

APRIL 2025

OBESITY PLAYBOOK

AN EDUCATIONAL RESOURCE BOOK FOR CONGRESSIONAL STAFF ON OBESITY AND HEALTH

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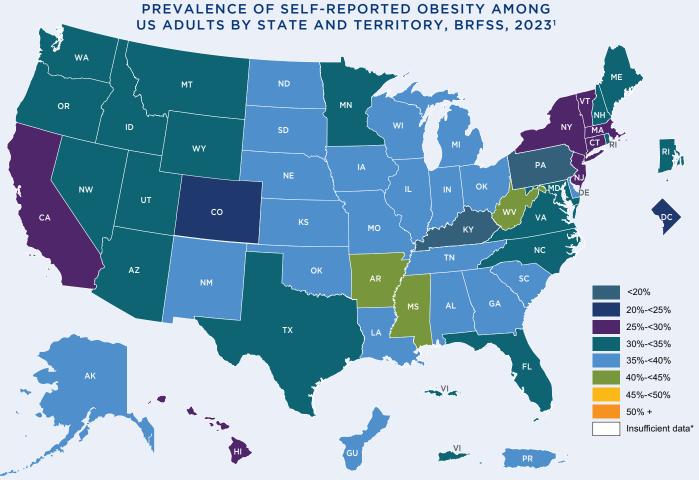
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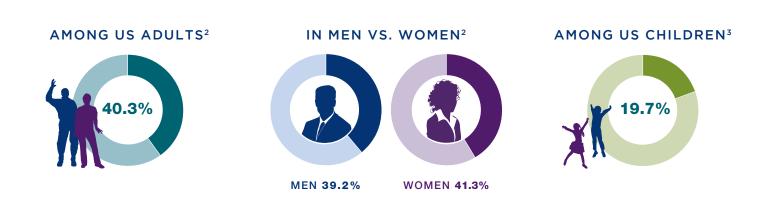
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OBESITY FACTS AND FIGURES



Source: Behavioral Risk Factor Surveillance System *Sample size <50, the relative standard error (dividing the standard error by the prevalence) \geq 30%, or no data in a specific year.



¹ https://www.cdc.gov/obesity/data-and-statistics/adult-obesity-prevalence-maps.html

- ² https://www.cdc.gov/nchs/products/databriefs/db508.htm
- ³ https://www.cdc.gov/obesity/childhood-obesity-facts/childhood-obesity-facts.html



NATIONAL SECURITY



OVER 1 IN 3 YOUNG ADULTS IS TOO HEAVY TO SERVE IN THE MILITARY.⁴



THE DEPARTMENT OF DEFENSE SPENDS

\$1.5 BILLION

IN ESTIMATED ANNUAL OBESITY RELATED HEALTH CARE COSTS FOR SERVICE MEMBERS AND THEIR FAMILIES.⁴



LOST WORKDAYS WERE DUE TO ACTIVE MILITARY PERSONNEL WITH OBESITY-RELATED CONDITIONS.⁴



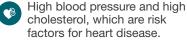
THE US ARMY FELL 25% SHORT OF ITS RECRUITMENT GOAL.⁴

MEDICAL CARE AND PERSONAL HEALTH





OBESITY IN CHILDREN AND ADULTS INCREASES THE RISK FOR THE FOLLOWING HEALTH CONDITIONS⁶

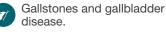


Type 2 diabetes.



Breathing problems, such as asthma and sleep apnea.

Joint problems such as osteoarthritis and musculoskeletal discomfort.





PEOPLE LIVING WITH OBESITY ARE 194% MORE LIKELY TO USE PAID TIME OFF THAN COLLEAGUES WHO DID NOT HAVE OBESITY.⁷

⁴ <u>https://www.cdc.gov/physicalactivity/resources/unfit-to-serve/index.html</u>

- ⁵ https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0247307
- ⁶ <u>https://www.cdc.gov/obesity/basics/consequences.html#:~:text=Obesity%20in%20children%20and%20adults,for%20</u> <u>the%20following%20health%20conditions.&text=High%20blood%20pressure%20and%20high,as%20asthma%20</u> <u>and%20sleep%20apnea</u>



⁷ https://pmc.ncbi.nlm.nih.gov/articles/PMC3047996/

Part One: Background

What Is Obesity?

Obesity is a *chronic multifactorial disease* characterized by an individual having an excess of body fat or abnormal fat accumulation that can result in serious complications. People who have obesity are at an increased risk for other serious diseases and health conditions. Obesity is associated with the leading causes of preventable death in the United States. Obesity is associated with a wide range of chronic diseases and health conditions such as high blood pressure, high cholesterol, prediabetes, type 2 diabetes, heart disease, chronic and end stage kidney disease, and 13 different cancers among others. Obesity is not a simple problem of willpower or self-control, but rather a disease that is the result of multiple genetic, developmental, physiological, hormonal, and environmental factors. Understanding obesity as a disease is critical to its management at both the individual and population levels.

While there are several screening tools available for obesity, none are consistently or widely used nationally in healthcare systems. BMI is one screening tool that is generally used as a health indicator and often used as one of many screening measures for individuals. A person with a BMI of 30 kg/m² or greater is considered a person with obesity. It is the most commonly used indicator at this time due to ease of use and cost. However, other measures including waist circumference, bioelectrical impedance, dual energy x-ray absorptiometry (DXA) and other measures exist but have not become a standard of care for assessing obesity due to a variety of factors including cost, lack of training in accurate measurement technique, and inconsistency across the country. Until a standard of care and measure is available, BMI continues to be used as one of the primary measures to assess excess body weight and associated risk.

In 2013, the Endocrine Society partnered with other medical societies to pass a <u>resolution</u> in the American Medical Association (AMA) House of Delegates officially recognizing obesity as a chronic disease.

Obesity Prevalence

Obesity is extremely common in the United States. More than 2 in 5 adults in the United States are living with obesity. It is estimated that more than 100 million adults are living with obesity and more than 22 million have severe obesity (BMI > = 40).¹ There are currently 23 states with an obesity rate at or above 35 percent. Prior to 2013, no state had an adult obesity rate at or above 35 percent.²



¹ https://www.cdc.gov/obesity/adult-obesity-facts/?CDC_AAref_Val=https://www.cdc.gov/obesity/data/adult.html

² https://www.cdc.gov/media/releases/2024/p0912-adult-obesity.html

Obesity also affects some groups more than others and can vary depending on where you live in the country. There are numerous studies showing the impact obesity has had on rural Americans with one study estimating that that obesity rates are approximately 6.2 times higher in rural America compared to urban areas.³ Prevalence also differs by income and education level. Men and women with less education have had higher rates of obesity compared to men and women with college degrees.⁴ There are also notable differences and heightened disparities among different communities.⁵

Additional Resources:

- Adult Obesity Maps The CDC released 2023 Adult Obesity Prevalence Maps for 48 states, the District of Columbia, and 3 US territories. The maps show selfreported adult obesity prevalence by race, ethnicity, and location. The data comes from the Behavioral Risk Factor Surveillance System.
- Nutrition, Physical Activity, and Obesity: Data, Maps, and Trends This interactive database provides national and state-level data about the health status and behaviors of Americans. Visitors can examine data by demographics such as sex and race/ethnicity. The data come from multiple sources.

Causes of Obesity

Obesity is a result of multiple genetic, physiological, hormonal, environmental and developmental factors. Several factors further contribute to excess weight gain, including diet and diet quality, physical activity level, certain medications, and sleep routines. Biology, stress, and environmental factors in the community also play a role.⁶

Additional resources:

- Nutrition Good nutrition is essential to health. Poor quality nutrition contributes to many costly diseases, such as obesity. The linked webpage is from the USDA Dietary Guidelines for Americans and discusses the role that nutrition plays in health outcomes.
- <u>Causes of Obesity</u> Obesity is a complex disease. The linked webpage is from the CDC and discusses the causes and what can be done and includes several national resources.
- Social Determinants of Health The conditions in which we live, learn, work, and play are called the social determinants of health (SDOH). When these conditions do not support health, it can be difficult to develop and maintain healthy lifestyle choices and behaviors. SDOH has a major impact on people's health, well-being, and quality of life, and contributes to health disparities and inequities. The linked



³ https://pmc.ncbi.nlm.nih.gov/articles/PMC8290986/

⁴ https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6650a1-H.pdf

⁵ https://ftp.cdc.gov/pub/Health_Statistics/NCHS/NHIS/SHS/2017_SHS_Table_A-15.pdf

⁶ <u>https://www.cdc.gov/obesity/risk-factors/risk-factors.html</u>

webpage is from the Health and Human Services Healthy People 2030 initiative. It explains what SDOH are and how they relate to health outcomes and includes links to further research.

Weight Stigma and Bias

According to the <u>World Obesity Federation</u>, weight stigma is defined as discriminatory acts and ideologies targeted towards individuals because of their weight and size. Obesity is often associated with stigma, which can affect a person's mental health, quality of life, and lead to biases in how people with obesity are treated. Weight stigma is a result of weight bias, which refers to the negative ideologies associated with obesity. Weight biases can interfere with the effective management of obesity care.

Additional Resources:

- <u>World Obesity Federation</u> the WOF has a webpage on this topic with more information on the consequences of weight stigma and bias.
- <u>Supportive Obesity Care</u> the University of Connecticut operates a program on weight stigma called Supportive Obesity Care. This page includes additional information on weight stigma in healthcare and how healthcare can be improved for those living with obesity.
- <u>Obesity Action Coalition (OAC)</u> the OAC has a webpage on this topic with more information on how to better understand weight stigma.

Food and Nutrition Security

Nutrition plays a critical role in keeping Americans healthy. Unfortunately, poor quality nutrition is making people more vulnerable to costly chronic diseases like obesity and diabetes. According to the <u>CDC</u>, fewer than 1 in 10 children and adults eat the recommended daily amount of vegetables. Only 4 in 10 children and fewer than 1 out of every 7 adults eat the recommended amount of fruit. According to <u>Trust for America's Health</u>, there are several theories explaining the link between food insecurity and obesity including social environment, financial situation, stress, and depression.

Additional Resources:

- <u>The State of Obesity: 2023</u> This report, published by Trust for America's Health, provides a retrospective on how obesity has impacted Americans over the past 20 years.
- <u>USDA Food Access Research Atlas</u> This atlas, published by the United States Department of Agriculture (USDA), is a search tool that provides a glimpse into a neighborhood or community's access to food stores that offer healthy and affordable food.



- <u>USDA Food and Nutrition Security</u>: Access to food alone does not ensure that all Americans have consistent and equitable access to healthy, safe, affordable foods essential to optimal health and well-being. This web page discusses the USDA efforts to address food and nutrition security in the US.
- <u>NIH and the Weight of the Nation</u>: The four-part series Consequences, Choices, Children in Crisis, and Challenges — highlighted several NIH research advances and addressed the factors contributing to the country's obesity problem.

Obesity Complications

Obesity and Chronic Disease

Obesity is associated with over 230 complications including a wide range of chronic diseases and health conditions such as high blood pressure, high cholesterol, prediabetes, type 2 diabetes, heart disease, chronic and end stage kidney disease, and 13 different cancers, among others. These diseases, combined with obesity, can lead people to have poor health, poor quality of life, disability, and even premature death. However, these consequences can be prevented or improved by achieving a healthy weight.

Additional Resources:

- <u>The Health Effects of Overweight & Obesity</u> This CDC webpage lists some of the common health conditions associated with obesity.
- <u>Obesity and Cancer</u> This CDC webpage discusses the links between obesity and cancer.
- <u>Health Risks of Being Overweight</u> This webpage from the NIDDK discusses the links between excess weight and many health conditions.
- <u>The Impact of Obesity on Body and Health</u> This webpage from the American Society for Metabolic and Bariatric Surgery discusses the impact that obesity can have on the body.
- Quantifying the Sex-Race/Ethnicity-Specific Burden of Obesity on Incident Diabetes Mellitus in the United States, 2001 to 2016: MESA and NHANES - Data from MESA (2000-17) and NHANES (2001-16) reported that US adults with obesity were approximately three times more likely to develop type 2 diabetes than those without obesity and 40% of new-onset was directly attributable to obesity.
- Obesity and Cardiovascular Disease: A Scientific Statement from the American <u>Heart Association, Circulation Volume 143, Number 2</u>: This review explores the impact of obesity on cardiac function and outcomes related to heart failure with



reduced and preserved ejection fraction. This review also describes the effects of lifestyle and surgical weight loss interventions on outcomes related to coronary artery disease, heart failure, and atrial fibrillation.

Obesity and Type 2 Diabetes

Obesity and type 2 diabetes are two chronic diseases that are closely related. Recent research has shown that obesity contributes to up to half of new diabetes cases each year in the United States.⁷ People with overweight are three times more likely to have type 2 diabetes compared to those considered to be "normal weight" according to body-mass-index (BMI). When a person at risk of developing diabetes has excess weight, the cells in the body become less sensitive to the insulin released from the pancreas which can eventually result in diabetes.⁸

Additional Resources:

 <u>Obesity Action Coalition: Understanding Obesity and Type 2 Diabetes</u> – This educational brochure has information about the relationship between obesity and type 2 diabetes.

Obesity and Cardiovascular Disease

According to a study reviewed by the National Institutes of Health (NIH), obesity is among the leading causes of elevated cardiovascular disease (CVD) morbidity and mortality.⁹ Overall, the rate of heart disease deaths associated with obesity increased by about 180%. According to research from the American Heart Association, the rate of deaths from ischemic heart disease due to obesity nearly tripled in the U.S. over a two-decade span.¹⁰

Additional Resources:

• <u>American Heart Association (AHA)</u>: This scientific statement summarizes the impact of obesity on the diagnosis, clinical management, and outcomes of atherosclerotic cardiovascular disease, heart failure, and arrhythmias, especially atrial fibrillation, and sudden cardiac death.

Obesity and Kidney Disease:

According to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), obesity increases the risk of developing diabetes and high blood pressure,

⁷ <u>https://newsroom.heart.org/news/obesity-contributes-to-up-to-half-of-new-diabetes-cases-annually-in-the-united-states</u>

⁸ <u>https://www.obesityaction.org/get-educated/public-resources/brochures-guides/understanding-obesity-and-type-2-diabetes-brochure/</u>

⁹ <u>https://pmc.ncbi.nlm.nih.gov/articles/PMC3250069/</u>

¹⁰ <u>https://www.heart.org/en/news/2024/11/13/death-rates-linked-to-obesity-related-heart-disease-are-up</u>

which are the most common causes of chronic kidney disease (CKD). Even without diabetes or high blood pressure, having obesity may increase risk of developing chronic kidney disease and speed up its progress.¹¹

Additional Resources:

• <u>Obesity and chronic kidney disease</u>: This review reveals that obesity is a risk factor for the onset and progression of CKD and should be recognized as a potential target for a preventive public health approach to reduce CKD rates within the general population.

Obesity and Cancer

Having overweight or obesity is linked with a higher risk of getting 13 types of cancer. In summary, nearly 40% of all cancers can therefore be attributed to overweight and obesity.¹² Scientists are beginning to establish precisely how obesity leads to this disease. For example, altered insulin response and estrogen levels are linked to cancer, and evidence indicates that excess body fat can trigger chronic inflammation that affects the levels of these important hormones.¹³

Obesity and Pregnancy

More than 50% of American women enter pregnancy with overweight or obesity, putting them at high risk of gestational diabetes and other pregnancy complications (operative deliveries, extended neonatal length of stay, stillbirth). The pregnancy period is a time of epigenetic developmental programming in the offspring. This seems to initiate a cycle of obesity in pregnancies complicated by obesity and gestational diabetes, putting the offspring at high risk of developing obesity.

Additional Resources:

• <u>Increases in Pre-pregnancy Obesity: United States, 2016–2019</u> – Using data from the National Vital Statistics System, this page evaluates pre-pregnancy rates of obesity by race/ethnicity, age group, and education level.

Economic Cost Burden

The economic costs of obesity are high, including both direct and indirect costs. Direct medical costs may include preventive, diagnostic, and treatment services while indirect costs relate to sickness, lost productivity, and death. Obesity accounts for \$173 billion in



¹¹ <u>https://www.niddk.nih.gov/health-information/weight-management/adult-overweight-obesity/health-</u>

risks#:~:text=Kidney%20disease%20means%20your%20kidneys,keep%20your%20kidneys%20healthier%20longer. ¹² https://pubmed.ncbi.nlm.nih.gov/25757865/

¹³ https://pubmed.ncbi.nlm.nih.gov/26516917/

higher medical costs each year.¹⁴ A study from Brookings estimates that obesity costs \$91.6 billion per year to Medicare and Medicaid.¹⁵

There is also a direct link between obesity and productivity and employment. The direct costs of obesity-related absenteeism ranges between \$3.38 billion and \$6.38 billion nationwide.¹⁶ Another study found that people living with obesity are 194% more likely to use paid time-off than their colleagues who do not have obesity.¹⁷

Additional Resources:

- <u>Direct medical costs of obesity in the United States and the most populous states</u>

 Cited above, this study showed that the effect of obesity is greater than suggested by previous studies. Much of the aggregate national cost of obesity –
 \$260.6 billion represents external costs, providing a rationale for interventions to prevent and reduce obesity.
- <u>Adult Obesity Causes & Consequences</u> This CDC webpage discusses some of the economic and societal costs of obesity.

Obesity and Military Readiness

Active-duty military members and potential recruits are subject to the same health problems that affect the rest of the US population. As such, the increase in nationwide obesity prevalence is reflected in the military population, and the impact on military readiness is substantial. 19% of active-duty service members had obesity in 2020, a 3% increase from the previous year. ¹⁸ These individuals are less likely to be medically ready to deploy. Consequently, active-duty soldiers had more than 3.6 million musculoskeletal injuries between 2008 and 2017. Obesity also impacts military recruitment. Over 1 in 3 adults are too heavy to serve in the military. Meanwhile only 3 in 4 young adults who meet weight requirements report having physical activity levels that adequately prepare them for the challenges faced during basic training. Consequently, this means that only 2 in 5 young adults are both weight-eligible and meet the threshold for physical activity to serve. ¹⁹ In 2022, the army fell 25% short of its recruitment goal and that number continues to rise. ²⁰

Obesity is also financially costly for the military. It is estimated that the Department of Defense (DoD) spends \$1.5 billion in obesity-related healthcare costs per year. Further, there are 658,000 lost workdays due to overweight and obesity for active-duty military personnel per year, costing the DOD \$103 million per year.



¹⁴ <u>https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0247307</u>

¹⁵ https://www.brookings.edu/articles/obesity-costs-evident-at-the-state-level/

¹⁶ https://pmc.ncbi.nlm.nih.gov/articles/PMC5640019/

¹⁷ <u>https://pmc.ncbi.nlm.nih.gov/articles/PMC3047996/</u>

¹⁸ <u>https://www.cdc.gov/physicalactivity/resources/unfit-to-serve/index.html</u>

¹⁹ https://www.cdc.gov/physicalactivity/resources/unfit-to-serve/index.html

²⁰ https://www.cdc.gov/physicalactivity/resources/unfit-to-serve/index.html

Additional Resources:

- <u>Obesity in America: Prevention, Coverage, and Impact on National Security</u>: The Endocrine Society hosted a virtual congressional briefing looking at the impact obesity has had on the military and national security.
- <u>Unfit to Serve</u> This CDC webpage explores the impact of obesity on national security, military readiness, and Department of Defense spending.
- <u>"Obesity—An Epidemic that Impacts our National Security"</u> This whitepaper from the American Security Project explores the impact of obesity on military recruitment. Published in 2023, "<u>Combating Military Obesity: Stigma's Persistent</u> <u>Impact on Operational Readiness</u>" is the follow up report to the 2018 whitepaper.

Obesity Treatment and Care

Treatment Options

Obesity can be treated but it requires a comprehensive approach:

- Intensive Behavioral Therapy: Intensive Behavioral Therapy (IBT for Obesity) promotes weight loss through high-intensity comprehensive and structured diet and exercise programs. IBT for Obesity is an effective way to treat obesity and is recommended by the <u>United States Preventive Services Taskforce (USPSTF)</u>.
- **Medical Nutrition Therapy**: Medical Nutrition Therapy (MNT) is nutrition-based treatment provided by a Registered Dietitian Nutritionist (RDN). MNT is proven to be a cost-effective component of treating obesity and other chronic diseases including diabetes.
- Anti-obesity medications: There are numerous medications available that have been scientifically proven to be effective against obesity. While these medications have been approved by the FDA, many insurers, including Medicare, do not cover them.

Barriers to Treatment

- **Medicare Part B**: Intensive Behavioral Therapy (IBT for Obesity) has been a covered benefit under Medicare Part B since 2011. However, the benefit must be provided by or under direct supervision of a primary care provider in a primary care setting. This means that IBT cannot be referred by a primary care provider to other providers such as registered dietitian nutritionists, or specialty physicians such as endocrinologists. (Obesity Care Advocacy Network Memo on IBT for Obesity)
- **Medicare Part D**: Anti-obesity medications are currently not covered under Medicare Part D. When Congress created the Part D program in 2003, there were no FDA approved obesity therapies on the market and the Medicare statute excluded "weight loss drugs" from being covered. In the 20 years since



Part D was created, there have been major medical advances in the pharmacologic treatment of obesity and the FDA has approved several antiobesity medications. (OCAN Memo on CMS Authority to Provide Coverage for Obesity Drugs Under Part D; TROA Fact Sheet)

GLP-1 (glucagon-like peptide-1)

A GLP-1 agonist is a class of medications that act like the GLP-1 hormone in your body. It stimulates insulin production to keep blood sugar at healthy levels. It can also help to achieve and maintain a healthy weight, which also contributes to the management of diabetes.²¹ There are two forms of GLP-1 medications: an injection and an oral medication. The first GLP-1 was approved in 2005 to treat diabetes, and researchers found that it also caused decreased appetite and weight loss.²² Individuals can lose up to 15% to 20% of their body weight on GLP-1 drugs.²³ This kind of weight management can help with managing and preventing chronic diseases that are linked to obesity. In 2014, the FDA approved the first GLP-1 medication for weight-loss.²⁴ Since coming onto the market, research shows that adding pharmacotherapy for weight management results in increased weight loss and overall improved health. For many individuals with obesity, taking an AOM results in changes in hormonal signals affecting hunger and satiety and facilitates greater adherence to lifestyle approaches. However, it is important for people living with obesity to have a balanced approach that also includes lifestyle intervention such as Intensive Behavioral Therapy (IBT).²⁵

Additional Resources:

- GLP-1 Agonists: The Clevland Clinic provided an overview of GLP-1s, their risk. and benefit, how they work, and treatment details.
- <u>GLP-1 receptor agonist drug's effectiveness</u>: UChicago Medicine provided research regarding the effectiveness of GLP-1 drugs, while exploring various concerns.
- The GLP-1 journey: This article explores the discovery of GLP-1, treatment details, and the future of GLP-1-based medicines.
- Emerging Role of GLP-1 Agonists in Obesity: This review summarizes numerous studies conducted on the main drugs in the GLP-1 agonists class, outlining the maximum achievable weight loss.
- Real-World Analysis of Medication Access and Clinical Outcomes for Obesity Treatment with GLP-1s: This review included valuable information about GLP-1

²² https://www.science.org/content/article/breakthrough-

²¹ https://health.ucdavis.edu/treatments/glp-1-medications

^{2023#:~:}text=This%20year%2C%20clinical%20trials%20found%20that%20thev.of%20the%20Year.%20Read%20the %20full%20story%E2%80%A6).

²³ https://pubmed.ncbi.nlm.nih.gov/36321278/

²⁴https://www.nejm.org/doi/full/10.1056/NEJMcibr2409089#:~:text=In%202014%2C%20liraglutide%20became%20the .<u>for%20a%20weight%2Dloss%20indication</u>. ²⁵ <u>https://www.endocrine.org/-/media/endocrine/files/advocacy/society-letters/2023/june/uspstf-obesity-</u>

comments061323.pdf

access and the efficacy of a comprehensive program despite GLP-1 treatment disruptions.

- <u>Physiology and Pharmacology of Effects of GLP-1-based Therapies on Gastric,</u> <u>Biliary and Intestinal Motility:</u> This review summarizes the effects of GLP-1 and incretin-based therapeutics on gastric, biliary, and small intestinal function. An improved understanding of these effects will optimize the use of these drugs.
- <u>2023 Obesity Science Writer's Conference</u>: The Endocrine Society hosted a virtual science writer's conference discussing how anti-obesity medications have changed the obesity treatment landscape. The conference explored how these medications and bariatric surgery can treat obesity and improve cardiometabolic health. You can also read some of the media coverage about the conference: <u>Clinical Advisor Article: Semaglutide and Tirzepatide: Top 5 Things Clinicians Should Know.</u>

Drug Compounding

Compounding and the FDA

Compounding is a process where a pharmacist will compound, or customize, a medication for a patient who cannot be treated with the FDA-approved medication. Compounded medications are not approved by the FDA and the agency does not review compounded versions of these medications for safety, efficacy, or quality. The FDA does permit compounding pharmacies to compound medications if they are on the FDA's drug shortage list. In recent years, both semaglutide and tirzepatide have been on and off the FDA's drug shortage list. Due to these shortages and the price, many patients are taking compounded versions of these medications. The Endocrine Society is concerned about the use of compounded GLP-1 medications. We hosted a <u>Science</u> <u>Writer's Conference</u> last year examining these concerns. The FDA also has resources on their website. In 2024, the agency issued <u>an alert</u> to providers in 2024 regarding the risk of dosing errors associated with using compounded GLP-1s. The agency also <u>has a</u> <u>page</u> detailing the agency's concerns with unapproved GLP-1 drugs used for weight loss.

Additional Resources:

- <u>Endocrine Society Science Writer's Conference on Compounding</u>: The Endocrine Society hosted a webinar which examined the concerns around the compounding of anti-obesity medications. During the webinar, Endocrine Society experts discussed the importance of prescribing FDA-approved medications to treat obesity.
- <u>FDA Page on Compounded GLP-1 Medications</u>: This page includes information detailing the FDA's concerns with unapproved GLP-1 drugs used for weight loss.
- <u>FBI Public Service Announcement</u>: Safety Concerns Related to Fraudulent Compounding Practices Associated with Weight Loss Drugs



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- <u>STOP Obesity Alliance Information about Compounding of GLP-1 Drugs</u>: This page provides background information for consumers about compounding of GLP-1 medications for weight-loss.
- <u>The Obesity Society Statement on Compounding</u>: The Obesity Society (TOS) issued a statement calling on FDA to better enforce unauthorized compounding.



Part Two: State of the Science

This section contains peer reviewed journal articles intended for a scientific audience. These articles provide information about the scientific basis of obesity, discuss how this knowledge can be applied in clinical practice, and identify areas that require additional research.

Scientific Statements from the Endocrine Society

- <u>The Science of Obesity Management: An Endocrine Society Scientific Statement:</u> This scientific statement documents the rising prevalence of obesity in both men and women in the United States, its hazardous health implications, treatment options, and further areas for research.
- <u>Obesity Pathogenesis: An Endocrine Society Scientific Statement</u>: This scientific statement seeks to elucidate obesity pathogenesis to better inform treatment, public policy, advocacy, and awareness of obesity in ways that ultimately diminish its public health and economic consequences.

Endocrine Society Journal Articles

The Endocrine Society frequently curates a special collection of journal articles focused on obesity. Below are journals and reviews that explore the overall understanding of obesity research and treatment.

- <u>2025 JCEM Obesity Thematic Issue</u>: This is a collection of articles published from the start of 2024. Topics include the multifaceted role of GLP-1 receptor agonist drugs in the treatment of obesity, diabetes, and metabolic disorders.
- <u>2023 JCEM Obesity Thematic Issue</u>: This is a collection of articles published from 2022-2023. Topics include new weight loss pharmacotherapies and their potential to move beyond the 5% weight loss goal, weight loss and lipids, mechanisms of weight loss after obesity surgery, and more.
- <u>2021 JCEM Obesity Thematic Issue:</u> This is a collection of articles published from 2019 to 2021. Topics include the relationship between obesity, diabetes, cancer, liver damage in children, the association between body mass index and stroke risk in patients with type 2 diabetes, and more.
- <u>2019 JCEM Obesity Thematic Issue:</u> This is a collection of articles published in 2019. Topics include the relationship between climate and the obesity epidemic, mindfulness and healthier eating habits, and more.

Below is a list of articles from our journal that focus on obesity:

 <u>Rapidly Increasing Use of Anti-Obesity Medications among Veterans in the</u> <u>Veterans Health Administration (VA)</u>: This article reviews a retrospective cohort study of VA patients from 7/1/2021-6/30/2023 and examined data from the VHA Corporate Data Warehouse separately for patients on GLP-1s without and with



diagnosed diabetes, since GLP-1s can be used at lower doses for the diabetes indication.

- <u>GLP-1 and the Neurobiology of Eating Control: Recent Advances</u>: This review provides a targeted synthesis of recent developments in the field of GLP-1 neurobiology, highlighting studies which have advanced our understanding of how GLP-1 signaling modulates eating, and identifies open questions and future challenges we believe still need to be addressed to aid the prevention and/or treatment of obesity.
- <u>Physiology and Pharmacology of Effects of GLP-1-based Therapies on Gastric,</u> <u>Biliary and Intestinal Motility:</u> This review summarizes the effects of GLP-1 and incretin-based therapeutics on gastric, biliary, and small intestinal function. An improved understanding of these effects will optimize the use of these drugs.
- Treatment of Hypothalamic Obesity With GLP-1 Analogs: This nonsystematic literature review was conducted to identify scientific papers published from January 2005 to February 2024 using the Pubmed and Embase databases. All case studies demonstrated weight loss and improved metabolic function. Key words used were GLP-1, GLP-1RA, hypothalamic obesity, suprasellar tumor, and craniopharyngioma.
- <u>Anti-obesity pharmacotherapy for patients with genetic obesity due to defects in</u> <u>the leptin-melanocortin pathway:</u> This review explores how pharmacotherapeutic options, including combination and gene therapies offer promising positive effects on body weight, hyperphagia, and quality of life for patients with a variety of genetic obesity disorders.
- <u>Real-World Analysis of Medication Access and Clinical Outcomes for Obesity</u> <u>Treatment with GLP-1s:</u> This review included valuable information about GLP-1 access and the efficacy of a comprehensive program despite GLP-1 treatment disruptions.

Endocrine Society Members' Work

- <u>Amy Rothberg: Retention and weight outcomes after transitioning an intensive</u> <u>behavioral weight management program from an in-person to a virtual format:</u> Endocrine Society Member, Amy Rothberg, MD, published a piece in Obesity Science and Practice showing that the transition from in-person to virtual program delivery improved retention and, by doing so, indirectly improved weight loss at 2 years.
- Jami Josefson: After a pandemic boom in child obesity, it's time for families to recommit to health: Endocrine Society member Jami Josefson, MD published a piece Chicago Tribune about the COVID-19 pandemic's impact on childhood obesity.
- <u>Diet Quality and Energy Intake Mediate the Association of Food Insecurity with</u> <u>Adiposity:</u> Endocrine Society members Lisa Morselli, MD PhD, Roland James, MS, and Srividya Kidambi, MD presented an abstract at ENDO 2022 to discuss a



new study finding that teens ate less ultra-processed food during the COVID-19 pandemic.

 Long-term Weight Loss Maintenance with Obesity Pharmacotherapy: a 5-Year <u>Retrospective Study</u>: Endocrine Society member Dr. Michael Weintraub presented an abstract at ENDO 2022 with results of a study that found that 10% weight loss could be maintained long-term with anti-obesity medications and lifestyle changes.

Obesity Research Areas

Epigenetic and Environmental Causes of Obesity

Scientists are working to understand how genetics influences obesity, and while genetics plays some role in inherited factors that lead to obesity, it does not provide a complete explanation of what we observe. Both changes to genes that occur across the lifespan (epigenetic changes) and environmental factors contribute to obesity in families across generations, and these factors may play a role in future preventive strategies.

Health Disparities

The prevalence of obesity in the US is increasing rapidly, with half the adult population projected to have obesity by 2030.²⁶ However, these rates are not the same among different populations. There are disproportionately high rates of obesity among different communities because of various social determinants of health. These conditions include socioeconomic status, education, access to healthcare, transportation, and social support.^{27,28,29} Scientists are working to understand how social determinants of health and other factors contribute to these health disparities, and how new interventions can deliver new solutions for disproportionately impacted populations.

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²⁶ <u>https://pubmed.ncbi.nlm.nih.gov/32016289/</u>

²⁷ https://pmc.ncbi.nlm.nih.gov/articles/PMC3464818/

²⁸ <u>https://pubmed.ncbi.nlm.nih.gov/22812021/</u>

²⁹ https://pubmed.ncbi.nlm.nih.gov/22253363/

Part Three: Policy Options

This section provides brief overviews of current laws and programs funded by Congress pertaining to obesity. It also includes recent legislation addressing obesity. This overview is meant to provide a synopsis of some of the key policy areas pertaining to obesity. This is not meant to be a fully inclusive list of every policy area on this issue.

As background, anti-obesity medications are currently not covered under Medicare Part D. When Congress created the Part D program in 2003, there were not FDA approved obesity therapies on the market and the Medicare statute excluded "weight loss drugs" from being covered. There have been major medical advances in the pharmacologic treatment of obesity in the 20 years since Part D was created, and the FDA has approved several anti-obesity medications. Congress should pass legislation to allow CMS to cover these FDA-approved anti-obesity medications.

If you have any questions about this section, please contact Rob Goldsmith on the Endocrine Society staff (contact information is listed in Part Five).

CMS Obesity Coverage Proposed Rule (Not Finalized)

In November 2024, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule which would allow Medicare and Medicaid to cover anti-obesity medications (AOMs) for weight-loss. The proposed rule would allow Medicare and State Medicaid programs to cover AOMs for obesity and acknowledges obesity as a chronic disease. In January 2025, the Endocrine Society <u>submitted comments</u> to CMS in support of the rule. Our letter urges the Administration to adopt the proposal because it would remove a major barrier which has prevented millions of Americans from receiving appropriate and evidence-based obesity treatment. On April 4, 2025, <u>CMS announced</u> that they would not be finalizing this proposal, but indicated that they may address this in future rulemaking.

Recent Legislation Introduced (Action Pending)

These bills were introduced in the 118th Congress. We will update the playbook as new pieces of legislation are introduced in the 119th Congress.

 Treat and Reduce Obesity Act: This legislation would expand access to intensive behavioral therapy (IBT) for obesity. IBT includes frequent face-to-face dietary/nutrition and physical activity assessments, and counseling on behavior change that promotes weight loss and long-term weight loss maintenance. Medicare will currently only cover IBT when these services are provided by a primary care provider in the primary care setting. The Treat and Reduce Obesity Act would expand Medicare coverage of IBT for obesity allowing additional qualified healthcare providers to offer IBT services. The bill would also allow for coverage of FDA-approved weight loss medications that can be offered in



conjunction with IBT. In the last Congress, the bipartisan legislation had 120 cosponsors in the House and 25 cosponsors in the Senate.

• Medical Nutrition Therapy Act: Medical Nutrition Therapy (MNT) is evidencebased nutrition therapy provided by Registered Dieticians which can include nutrition assessment and intervention. This legislation would provide Medicare Part B coverage of outpatient MNT for several uncovered conditions and diseases such as prediabetes, obesity, and cancer. Currently, Medicare Part B only covers outpatient MNT for people with diabetes, renal disease, and those post-kidney transplant. MNT was introduced by Senators Susan Collins (R-ME) and Gary C. Peters (D-MI). In the last Congress, the legislation had 29 cosponsors in the House and 8 cosponsors in the Senate.

Relevant Legislation Introduced (Action Pending)

Members of Congress have also introduced legislation that promotes accessibility to physical activities and healthy eating. Below is a list of several bills that were introduced in the last Congress. We will update the playbook as new pieces of legislation are introduced.

- Transit to Trails Act: This legislation would provide equitable access to parks, green spaces, and public lands and waters. The bill would establish a grant program that will fund projects to make transportation to these spaces more accessible for underserved communities. The Transit to Trails Act was introduced by Senators Booker (D-NJ) and Markey (D-MA) with 9 cosponsors last Congress. Representatives Jimmy Gomez (D-CA) and Nanette Diaz Barragan (D-CA) introduced a House companion with 73 cosponsors last Congress.
- Reducing Obesity in Youth Act: This legislation would require the Centers for Disease Control and Prevention (CDC) and the Administration for Children and Families (ACF), to award grants to nonprofits, institutions of higher education, or other entities to promote healthy eating and physical activity and address food insecurity among children in early care and education settings. The bill was introduced in the Senate by Senator Booker (D-NJ) and by Representative Steve Cohen (D-TN) in the House.
- Bicycle Commuter Act: This legislation would reinstate bicycle commuter benefits, allowing employees to receive a bicycle benefit of up to 30% of employer-offered parking benefits. The bill was introduced by Senator Brown (D-OH) in the Senate, and Representative Earl Blumenauer (D-OR) in the House. The House Bill had 32 cosponsors last Congress.

Childhood Obesity Research Demonstration (CORD)

• The Childhood Obesity Research Demonstration (CORD) project focuses on developing and implementing strategies to reduce obesity among low-income



children. Funding for CORD was first made available through the Patient Protection and Affordable Care Act in 2011 and has been reauthorized twice. The program, which is administered by the CDC, is the primary source of CDC funding for childhood obesity research focused on low-income children.

For more information: GAO Report on CORD, CDC Page on CORD 3.0

Child Nutrition and Food Security

 The Child Nutrition Programs are a group of different programs focused on nutrition for children and adults reauthorized by Congress. The programs include the National School Lunch Program, the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), and the School Breakfast Program. Many of the Child Nutrition Programs are funded through annual appropriations. The most recent reauthorization was the Healthy, Hunger-Free Kids Act (HHFKA) of 2010 (P.L. 111-296). The HHFKA required the USDA to create new nutrition standards for school meals utilizing the latest science on nutrition. It also created a Community Eligibility Provision (CEP) to provide free meals to students in eligible schools. Issues for next reauthorization: updated nutrition standards for school meals, implementation of CEP, updates to Fresh Fruit and Vegetable Program.

For more information: <u>CRS Report, Child Nutrition Reauthorization</u> Overview, <u>CRS Report: Child Nutrition Programs: Issues in 115th Congress.</u>

• The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) is a food assistance program that provides nutritious food and nutrition education to low-income women, infants and children. WIC is funded through discretionary spending. WIC is usually included as part of the Child Nutrition Programs reauthorization.

For more information: <u>CRS Report</u>, <u>A Primer on WIC</u>: <u>The Special Supplemental</u> <u>Nutrition Program for Women</u>, <u>Infants</u>, <u>and Children</u>

• The Supplemental Nutrition Assistance Program (SNAP) provides assistance to low-income households to ensure they buy nutritional low-cost food. SNAP is included in the reauthorization of the Farm Bill.

For more information: <u>CRS Report, Supplemental Nutrition Assistance Program</u> (SNAP): A Primer on Eligibility and Benefits_



Federal Nutrition Labeling Rules

 The Affordable Care Act (ACA) (P.L. 111-148) includes a provision which requires menu labeling in some restaurants and other retail food establishments. It also required calorie labeling for some items sold in vending machines. In 2014, the FDA finalized two rules that established calorie labeling requirements for food sold in vending machines and some restaurants. However, the compliance requirements pertaining to these rules were delayed for many years. In April 2020, the FDA suspended the federal menu labeling requirements due to the COVID-19 pandemic.

For more information: <u>CRS Report: Nutrition Labeling of Restaurant Menu</u> and Vending Machine Items



Part Four: The Administration and Federal Agencies

National Institutes of Health (NIH)

The NIH Obesity Research Task Force

This task force was established to accelerate progress in obesity research and promote collaboration and coordination across the NIH. The task force is made up of participants across the NIH's Institutes and Centers and is chaired by the Director of the National Institute of Diabetes and Digestive and Kidney Diseases, Dr. Griffin P. Rodgers; Director of the National Heart, Lung, and Blood Institute, Dr. Gary H. Gibbons; and the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, Dr. Diana W. Bianchi.

For more information: The NIH Obesity Research Task Force Webpage

Office of Obesity Research, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

This office is responsible for coordination of obesity-related research across NIDDK and carrying out the functions of the NIDDK Obesity Research Working Group.

For more information: NIDDK Office of Obesity Research Webpage

Centers for Disease Control (CDC)

Division of Nutrition, Physical Activity, and Obesity (DNPAO)

This division aims to improve the overall health and well-being of all people, with a focus on promoting health equity among groups experiencing more risk factors for chronic diseases. DNPAO provides grant funds to states and local governments to address obesity in their local communities.

For more information: CDC Division of Nutrition, Physical Activity, and Obesity Website

Department of Health and Human Services (HHS)

Healthy People 2030

Every ten years the Department of Health and Human Services (HHS) releases a tenyear plan for addressing the nation's most critical public health priorities and challenges. Last August, HHS released Healthy People 2030 which consists of several objectives to improve the health and well-being of the nation. This effort is led by the HHS Office of Disease Prevention and Health Promotion in partnership with the National Center for Health Statistics at the Centers for Disease Control and Prevention.



For more information: Healthy People 2030 Website

Department of Defense (DoD) & Veterans Administration (VA)

The Department of Defense (DoD) and the Veterans Administration (VA) have treatments and resources available to provide help and support for people living with obesity but there are coverage restrictions and systematic issues that need to be addressed at both agencies. The VA/DoD have a joint clinical practice guideline which suggests that weight management medications for long-term weight loss be offered to patients with a body mass index (BMI) > 30 kg/m2 and to those with a BMI > 27 kg/m2 if they have another condition associated with obesity.³⁰ TRICARE, the health insurance program for active duty military service members, retirees, and their families, covers anti-obesity medications for beneficiaries with some limitations.³¹ The VA also covers AOMs and bariatric surgery through their Weight Management Program for Veterans (MOVE!) but there are also some restrictions and prior authorization requirements.³² The Endocrine Society is concerned about the prevalence of obesity in the military. In April 2024, the Endocrine Society joined various medical organizations to advocate for the DOD to rectify systematic issues which prevent individuals with obesity from accessing evidence-based treatments. ³³

Additional Resources:

- <u>Obesity in America: Prevention, Coverage, and Impact on National Security</u>: The Endocrine Society hosted a virtual congressional briefing looking at the impact obesity has had on the military and national security.
- VA/DoD Guidance for Treatment of Weight Management Medications for Chronic Use: In January, 2024, the VA and DoD issued guidance on the use of weight management medications for chronic use.
- VA/DoD Clinical Practice Guidelines on Management of Adult Overweight and <u>Obesity</u>: This guideline describes the critical decision points in the management of obesity.
- Department of Veterans Affairs (VA) Page on MOVE! Weight Management <u>Program</u>: This page provides additional information about the VA's Weight Management Program for Veterans (MOVE!), supported by VA's National Center for Health Promotion and Disease Prevention (NCP).

³³ https://www.endocrine.org/advocacy/society-letters/2024/obesity-in-armed-forces



³⁰<u>https://www.va.gov/formularyadvisor/DOC_PDF/CRE_Weight_Management_Medications_Guidance_Rev_Jan_202</u> 4.pdf

³¹<u>https://tricare.mil/FAQs/Pharmacy/PharmProg_Wegovy#:~:text=TRICARE%20only%20covers%20Wegovy%20and,out%20a%20prior%20authorization%20form.</u>

³²https://www.move.va.gov/#:~:text=VA%20also%20offers%20weight%20management,Stories:%20The%20Power% 20of%20Change.

Part Five: Contacts & Other Resources

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Endocrine Society Obesity Advocacy Webpage

The Society has a page on our website with obesity advocacy resources. Please go to this <u>page</u> on our website for additional information including our obesity position statements and virtual congressional briefings.

Media Resources & Coverage

2024 Obesity Science Writers Conference

The Endocrine Society hosted a virtual Science Writers Conference on anti-obesity medications and compounding concerns that emphasized the importance of prescribing FDA-approved medications to treat obesity. Journalists from *The New York Times*, CNN, and the Associated Press were among those who registered for the event. You can watch a recording of the conference <u>here</u>.

2023 Obesity Science Writer's Conference

The Endocrine Society hosted a virtual science writer's conference which discussed how anti-obesity medications (AOMs) have changed the obesity treatment landscape. The conference explored how AOMs and bariatric surgery can treat obesity and improve cardiometabolic health. You can watch a recording of the conference <u>here on our website</u>. You can also read some of the media coverage about the conference:

- Clinical Advisor Article, <u>Semaglutide and Tirzepatide: Top 5 Things Clinicians</u> <u>Should Know</u>
- Medscape Article, <u>Bariatric Surgery Still Best Option for Some With Obesity</u>

"Talking Obesity" Video Series



The Society also launched its <u>"Talking Obesity with Experts"</u> video series with Daniel Drucker, MD, who shared his story as one of the first researchers to discover GLP-1s for treating diabetes and obesity.

Obesity Media Coverage

Endocrine Society members are frequently interviewed on national and local media outlets on the issue of obesity. Here are some recent articles featuring our members and their research:

- The Hill: Exposure to 'forever chemicals' during early pregnancy may be linked to future obesity, heart issues: Study
- Cardiology Advisor: <u>Vitamin D Supplements May Lower Blood Pressure in</u> <u>Seniors With Overweight</u>
- Everyday Health: <u>Ozempic May Reduce Sugar Cravings by Heightening</u> <u>Sensitivity to Sweets</u>
- Medical News Today: <u>Risk for heart attack and stroke higher in younger adults</u> who have had obesity for a decade or more
- Endocrine Today: <u>Bariatric surgery tied to improved cardiometabolic health</u>, <u>lower CVD risk</u>
- CNN Health: Forget TikTok claims: <u>'Nature's Ozempic' is no such thing, experts</u> say
- Reuters: Focus: As weight-loss drugs hit the U.S. market, doctors debate how to use them
- NBC News: <u>BMI is a flawed way to measure obesity, experts say. What else</u> works?
- HealthDay: <u>Cases of Obesity-Linked Liver Disease Rising Steeply Among</u> <u>Americans</u>
- USA Today: <u>Type 2 diabetes crisis can be controlled. These solutions are how</u> we get there.

Obesity Related Coalitions

The Strategies to Overcome and Prevent (STOP) Obesity Alliance

STOP Obesity Alliance is a coalition of business, consumer, advocacy, and health organizations dedicated to reversing the obesity epidemic in the United States. In 2020, the Endocrine Society partnered with the STOP Obesity Alliance to issue <u>Weight Can't</u> <u>Wait: A Guide for the Management of Obesity in the Primary Care Setting</u>. This guide fills the gap in obesity management training and provides healthcare professionals with a short, accessible, practical, and informative guide to effective obesity care.

For more information: STOP Obesity Alliance Website



The Obesity Care Advocacy Network (OCAN)

OCAN is a coalition of diverse organizations dedicated to addressing obesity issues. OCAN's mission is to unite and align key obesity stakeholders and the larger obesity community around key obesity-related education, policy, and legislative efforts in order to elevate obesity on the national agenda.

For more information: OCAN Website

The CDC Coalition

The CDC Coalition is a nonpartisan coalition of organizations committed to strengthening our nation's public health infrastructure and prevention programs. Its mission is to ensure that health promotion and disease prevention are given top priority in federal funding, to support a funding level for CDC that enables it to carry out its prevention mission and to assure an adequate translation of new research into effective state and local programs. Coalition member groups represent millions of public health workers, researchers, clinicians, educators and citizens served by CDC programs.

For more information: CDC Coalition Website

