true, obesity must be taken seriously as an important public health issue. If false, then obesity can continue

to be trivialized or ignored. One way dictates millions of dollars for research, prevention and treatment and carries implications for regulation of the causes. The second approach can leave the present allocation of health care dollars intact ... "20

## North American Association for the Study of Obesity

NAASO and its parent, the International Association for the Study of Obesity, shape professional notions about obesity by publishing the top two journals on the subject.

The North American Association for the Study of Obesity is a professional organization representing the interests of clinicians and physicians treating obesity. Past NAASO president Barbara Rolls acknowledged that "most of our donations come from a number of pharmaceutical companies."21 In 1996, a NAASO newsletter noted that its Corporate Advisory Board consisted of representatives from contributing companies: Amgen, Eli Lilly, Roche, Interneuron, Knoll, Procter & Gamble Co., Slimfast Foods, and Wyeth-Ayerst Laboratories.<sup>22</sup>

According to NAASO Executive Director Edward Bernstein, obesity is a good industry to be in: "There's no disease state in existence that represents such a large market."23

In 1998, an unrestricted grant from Knoll allowed NAASO to conduct "an extensive public relations campaign" that "helped NAASO shape news reports about obesity with key messages."24 NAASO's newsletter reported that this campaign involved targeting "more than 700 health and medical reporters at major print, television, trade publications, and radio outlets," as well as members of Congress. NAASO's "Practical Guide" for understanding obesity was distributed by Knoll to all attendees of an annual meeting of the American Academy of Family Physicians.<sup>25</sup>

NAASO also influences doctors through its industry-funded continuing medical education (CME) classes. Sanofi-Aventis, which is currently testing its weight-loss pill Acomplia, sponsors a NAASO-run CME course titled "Understanding and Treating Obesity."26 Which researchers reviewed this course to ensure the best possible education for America's physicians? One was Xavier Pi-Sunyer, the lead Acomplia researcher.<sup>27</sup> Another, Steven Haffner, was a consultant for Sanofi and a member of the speakers' bureaus for Pfizer, GlaxoSmith-Kline, and AstraZeneca.<sup>28</sup> Roche, meanwhile, helped to fund NAASO's CD-ROM "Clinical Management of Obesity," featuring AOA board member emeritus George Bray.<sup>29</sup> Abbott, maker of Meridia, sponsored a NAASO CME project called "Office Management of Obesity."30

NAASO and its parent, the International Association for the Study of Obesity (IASO), shape professional notions about obesity by publishing the top two journals on the subject. NAASO's Obesity Research has been edited by the group's founder, former CORE unit director George Bray, and by Pi-Sunyer. Meanwhile, AOA's Atkinson edits IASO's International Journal of Obesity, along with editorial board members such as Pi-Sunyer and David Allison.

IASO oversees the International Obesity Task Force (IOTF), which makes recommendations to the World

Health Organization. IOTF panels have been populated by top industry-funded obesity researchers such as Pi-Sunyer, Weight Watchers advisory board member Shiriki Kumanyika, Phillip James, and William Dietz, currently director of the CDC's division of nutrition and physical activity (These four researchers are profiled below). IOTF has stated it "would like to acknowledge the financial support received in the form of educational grants from Hoffman-La Roche, BASF Knoll and Servier."31 Britain's Daily Mail reported that three-quarters of IOTF's funding comes from the pharmaceutical industry.32

## Centers for Obesity Research and Education

"Since we don't fully understand the causes of obesity, we should take the patient's responsibility out of it."33

-George Bray

Many top obesity researchers whose opinions trickle down to family physicians and the media are affiliated with one of the Centers for Obesity Research and Education. The eight centers are designed to educate doctors on the dangers of obesity and ways to treat it.34 Who funds those centers? Abbott Laboratories, Aventis Pharmaceuticals, GlaxoSmith-Kline, Ortho-McNeil Pharmaceuticals, Procter & Gamble, Roche Laboratories, and Slim-Fast Foods<sup>35</sup>—all of which also support AOA.36

CORE has gone to great lengths to defend its industry sponsors. When there were calls to remove Abbot's weight-loss drug Meridia from the market, CORE issued a press release defending the pill. 37 The release even cited a wildly bloated statistic: "A recent Harris Poll estimates that 85% of U.S. adults are overweight or obese" (the already-inflated number usually cited is 65 percent). The CORE release went on to attack the role of personal responsibility, claiming: "In the medical community, the old notion that obesity is due to lack of willpower has been displaced by scientific evidence that obesity is the result of complex interaction between genetics, physiology, environment, and behavior."

The Centers include the Beth Israel Deaconess Medical Center (run by George Blackburn and Caroline Apovia); the Pennington Biomedical Research Center (run by Claude Bouchard, George Bray, and Eric Ravussin); UCLA's Center for Human Nutrition (run by David Heber); the Obesity Research Center at St. Luke's/Roosevelt Hospital, (run by Xavier Pi-Sunyer); and the Northwestern Memorial Wellness Institute (run by Robert Kushner).<sup>38</sup>

These are among the most influential obesity researchers in the country. Kushner, who sat on Knoll's grant-making Weight Risk Investigation Study Council,<sup>39</sup> was tapped to author the American Medical Association's "primer" for physicians treating obesity.<sup>40</sup> That document was reviewed by other industry-funded researchers, such as the CDC's William Dietz and at least five CORE leaders, including Bray and Pi-Sunyer.<sup>41</sup> Other expert reviewers of Kushner's AMA guidelines included Thomas Wadden and Samuel Klein of NAASO, and AOA advisory council member Denise Bruner.<sup>42</sup>

CORE began publishing a journal in 2005. The first issue of its *Obesity Management* was chock-full of pro-industry tactics. In one interview, George Bray attempted to medicalize excess weight by claiming:

"Since we don't fully understand the causes of obesity, we should take the patient's responsibility out of it. Rather than focusing on the gluttony, sloth, and moral issues, it is far better to address the neurochemical imbalance and why it occurs."43

In the same issue, Robert Kushner authored an article reviewing the Weight Watchers program.44 He'd commented on the subject before, publicly pronouncing it an "excellent program."45 Not disclosed in either case was the fact that Kushner had received a grant from the Weight Watchers Foundation to train residents.46

CORE's New York Obesity Research Center, run by Xavier Pi-Sunyer, also hosts the Theodore VanItallie Center, named after the man who was the first to grab headlines in 1985 for labeling obesity a "killer disease." The Center has also employed David Allison and Kevin Fontaine, who, along with VanItallie, crafted the deeply flawed study that blamed obesity for 300,000 deaths each year.48

The New York Obesity Research Center's website boasts a long history of conducting clinical trials on weightloss products. It studied dexfenfluramine, a component of fen-phen, for the French company Servier. It investigated sibutramine (Meridia) for Boots, Orlistat for Roche, Ephedra for NutriSystem, and the Weight Watchers program.<sup>49</sup> The Center's external advisory group includes industry-funded researchers such as Claude Bouchard and Albert Stunkard,<sup>50</sup> as well as employees of Novartis and Jackson Laboratories.<sup>51</sup> Jackson breeds mice for obesity and diabetes research.<sup>52</sup>

AOA, NAASO, and CORE are so closely connected that they entered into merger talks in late 2003;53 NAASO eventually subsumed CORE as a "continuing medical education" program.54

In March 2005 the Endocrine Society announced a "consensus statement" recommending the government officially recognize childhood obesity as a disease and calling for reimbursement of weight-loss treatments. The Endocrine Society has received at least \$100,000 from each of the following companies: Aventis, Eli Lilly, Knoll, Novartis, Abbot, Genentch, Pfizer, Roche, and Wyeth-Ayerst. These companies are all involved in developing and selling weight-loss products.

## **Shape Up America!**

Shape Up America's founder, C. Everett Koop, sits on the advisory council of AOA. Former New England Journal of Medicine Editor-in-Chief Jerome Kassirer has noted that a "widely distributed book of recommended treatments for obesity"-published under the joint banners of AOA and Shape Up America!—was funded by American Home Products, the parent company of Wyeth-Ayerst.55

Shape Up CEO Barbara Moore said Hoffman La-Roche, makers of Xenical, at one time considered contributing \$1 million to the group.56 She testified at the FDA hearing on Xenical.57

Weight Watchers agreed to donate \$1 million to Shape Up America!58 According to the Center for Science in the Public Interest (CSPI), other million-dollar donors include Slim-Fast and Jenny Craig.59 CSPI reports that in 1995 Slim-Fast paid for a one-page insert in Sunday newspapers, which featured Shape Up America! on one side and an ad for Ultra Slim-Fast on the other. 60

Shape Up America! even trademarked the term "Diabesity."61 A 2001 conference the group hosted on "Diabesity" was sponsored by weight-loss companies Aventis, Ortho-McNeil, Ross Nutrition, Tanita, Ethicon Endo-Surgery, Novartis Nutrition, and NatraTaste (which produces an artificial sweetener).62

## Myth ≝Makers: Individuals



—The Center for Consumer Freedom

While there are many researchers working in the field of obesity, the following weight loss industry—funded individuals are among the most influential. They sway professional, public, and medical opinions about the issue while receiving compensation through research support or honoraria from companies that directly profit from their efforts.

## **Caroline Apovian**

Caroline Apovian is a leader at George Blackburn's CORE unit. According to *The Boston Globe*, she said "only half-joking" that "to deal with our world today, we need Lipitor and an antiobesity drug and Prozac in our water." Apovian authored an editorial that blamed soft drinks for childhood obesity. The editorial appeared in *JAMA*, which disclosed that she has received "honoraria or grants" from CORE and AOA sponsors Abbott and GlaxoSmithKline.<sup>2</sup>

#### Louis Aronne

Louis Aronne, an AOA advisory board member and NAASO's president in 2005, coauthored an article in CORE's premier issue of Obesity Management in which he examined the use of drugs to treat obesity.3 Along with discussing obesity drugs in the pipeline and the "off-label" use of several other drugs, Aronne described in detail the use of sibutramine, Orlistat, and phentermine. It was not disclosed that Aronne was a principal investigator for Orlistat<sup>4</sup> and that he has received financial support from the pill's maker.<sup>5</sup> In December 2004, when The Wall Street Journal reported that there were significant problems with the CDC's exaggerated conclusion that excess weight causes 400,000 deaths per year, Aronne told the paper: "I would argue, gee, maybe they're underestimating it." 6

#### Richard Atkinson

"[O]besity is the most prevalent, fatal, chronic disease of the 21st century," said AOA president and co-founder Richard Atkinson, after his group successfully lobbied the government to allow Medicare to cover weight-loss treatments.7 Atkinson isn't just the president of AOA. He's the founder of a company that hawks \$100 kits that supposedly test for an "obesity virus."8

According to The Wall Street Journal, Atkinson "says drug companies 'love me' because of his strong support for diet pills."9 And the Center for Science in the Public Interest's "Integrity in Science" online database discloses that Atkinson has:10

- Been a consultant to Boots Pharmaceuticals, Cambridge Plan International, Eli Lilly, Gates Pharmaceuticals, Glaxo, Glaxo-Wellcome, Interneuron, Knoll Pharmaceutical, Lederle, Pfizer, Ross Laboratories, Slim-Fast, Thompson Medical, Wyeth-Ayerst.
- Been an industry-sponsored lecturer for Boots, Hoffman-LaRoche, Interneuron, Knoll, Ross Laboratories, Slim-Fast, Wyeth Ayerst.
- Received research support from AH Robins, Cambridge Plan International, DuPont Pharmaceuticals, Eli Lilly, Gates Pharmaceuticals, Mead Johnson, Natural Nutrition, Thompson Medical, and the Weight Watchers Foundation.

## A 2000 article in *The Hartford Courant* quotes Atkinson:

"I mean, obviously I like to get paid. I like to have money. They have the meetings sometimes in pretty nice places. I love that. That's great. But I really hope that I don't allow those relatively trivial and in many cases completely trivial material things to get in the way of science. That would just be awful. I think I've been pretty honest and uncorrupted by the money ... But who knows, maybe it's so insidious that I don't notice it."11

Despite his industry funding and connections, Atkinson chaired a government panel on standards for weight management in the military.<sup>12</sup> Atkinson has also spoken at FDA hearings in favor of the weight-loss drugs Xenical<sup>13</sup> and Meridia.14

## George Blackburn

George Blackburn is a perfect example of an obesity researcher who influences medical, governmental, and popular perceptions of obesity while working for companies—even receiving royalties from some—that profit from selling weight-loss products. Blackburn sits on the scientific advisory board of Shape Up America! He is a board member of AOA, a past president of NAASO, and director of a CORE facility.

Blackburn has received grants for clinical research from Aventis, GlaxoSmithKline, and R.W. Johnson Pharmaceuticals.15 He has served as an advisor or consultant to Ross. Amgen, Bristol-Myers Squibb, GlaxoSmithKline, Roche, and Sanofi-Synthelabo. 16 He has served in the speakers bureaus of Ross and Roche, and he has received royalties from Abbott and Novartis.17

Blackburn has warned doctors of the consequences of obesity in several CME courses sponsored by Slim-Fast.<sup>18</sup> While he discloses that he has been an advisor or consultant to the company, he is also a trustee of the Slim-Fast Institute.<sup>19</sup> Upon completion of a long-term study of Slim-Fast users<sup>20</sup> (located, appropriately, in Pound, Wisconsin), Blackburn appeared in a video news release sponsored by the company.21

Blackburn doesn't just pitch products and teach classes. Along with fellow AOA leaders John Foreyt, Judith Stern, and Sachiko St. Jeor, Blackburn helped review obesity-treatment criteria for the Commission on Dietetic Registration,<sup>22</sup> a credentialing service that has overseen the tests of more than 75,000 dietitians and dietetic technicians.<sup>23</sup> Blackburn has also been a member of the National Institutes of Health's National Task Force on the Prevention and Treatment of Obesity.

## From Alicia Mundy's Dispensing With The Truth: 24

In her 2001 book Dispensing With The Truth, investigative reporter Alicia Mundy detailed George L. Blackburn's close financial ties to companies that sell weight-loss pills and products. She reported:

"In January and February 1996, Blackburn, a famous obesity expert, was instrumental in supporting the use of fen-phen and Redux before the Medical Society of Massachusetts. He



was the chairman of its Committee on Nutrition, which produced a White Paper on the importance of weightloss drugs, though cautioning the need for medical monitoring. Despite the national fen-phen craze, it had been illegal to prescribe Pondimin or Phentermine in Massachusetts, the last state to prohibit them, but that ban was lifted in February, due in part to his influence. Blackburn called the removal of the ban "an important change" that recognized "several advances in our understanding of obesity and its treatment." [...a lawyer suing the makers of fen-phen] then produced a one-sentence letter Blackburn had written on October 31, 1996, apparently in a fit of self-congratulation."

What Have I Done for Wyeth-Averst Laboratories Lately? Enclosed are activities with Wyeth ... that I have participated in during the past year and meetings that I am committed to for 1997 '

"There were seventeen, plus confirmation of three upcoming appearances for early 1997 ... Programs Blackburn had run, panels he had moderated, almost all sponsored by Wyeth-Ayerst either directly or through a grant to a continuing medical education program."

#### Claude Bouchard

Claude Bouchard is a board member of AOA and director of a CORE facility. In 1997 his university stated that he "has been awarded \$1 million" as the recipient of a chair endowed by Roche Canada and a pharmaceutical trade group.<sup>25</sup> According to a company spokesman, the "team effort" between Roche and Bouchard's university would help "shape the future of health research in Canada."26

Bouchard, who has been an influential leader in and president of both IASO and NAASO, was among the financially conflicted researchers on the NIH panel that in 1998 lowered the government's official threshold for "overweight" to include an extra 35 million Americans. Bouchard serves on the scientific advisory board of Weight Watchers International.<sup>27</sup>

## **George Bray**

George Bray is a leading obesity researcher and is the former director of a CORE facility. He is also Director Emeritus of AOA. Bray has been described by author Ellen Ruppel Shell as a "tireless proselytizer for obesity drugs." A July 2005 Seattle Times article noted:

"A consultant for numerous drug companies for more than three decades, Bray holds patents for such things as low-fat potato chips, a cream to reduce fat thighs, and treatment for metabolic disorders."29

Bray was a leading investigator of Roche's Xenical, along with Xavier Pi-Sunyer. The financial disclosure of one study on the drug's effects stated that Bray:

"...has received research grant support for the study of Orlistat from Hoffman-La Roche. He has also received research grants from Johnson & Johnson, Regeneron, Proctor and Gamble, and Novartis and has been a member of advisory boards and speaker bureaus for Johnson & Johnson and Takeda Pharmaceuticals."30

These are companies that benefit from the notion that obesity is a disease, rather than an issue of personal responsibility—as do the companies that produced the weight-loss thigh cream he researched.<sup>31</sup> Bray has come under fire for testifying on behalf of fen-phen makers at FDA advisory panel hearings<sup>32</sup> and for being paid for court testimony on behalf of a company whose ephedra product his center researched.<sup>33</sup> In a 2005 interview with CORE's journal, Bray attempted to medicalize excess weight by claiming:

"Since we don't fully understand the causes of obesity, we should take the patient's responsibility out of it. Rather than focusing on the gluttony, sloth, and moral issues, it

is far better to address the neurochemical imbalance and why it occurs."34

#### William Dietz

The director of the Division of Nutrition and Physical Activity at the Centers for Disease Control and Prevention is William Dietz, who has been a consultant to Roche and Knoll.35 As recently as 2004, he lectured on a NAASO speaking tour supported by drug maker Sanofi-Aventis.<sup>36</sup> Dietz chaired the CDC's obesity "Reimbursement Initiative"—supported by industry-funded groups such as NAASO—which successfully lobbied for a government rule change allowing Medicare to cover obesity treatments.37

A former IOTF working-group chairman,<sup>38</sup> past president of NAASO,39 and former advisory council member of the American Obesity Association, 40 Dietz was also a member of the 1998 NIH panel that lowered the threshold for the government's definition of "overweight."

## **Arthur Frank**

Arthur Frank, treasurer of the American Obesity Association and director of a George Washington University weight-loss clinic, helped publicize Xenical in 2000 at an "X Out The Fat X-Travaganza" shopping mall tour stop.41 Reminiscent of Wyeth-Ayerst's "Redux Road Tour," Roche sponsored the event, which included doctors in white lab coats and an image-morphing machine that allowed potential customers to see what they'd look like if they lost weight. Frank's participation in this road show is particularly amusing, given his past complaint:

"What we're saying is this [the diet industry] is a huge enterprise with \$33 billion a year (in sales), and it's entirely unregulated. They may be good people, but there's no bounds on them ... you just get a sign, a white coat, preferably, and you spend some money on advertising."42

## In June 2005 Frank told *The Washington Post*:

"Shouldn't we take a lesson from what has worked with tobacco and other issues and examine how environmental factors have helped to create this public health problem? What about changes in public policies, such as advertising restrictions, banning vending machines in schools, putting a tax on unhealthy foods, etc. Shouldn't this angle be part of any discussion about obesity?"43

## **David Heber**

In November 2004, Dateline NBC aired a story titled "Is U.S. obesity epidemic a myth?"44 David Heber, who runs the UCLA Center for Human Nutrition, was chosen by Dateline to make the case for obesity as a massive health problem. To its credit, Dateline asked Heber how he answers critics who say the risks of obesity are exaggerated because of funding from the weight-loss industry. Heber responded by attacking the critics.

Who is Heber? He sits on AOA's advisory council, and his outfit is one of eight highly influential CORE facilities funded by the weight-loss industry. His center hosts the S. Daniel Abraham/Slim-Fast Foods Nutrition Research Kitchen and the Pharmanex Phytochemical Laboratory. 45 Heber wrote a journal article titled "Dietary supplement or drug? The case

for Cholestin"46 (an anti-cholesterol product made by Pharmanex). In 2003 Forbes magazine reported:

"When David Heber appeared recently on ABC's Good Morning America, viewers believed the noted nutritionist was pitching his new book, The L.A. Shape Diet. That wasn't the only item on his agenda. In whipping up a soy-milk-and-blueberry shake from Herbalife's Shape-Works protein powder, Heber was also promoting the controversial dietary supplement company. Heber sits on Herbalife's newly created scientific advisory board, a perch he accepted around the time the multilevel marketer made a \$3 million donation to the Center for Human Nutrition at UCLA, where he is the director. Herbalife's money was well spent. The name of Heber's weight-loss plan and his book promote the company's signature product."47

## Philip James

"While issuing warnings that obesity has become an 'epidemic', he has been the leading researcher in trials of weight-loss drugs and has been paid fees by pharmaceutical firms that stand to make billions of pounds from slimming pills and potions."48

—The Daily Mail, 2005

Great Britain's Daily Mail reported in March 2005: "The Government's anti-obesity guru was at the centre of a sleaze row last night after it was revealed he has been paid undisclosed consultancy fees by makers of weight-loss drugs."49 The paper was referring to International Obesity Task Force (IOTF) chairman Philip James, who has had significant influence in setting obesity policy in America and Europe. As the Daily Mail explained:

"While issuing warnings that obesity has become an 'epidemic', he has been the leading researcher in trials of weight-loss drugs and has been paid fees by pharmaceutical firms that stand to make billions of pounds from slimming pills and potions ... Prof James's task force receives 75 per cent of its £626,000 annual income from drug companies, including international pharmaceutical giants F. Hoffman-La Roche and Abbott Laboratories, which are thanked in its annual report for their 'generous contributions.' The IOTF has also received contributions from Servier, the pharmaceutical company that produces the weight-loss drug Redux."

James was a principal researcher of Knoll's weight-loss drug Meridia<sup>50</sup> and Roche's weight-loss drug Xenical.<sup>51</sup> Roche turned to James to present the Roche Gulf Journalism Awards for Obesity Reporting, awarded by the company to continue "its campaign to raise awareness of the disease by encouraging the media to tackle the topic in a responsible manner."52 According to one British watchdog organization, James "is regularly engaged in what can only be described as PR activities for Roche."53

In June 2005 *The Seattle Times* reported of IOTF:

"An international group of obesity experts, with financial backing from drug companies, works to 'convince WHO [World Health Organization] that obesity had become a global issue that could be ignored no longer.' At WHO headquarters in Geneva, they lay the groundwork for an official definition of obesity based on BMI. Task-force members include doctors who are heading clinical trials of weight-loss drugs ... WHO declares obesity a pandemic after an expert consultation funded by members of the International Obesity Task Force."54

In fact, as a key advisor to the World Health Organization regarding obesity, James's IOTF has encouraged "fat taxes" and marketing restrictions on some foods.55 The IOTF not only drafted the WHO's original report, but the group also funded the project with, according to James, a "substantial grant." 56

As a principal architect of Britain's Select Committee on Health,<sup>57</sup> James had great sway in drumming up obesity fears. And at a 2004 conference intended to encourage obesity lawsuits,58 James took credit for helping industryfunded researcher Xavier Pi-Sunyer lower the American government's body mass index threshold for being "overweight." James has also advocated lowering the BMI threshold for Asian populations, 59 a plan that would further increase the world's "overweight" population.

## Shiriki Kumanyika

University of Pennsylvania professor Shiriki Kumanyika has been a committee chairperson for the International Obesity Task Force<sup>60</sup>—a policy-pushing body of the pharmaceutical company-funded IASO. Kumanyika was a member of Xavier Pi-Sunyer's NIH panel that in 1998 lowered the government's threshold for "overweight." She also sits on the scientific advisory board of Weight Watchers International.61

Along with IOTF's Philip James, Kumanyika co-authored an article for a conference encouraging obesity lawsuits. The article advocated "health impact assessments on trade arrangements" and the use of "powers so far reserved largely for acute food safety issues to restrict trade" for calorie-dense food.62 Kumanyika was Vice-Chair of the World Health Organization Expert Panel on Diet, Nutrition and Chronic Diseases. 63 She also chaired a panel for the World Health Organization that recommended lowering the BMI threshold for being "overweight" in Asian populations.64

#### Robert Kushner

A CORE unit director, Robert Kushner was tapped to author the American Medical Association's primer for physicians treating obesity.65 In the first issue of CORE's journal, Kushner authored an article reviewing the Weight Watchers program. 66 He'd commented on the subject before, publicly pronouncing it an "excellent program." 67 Not disclosed in either case was the fact that Kushner has received a grant from the Weight Watchers Foundation to train residents. 68 Kushner sat on Knoll's grant-making Weight Risk Investigation Study Council and has received financial support from Abbott.<sup>69</sup>

## JoAnn Manson

Harvard professor JoAnn Manson appeared at FDA hearings on behalf of the makers of fen-phen. 70 As Laura Fraser notes in her book Losing It, one of the drug's makers "presented evidence to the FDA that the risks of obesity outweighed the potential harm of the drugs. Much of that evidence was based on a study by JoAnn Manson of the Harvard University School of Public Health, a paid consultant to Interneuron Pharmaceuticals, the company that developed the drug."71

Manson's financial conflict was not noted in an ensuing New England Journal of Medicine editorial,72 in which she argued that the harm from obesity outweighed the risks of the drug. Upon discovering Manson's undisclosed interest, the editors of the respected journal conceded two months later:

"[Faich and Manson] concluded their editorial with the sentence, 'Although physicians and patients need to be informed, the possible risk of pulmonary hypertension associated with dexfenfluramine is small and appears to be outweighed by benefits when the drug is used appropriately.' When considered as the conclusion of people who were paid consultants for companies that sell dexfenfluramine, it raises troubling questions ... Were they too quick to attribute the risks associated with obesity to obesity itself?"73



#### Judith Stern

American Obesity Association vice president and cofounder Judith Stern is frequently presented as an impartial expert<sup>74</sup> while her comments advance the agenda of her organization's pharmaceutical and weight-loss benefactors. Stern regularly uses hyperbole to describe obesity. In one case she said: "If we don't try something new, in about 10 years everyone in the country will be overweight or obese."75

In 1997 the Newark Star-Ledger reported that eight of nine members of an influential government obesity panel were financially conflicted.<sup>76</sup> One of those individuals was Stern, who sits on the scientific advisory board for Weight Watchers77 and has received "honoraria" from Knoll and Wyeth-Ayerst.78

In 1995 Stern sat on the other side of the government table, showing up at FDA hearings on Redux to detail the health risks of obesity.<sup>79</sup> That same year Stern chaired a government panel designed to set criteria for judging weight-management programs.80 Stern's group, AOA, is funded by Weight Watchers, Jenny Craig, and Slim-Fast. In other words, the cofounder of an organization funded by weight-loss companies was setting the government's standard by which her donors should be judged.

According to the owner of a fen-phen clinic in Florida, Wyeth-Ayerst encouraged him to send money to Stern. The St. Petersburg Times reported:

"A month after opening his clinics in February 1995, [John] Trevena sent Stern a \$2,500 retainer. Stern testified several times before the FDA favoring approval of Redux, a second-generation version of fenfluramine. A few months later, Trevena made a \$5,000 contribu-

tion to the legal defense fund of the American Society of Bariatric Physicians, composed of doctors who specialize in weight loss. These friends came in handy. When the FDA's advisory committee initially hesitated to approve Redux, Stern was quoted in an Associated Press story saying that doctors voting against the drug 'ought to be shot." 81

#### Theodore VanItallie

George Washington University Center for Health Services Research and Policy fellow Thomas J. Moore describes in his book Lifespan how a 1985 NIH panel on obesity was a "pivotal event" because the imprimatur of the agency meant that "any judgments would be widely quoted as authoritative interpretation of the best scientific evidence now available."82 Moore explains: "The participants would barrel through 19 complex presentations in a mere one and a half days and issue an authoritative declaration." The result? According to Moore, the panel supplied an "unusually generous definition of the risk factor disease of obesity. It declared that 26 percent of the adult population was medically obese and required medical treatment."83 The organizer of this panel was Theodore VanItallie.84

VanItallie co-founded United Weight Control Corporation, a liquid diet program, in 1986. In 1989 a business journal reported the company was aiming for \$100 million in business within five years.85 As Laura Fraser notes in Losing It, VanItallie's company "provided a liquid diet to five hospital centers, including St. Luke's/Roosevelt Hospital,"86 which now hosts the Theodore B. VanItallie Center for Nutrition and Weight Management.

In 1993 VanItallie again influenced the government's view of obesity, this time as a member of the NIH's National Task Force on the Prevention and Treatment of Obesity. That body determined physician guidelines for very-low-calorie diets.



—The Center for Consumer Freedom

Like most of his colleagues, VanItallie not only sits on government panels that shape the official view of obesity, but he also promotes weight-loss pills at FDA proceedings. In 1996, VanItallie offered a presentation on behalf of Redux maker Interneuron.<sup>87</sup> There, according to *The Wall Street Journal*, VanItallie distributed unpublished figures that purported to demonstrate that 20 percent of all U.S. deaths were related to obesity.<sup>88</sup>

#### Thomas Wadden

University of Pennsylvania professor Thomas Wadden has been a consultant to Novartis, and Abbott Laboratories, and has been in the speakers bureaus of, and consultant to, Knoll and Hoffman-LaRoche.89 In 2004 he was named NAASO's president-elect. Wadden was a member of the NIH's National Task Force on the Prevention and Treatment of Obesity, which determined physician guidelines for very-low-calorie diets. Author Laura Fraser has reported that Wadden conducted numerous studies funded by Sandoz Nutrition Corporation, which makes low-calorie diet products:

"Sandoz makes Optifast liquid diets, sponsors medical conferences, has paid for at least sixty published studies on liquid diets and countless others that didn't make it into the journals (often because they showed no success), and is one of the three hundred largest companies in the United States ... Wadden, at one point, worked for Sandoz."90

# Myth Ripped From Akers: The Headlines



## A Gaggle of Experts

"[L]argely overlooked is the critical role played by prominent academic scientists with financial links to the manufacturer. Benefits were hyped; risks minimized. From the beginning, university researchers helped the company navigate a gauntlet of regulatory and marketing obstacles with a message remarkably in step with the drug maker's mission ... The FDA strung together four large conference rooms to accommodate the [FDA hearing], and as the starting time approached, the crowd became a Who's Who of obesity research. There was JoAnn Manson of Harvard, who just that month had a major article published in the New England Journal of Medicine; Theodore VanItallie of Columbia University, who was introduced as one of the country's leading obesity researchers; George Bray of Louisiana State University, the editor in chief of Obesity Research ... They were all there. And they were all there as paid consultants to Wyeth-Ayerst or the other companies involved in making and selling Redux."

## Continued from Hartford Courant

## For \$1,500, Sign Here

"To make Redux a success ... Wyeth had to change physicians' attitudes. In an effort to find voices that would carry weight with practicing physicians, the company recruited academic researchers to aid in the campaign. In 1994, Wyeth signed a \$180,000 contract with a New Jersey medical publishing company called Excerpta Medica that offered pharmaceutical companies an invaluable tool: ready-made scientific articles, placed in leading medical journals, and carrying the imprimatur of influential academic leaders. According to company documents, Excerpta laid out for Wyeth a schedule of nine articles, each with a carefully crafted message aimed at a carefully targeted audience, from primary-care physicians to cardiologists to nurse practitioners to pharmacists. The articles would have a "writer" and an 'author'—but they wouldn't be the same person. The writer was a free-lancer who was paid \$5,000 to do the heavy lifting: actually researching and writing the articles. The author was often a top university scientist who was paid \$1,500 to review the work and assign his or her name to it for publication ... But company officials frequently tinkered with the text of the articles, removing unflattering references to the chemical compound in Redux—dexfenfluramine—or deleting positive references to other drugs."

## Continued from Hartford Courant

## A Scientist Signs On

"One of those scientists [hired by Excerpta] was Richard Atkinson of the University of Wisconsin, a nationally known obesity expert and co-founder of the American Obesity Association, a research organization that is almost entirely funded by pharmaceutical companies. 'Let me congratulate you and your writer on an excellent and thorough review of the literature,' Atkinson wrote to Excerpta after the hefty manuscript arrived in the mail. 'Perhaps I can get you to write all my papers for me!""

## **Shopping For Science**

"... company officials said the money was needed in part to 'establish and maintain relationships with experts in obesity . . . to gain their support as advocates'"

"One day after [an article questioning the safety of Redux] appeared in the New England Journal of Medicine, company employees drafted a budget request for more than \$5.8 million to pay for new studies, most of which would be conducted by university scientists who already had financial ties to the company. And for some of the studies, the drug company officials

## Continued from Hartford Courant

seemed to possess a strange prescience that the data would come out in their favor, according to an internal memo turned over by Wyeth-Ayerst as part of the diet drug litigation. One research project, aimed at health insurers, was designed to compare the cost of Redux to the cost of treating ailments caused by obesity. 'This study will highlight and reinforce the need for effective obesity management and pharmacotherapy in the managed care setting,' the group wrote in an Aug. 30, 1996, internal memo ... In the same memo, company officials said the money was needed in part to "establish and maintain relationships with experts in obesity ... to gain their support as advocates" and to 'establish and maintain relationships with opinion leaders at the local and national level to communicate to their colleagues the benefits of Redux and to encourage its use."

# THE WALL STREET JOUR

February 9, 1998

# "Dire Warnings About Obesity Rely on a Slippery Statistic"2

"[T]he FDA rushed letters to 700,000 physicians warning of the potential dangers of both fen-phen and Redux. Wyeth-Ayerst said the new study was 'inconclusive' and that further studies 'must be conducted before any possible link can be confirmed.' And Atkinson appeared in press releases for the company, reminding readers that obesity had reached epidemic proportions."

"In part, the FDA appears to accept that obesity is a disease because of oft-repeated testimony, from drug companies and others, that fatness results in a measurable number of deaths. In its Meridia approval, the agency repeated that obesity 'contributes to the deaths of an estimated 300,000 Americans each year."

"That figure first surfaced three years ago when former Surgeon General C. Everett Koop launched Shape Up America!, a physical-fitness campaign coordinated by a nonprofit coalition of industry and health-related organizations. Standing on the South Lawn of the White House, Dr. Koop called obesity 'a major public health threat' and said it had become the nation's No. 2 cause of death, behind smoking, 'resulting in about 300,000 lives lost each year."

#### Continued from THE WALL STREET JOURNAL.

- "Dr. Koop says he derived the statistic from a study called 'Actual Causes of Death in the United States' that appeared in November 1993 in the Journal of the American Medical Association. But the study—a review of death certificates filed in 1990—never said obesity killed that many people. It said, rather, that 'dietary factors and activity patterns that are too sedentary are together accountable for at least 300,000 deaths each year."
- "Some highly publicized findings have spotlighted the genetic antecedents of obesity in mice. But no such link has been established in humans, except in very rare cases. Even if some people are genetically predetermined to be fat, others 'just like to eat—and in that case it's no more of a disease than bank robbery is a disease,' says Marcia Angell, author of a recent editorial in the New England Journal of Medicine that questioned the obesity-as-a-disease model."
- "Barbara J. Moore, who became executive director of Shape Up America! in June 1995, says she warned Dr. Koop that he was misrepresenting the study's findings by making so direct a link between obesity and death. But Dr. Koop defends his interpretation and predicts that 'it will eventually be shown' that obesity does kill as large a number as 300,000—just as preliminary findings on smoking led to more definitive research later."

#### Continued from THE WALL STREET JOURNAL.

- "Dr. Koop's declaration at the White House soon found its way into numerous news articles and other publications. It has often been quoted by Interneuron Pharmaceuticals Inc., the developer of Redux, a diet pill the FDA approved in 1996 but which was withdrawn at its request in 1997 amid concerns that it damages heart valves. Interneuron Chief Executive Glenn Cooper and Redux supporters cited the figure at least seven times at FDA advisory panel hearings on the drug."
- "Interneuron says the statistic was supported by an independent analysis by Theodore VanItallie, a professor emeritus of medicine at Columbia University in New York and a consultant to Laboratoires Servier SA, the French company that licensed Redux to Interneuron. Dr. VanItallie, in a 27-page document labeled "confidential" and distributed only to the FDA and its advisory committee during Redux deliberations, calculated that 20% of Americans, or about 292,000 people a year, die from obesity."
- "But a copy of that document shows that Dr. VanItallie's figures may be exaggerated ..."
- "The 300,000 figure has also been promulgated by officials from the American Obesity Association, who testified at hearings on Redux and Meridia and who have lobbied Congress to urge greater funding for obesity research. In 1996, the group worked with

## Continued from THE WALL STREET JOURNAL.

Shape Up America! to produce a book of recommended treatments for obesity, including drugs, that was distributed to 30,000 doctors and healthcare professionals. It was supported by a grant from American Home Products Corp., marketer of Redux and Pondimin."



"In fall 1995, the FDA first took up the approval of Redux, owned at the time by Interneuron Pharmaceuticals. If approved, Redux would be the first new weight-loss drug in more than 20 years. At the hearings, Interneuron presented data showing an obesity pandemic and said desperate measures were required to stop it from prematurely killing 300,000 Americans a year. That controversial figure came from weight-loss experts and researchers who used epidemiological data from decades-old health studies to build the case that excess body fat was a crisis more urgent than even AIDS ..."

"In the years after the Redux fiasco, the weight-loss industry-doctors, nutritionists, weight-loss clinics, drug makers—supported efforts to keep obesity classified as a disease and successfully lobbied for insurance to cover its treatment. Industry-sponsored obesity experts continued to support treatment guidelines for obesity that included prescribing drugs. Guidelines are essentially detailed steps for doctors in diagnosing and treating an ailment, including recommended drugs to prescribe. The doctors who write guidelines are a powerful force in health care because their opinions become the blueprints that drug companies and medical societies use to teach doctors in the trenches how to prescribe newly approved drugs ..."

## Continued from The Seattle Times

"Many of the doctors who supported Redux, including Bray of Louisiana State University and others, worked on the obesity guidelines for the NIH and the World Health Organization."

## Excerpts From Alicia Mundy's *Dispensing* With The Truth 4

## Mundy on the "300,000 Figure"

"The company [Redux maker Wyeth-Ayerst] had been flooding doctors' conventions, continuing education programs, and medical societies with studies linking '300,000 deaths' and obesity ..."

"The '300,000 deaths per year' shibboleth was more than a slogan at Wyeth and Interneuron. It was the key to their weak risk-benefit analysis, which helped get Redux approved. Yes, they could say, the drugs had some terrible side effects. But the side effects paled in comparison to 300,000 deaths from obesity."

"But where did that '300,000' come from? No one was sure. Dozens of diet drug studies quoted it. Dr. Everett Koop had even cited it; Interneuron's Glenn Cooper mentioned it a half dozen times during the FDA Advisory Committee meetings ..."

"On a fact sheet to be handed out to the medical community and media as part of the Redux launch, Wyeth's Joan Barton edited the line 'Obesity is the second leading cause of preventable death accounting for at least three hundred thousand deaths per year.' She wrote: '[This] has not been substantiated. Delete and use statement re: contributes to four of seven leading causes of death.""

## Mundy on PR and Shape Up America!

"In May [1996], Wyeth executives officially launched their new diet wonder drug with a \$52 million PR campaign ... [PR firm Burson-Marsteller] suggested the companies underwrite a special in USA Today on obesity. 'Oneon-one briefings between high-profile spokespeople [Dr. Koop and Blackburn were mentioned and major media outlets-the NY Times, the Today show, US News & World Report. ..."

"Leverage alliance with Shape Up America!' they exhorted Wyeth to make insurance coverage of diet drugs a national issue and get the U.S. government to evaluate the costs of obesity. Some of this advice took root. Wyeth budgeted over \$700,000 for Shape Up America!, Dr. Koop's new advocacy group. That summer, Shape Up America! hit the airwaves, including The Brian Williams News Hour on MSNBC, to trumpet the new pharmacological treatment of obesity ..."

"In addition, Wyeth budgeted money for grants to the American Diabetes Association, the American Academy of Family Physicians, the North American Association for the Study of Obesity, and the American Society of Bariatric Physicians. The work of tilling and fertilizing never stopped."

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