BMI categories, drug companies, and the drive for reimbursement

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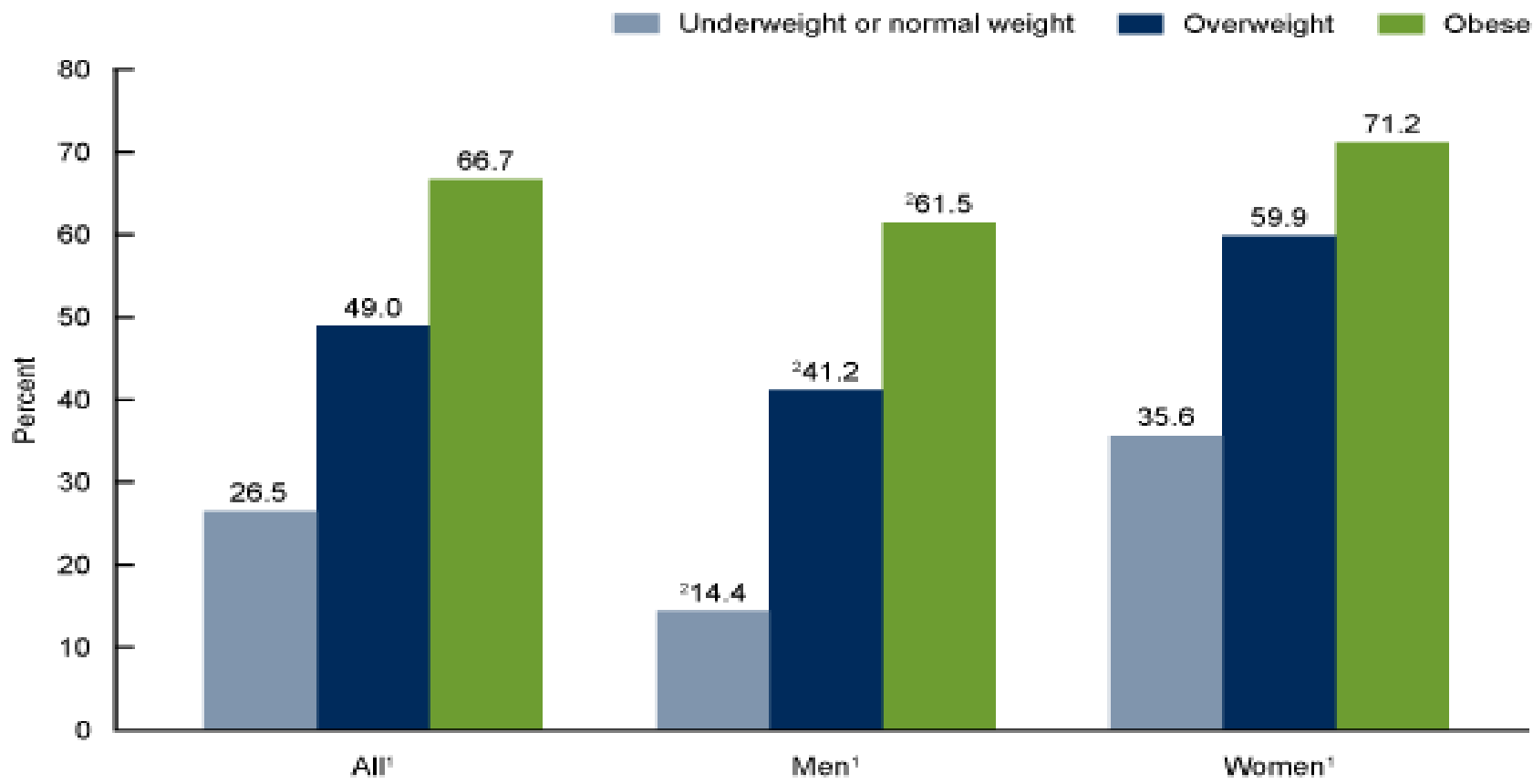
Attempts to lose weight in past year



SOURCE: Martin, Attempts to lose weight among adults in the United States, 2013–2016. NCHS Data Brief, no 313. 2018.

“Prior to the late 20th century, overweight and obesity were not considered a population-wide health risk” - a 2012 report

- Weight loss was largely seen as a cosmetic issue, not as a health issue
- Weight loss treatment was not allowed as a medical deduction for tax purposes
- Health insurance did not cover weight loss treatments
- Weight loss drugs were relatively ineffective and had a checkered history

SOURCE: Institute of Medicine 2012. Accelerating Progress in Obesity Prevention: Solving the Weight of the Nation. Washington, DC: The National Academies Press.

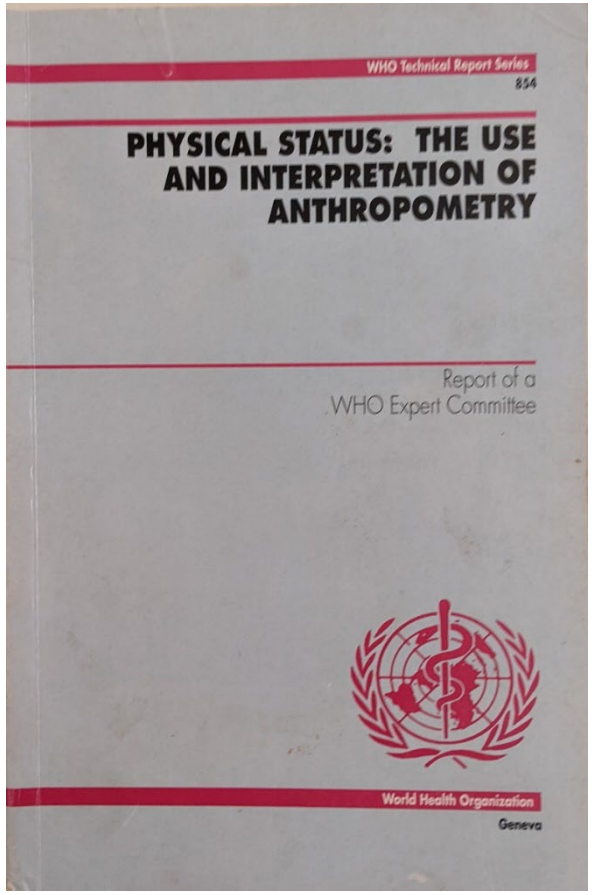
What changed in the late 20th century?

- A transition to the use of prescription weight loss drugs for long-term treatment began with phen-fen in 1992
- The US FDA approved Redux (dexfenfluramine) in 1995. Just three months later, doctors in the US were writing 85,000 prescriptions a week. One securities analyst projected that it would hit $1 billion in sales in five years. [Withdrawn 1997]
- Meridia (sibutramine) was approved in 1997 [Withdrawn 2010]
- Xenical (orlistat) was approved by the FDA in 1999
- A Roche spokesman said "Part of our challenge moving forward with Xenical is to 'medicalize' weight management to physicians."

A huge amount of money to be made

- “By the 1990s, food companies and, more to the point, the pharmaceutical industry, … realized there was a huge amount of money to be made.”
- “A key turning point was 3 June 1997. On this date the World Health Organization (WHO) convened an expert consultation in Geneva that formed the basis for a report that defined obesity not merely as a coming social catastrophe, but as an ‘epidemic’.”
- Source: Peretti, Fat profits: how the food industry cashed in on obesity The Guardian Wed 7 Aug 2013

WHO 1995 report



- 2 years in the making
- 400+ pages
- Dozens of scientists involved
- Covered infants, children, adults, older adults, stunting, thinness and overweight
- No definition of obesity in terms of body fat.
- No definition of obesity in terms of BMI.

WHO report: Physical Status the Use and Interpretation of Anthropometry 1995

- BMI used to define three grades of overweight, with selected cut points of 25, 30 and 40. Cut-off points described as “largely arbitrary”
- Obesity defined as the degree of fat storage associated with elevated health risks. Lack of scientific consensus on exactly what level of fat this might be.
- No clearly established cut-off points for fat mass or fat percentage that can be translated into cut-offs for BMI

The International Obesity Task Force (IOTF)

- The IOTF was formed in 1995
- Established with the express purpose of having a special consultation in WHO Geneva, which would be solely devoted to obesity.
- Mission to inform the worlds' governments about the urgency of the "obesity" problem and to persuade them that the time to act was now.
- Not part of WHO, the IOTF was a stand-alone entity
- Included 20+ members ("obesity experts") from 19 different countries and full-time staff

SOURCE: James WP. WHO recognition of the global obesity epidemic. Int J Obes (Lond). 2008;32 Suppl 7:S120-6.

IOTF and the WHO 1997 Consultation on Obesity

- WHO was initially reluctant to have a consultation on obesity.
- IOTF provided a substantial grant to WHO to fund the consultation
- IOTF staff wrote the draft report which was adopted with almost no changes
- WHO took the unusual step of disseminating an interim version of the report, published in 1998. This was funded by the IOTF, which paid to have free copies sent to health ministers of all UN countries and to any others who requested it.

SOURCE: James WP. WHO recognition of the global obesity epidemic. Int J Obes (Lond). 2008;32 Suppl 7:S120-6.

The IOTF was funded by drug companies

In 2013 a reporter asked [the IOTF chair] where the funding for the IOTF came from. "Oh, that's very important. The people who funded the IOTF were drug companies." And how much was he paid? "They used to give me cheques for about 200,000 [British pounds] a time. And I think I had a million or more," (roughly the equivalent of 2.5 million U.S. dollars today.)

Source: Peretti, **Fat profits: how the food industry cashed in on obesity** The Guardian Wed 7 Aug 2013

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OBESITY

PREVENTING AND MANAGING THE GLOBAL EPIDEMIC

Report of a WHO Consultation on Obesity

Geneva, 3-5 June 1997

Division of Noncommunicable Diseases

World Health Organization
Geneva

Programme of Nutrition
Family and Reproductive Health

Modified terminology for BMI categories

	1995 WHO Physical status report	1997 WHO Consultation, Obesity preventing and managing the global epidemic*
BMI 18.5-<25	Normal range	Normal range
BMI 25-<30	Grade 1 Overweight	Pre-obese
BMI 30-39.9	Grade 2 Overweight	Obese Class I, Obese Class II
BMI >40	Grade 3 Overweight	Obese, Class III

* The classification is described as "in agreement" with the 1995 report

IOTF, WHO and NIH

- In the US, an NIH committee was preparing new clinical guidelines for overweight/obesity
- 4 members of the NIH committee, including the chair, were also IOTF members
- In 1998 the new guidelines were presented using new classifications based on the interim report from the WHO consultation

New NIH Terminology

	1995 WHO Physical status report	1997 WHO Consultation, Obesity preventing and managing the global epidemic*	1998 NHLBI Clinical Guidelines**
BMI 18.5-<25	Normal range	Normal range	Normal
BMI 25-<30	Grade 1 Overweight	Pre-obese	Overweight
BMI 30-39.9	Grade 2 Overweight	Obese class I and II	Obese
BMI >40	Grade 3 Overweight	Obese, Class III	Severe obesity

- The classification is described as "in agreement" with the 1995 report

** The source of the classification is given as the 1998 interim report

New US guidelines were criticized by some

- Several people, including a committee member, expressed concern that the new guidelines opened the door for widespread use of diet drugs and may unnecessarily stigmatize people.

- Former Surgeon General Koop urged the panel not to broaden the definition of overweight, saying "it will confuse the public and the medical community. It needlessly stigmatizes millions of Americans and lacks a solid scientific rationale."

A silver platter for drug companies?

The New York Times described the new cut points as providing the pharmaceutical industry with “a booming new market for diet pills for the obese, practically served to the companies on a silver platter by the government”

SOURCE: Stolberg, S. G. (1999, May 2). Ideas & trends: The fat get fatter; overweight was bad enough. New York Times.

Who will pay for weight loss drugs?

- “Reimbursement” became a huge issue in the obesity research world. This is shorthand for the idea that medical providers should be reimbursed for treating obesity.
- A Roche spokesman said "Part of our challenge moving forward with Xenical is to 'medicalize' weight management to physicians”
- The US Medicare Coverage Manual stated bluntly that “Obesity itself cannot be considered an illness… Program payment may not be made for treatment of obesity alone since this treatment is not reasonable and necessary for the diagnosis or treatment of an illness or injury”.

Barriers to reimbursement fell

- In 2001, an IOTF member who had joined CDC organized and chaired a meeting at CDC entitled “Including Obesity Treatment in Benefit Plans” on the topic of reimbursement of health care providers for obesity treatment.
- As a follow-up to this meeting, CDC put in a request to remove the Medicare language which stated that “Obesity is not an illness.”
- In 2013, the American Medical Association (AMA) recognized obesity as a chronic disease, although the AMA’s own Council on Science and Public Health had recommended against adopting the resolution. European guidelines also endorsed the view of obesity as a disease, not without some discussion

Some new directions?

Diagnosis of obesity based on body composition-associated health risks—Time for a change in paradigm, Bosy-Westphal and Muller, Obes Rev 2021

- Characterization of obesity as “overfat” does not facilitate a comprehensive understanding of obesity-associated health risk. …
- It is time to call the adipocentric paradigm of obesity into question and to avoid the use of BMI and body fat percentage.
- Instead, obesity should be viewed as a problem of limited fat-free mass/muscle mass together with a limited capacity of fat storage.

Lancet Diabetes & Endocrinology Commission on the Definition and Diagnosis of Clinical Obesity, Lancet Diabetes, 2023

- The BMI thresholds used for the definition of obesity have been intended and studied as predictors of future disease or mortality, but not as measures of existing illness.
- In this context, the attribution of disease status to obesity defined exclusively by a BMI threshold, as it is today, is an intrinsically flawed concept.
- A blanket definition of obesity as a disease would classify approximately 30–40% of people in many nations as having this illness.9 This definition could render over a third of these populations suddenly eligible for claims of disability or expensive treatments. Such claims would effectively make obesity a financially and socially intractable issue