

**Testimony of the Endocrine Society
Submitted to the
Food and Drug Administration
Endocrinologic and Metabolic Drugs Advisory Committee**

The Endocrine Society is the world's largest professional organization of endocrinologists, representing the interests of over 18,500 physicians and scientists engaged in the treatment and research of endocrine disorders, including diabetes and obesity. The Society appreciates the opportunity to provide testimony to the FDA as it considers treatment options, such as semaglutide, to improve glycemic control in adults with type 2 diabetes. We look forward to working with the agency as it moves forward in its review of these therapies.

As members of the committee are aware, diabetes is a growing epidemic that affects more than 422 million individuals worldwide¹, 30 million² of whom reside in the United States. Diabetes contributes to the development of many complications, including cardiovascular disease, kidney failure, high blood pressure and cholesterol, which may lead to an increased risk of death if left untreated. In addition, more than 87% of individuals with type 2 diabetes are overweight or obese which further contributes to these complications.³ Treatments that reduce or delay these complications experienced by people with diabetes are needed to improve quality of life and increase life expectancy.

The SUSTAIN 7 study found that treatment of type 2 diabetes with one-weekly semaglutide resulted in statistically significant reductions in HbA1C and weight loss. While the Society does not endorse specific therapies or medications undergoing FDA approval, it is encouraged by emerging therapies that have been shown to safely and effectively treat diabetes and reduce life-threatening complications such as cardiovascular disease.

Recent advancements in science have proven effective in reducing co-morbidities associated with the disease and have the potential to reduce the economic burden of diabetes on the healthcare system. Because each person faces unique challenges in the management and severity of their diabetes, it is important that a variety of therapeutic options are available.

The Society urges the FDA to give fair consideration of new options in combating this disease and to expedite the approval process for emerging therapies that, based on safety and efficacy data, have the potential to reduce complications and impact the progression of diabetes. Thank you.

¹ Worldwide trends in diabetes since 1980: a pooled analysis of 751 population-based studies with 4.4 million participants. The Lancet, Volume 387, Issue 10027, 1513 – 1530.

² National Diabetes Statistics Report, 2017. The Centers for Disease Control and Prevention. <http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf>

³ Ibid.