

April 5, 2021

The Honorable Rachel Levine Assistant Secretary of Health Department of Health and Human Services 200 Independence Ave SW Washington, DC 20201

Dear Assistant Secretary Levine:

I write to congratulate you on your confirmation as Assistant Secretary of Health at the Department of Health and Human Services (HHS) and to offer our assistance as you lead HHS in developing and implementing programs and policies that will affect our members who treat patients and/or conduct research and advance the public's health. We would also like to request a meeting with you and your staff to discuss our shared policy priorities described below.

Founded in 1916, the Endocrine Society represents approximately 18,000 physicians and scientists engaged in the treatment and research of endocrine disorders, such as diabetes, infertility, obesity, osteoporosis, endocrine cancers (thyroid, adrenal, ovarian, pituitary) and thyroid disease. Endocrinologists are at the core of solving some of the most pressing health problems of our time. We promote policies to help ensure that all individuals with endocrine-related issues have access to high quality, specialized care and adequate, affordable health insurance. We hope to work with you on the following areas of shared concern and commitment:

Transgender Health

Endocrinologists are important members of the transgender care team. The Society advocates for developing evidence-based policies for transgender people, protecting their access to care, and better funding and research to address transgender health gaps. We are deeply concerned about the increasing number of state legislative efforts to deny care to transgender people and criminalize use of puberty blockers in minors with gender dysphoria. Our clinical practice guideline on gender dysphoria/gender incongruence provides the standard of care for supporting transgender individuals. The guideline establishes a methodical, conservative framework for gender-affirming care, including pubertal suppression, hormones and surgery and standardizes terminology to be used by healthcare professionals. The Society also has developed a position statement on transgender health with five key principles to improve transgender health. We look forward to partnering with you to improve transgender care and make these priorities a reality:

2055 L Street NW Suite 600 Washington, DC 20036 T. 202.971.3636 F. 202.736.9705 endocrine.org



- 1. There is a durable biological underpinning to gender identity that should be considered in policy determinations.
- 2. Medical care providers and health insurance companies should not discriminate against or deny coverage to individuals based on their gender identity.
- 3. Medical intervention for transgender individuals—including both hormone therapy and medically indicated surgery—is effective, relatively safe (when appropriately monitored), and has been established as the standard of care.
- 4. The treatment of gender dysphoria/incongruence is medically necessary and should be covered by insurance.
- 5. Increased funding for national research programs is needed to close the gaps in knowledge regarding transgender medical care and should be made a priority.

Women's Health

Endocrinologists treat many conditions affecting women that are caused by a loss of normal hormonal function, including menopause, infertility, breast cancer, and Polycystic Ovary Syndrome. Ensuring that all women have access to necessary health care services, contraception, and preventative screenings is a top priority for the Society.

A growing body of research shows that sex and gender differences influence our health across the lifespan. The COVID-19 pandemic provides a clear example of why we must consider both sex and gender in research. For instance, men are more likely than women to die from the virus, while women seem more likely to suffer long-term side effects. To advance women's health -- and ensure better health care for all -- there needs to be a commitment to including sex as a biological variable (SABV) in research and support for inclusion policies. We hope to work with you to implement the Biden Agenda for Women, expand the NIH inclusion and SABV policies, and achieve the HHS Health People 2030 women's health objectives.

Making Insulin Affordable

Access to affordable insulin continues to be a serious problem for people with diabetes across the country. The average price of insulin has nearly tripled over the past 15 years despite the fact insulin has been available for 100 years. An increasing number of patients are becoming increasingly exposed to these costs due to high deductible plans and higher levels of coinsurance. In January, the Society released updated recommendations to address insulin access and affordability. The position paper, which was <u>published</u> in the *Journal of Clinical Endocrinology & Metabolism*, offers a range of recommendations to lower the cost of insulin including allowing government negotiation of drug prices, increasing transparency, lowering patient cost-sharing, increasing competition through the approval of biosimilar insulin, limiting future insulin price increases to the rate of inflation, and including real-time benefit information in electronic medical records. We hope to work



with you in the coming months as the Administration considers how to address drug pricing in general and insulin affordability specifically.

Diabetes and Obesity Epidemics

The prevalence of diabetes in this country is staggering: 34.1 million Americans – or 13% of all US adults – have diabetes. 88 million American adults – approximately 1 in 3 – have pre-diabetes. Diabetes is the most expensive chronic condition in our nation. \$1 out of every \$4 in US health care costs is spent on caring for people with diabetes. \$237 billion is spent each year on direct medical costs and another \$90 billion on reduced productivity. Meanwhile, obesity continues to increase with approximately 42.4% of adults and 19.3% of children considered obese.

Layered onto the diabetes and obesity epidemics is the COVID-19 pandemic. And while research is still emerging, we know that COVID-19 has put people with diabetes and/or obesity at increased risk for poor outcomes and death; COVID has also further exposed and exacerbated existing health disparities among communities of color, lower-income, and other underserved populations, communities that also have a higher prevalence of diabetes. This combination of COVID, diabetes, obesity and disparities has created unique and urgent challenges to both people with these conditions and to health care workers.

There are wide range of programs and agencies within HHS that are important for research and prevention of diabetes and obesity. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH) is critical for discoveries to prevent and better treat diabetes and obesity and is helping us understand the unique aspects of how COVID-19 presents and progresses in patients with these diseases. The National Diabetes Prevention Program (DPP) is an evidence-based lifestyle intervention program funded through the NIH, which has demonstrated that a 5-7 percent weight loss could reduce the risk of developing diabetes by 58 percent. The Center for Disease Control and Prevention (CDC) Division of Nutrition, Physical Activity, and Obesity (DNPAO) aims to improve the overall health and well-being of people by providing grant funds to states and local governments to address obesity in their local communities. We strongly support these programs because of the important work they are doing to prevent and better understand diabetes and obesity and we recognize the importance of interagency coordination of these issues.

Access to Care

Endocrinologists care for people who suffer from multiple chronic conditions that require access to coordinated care by many specialists. Many of these patients benefit from the ACA's guarantee of health insurance with no annual or lifetime caps or pre-existing condition exclusions. We have joined with other health organizations in amicus briefs to



support the ACA. We urge HHS to not only protect a health care system that ensures patient access to care that is continuous, high-quality, adequate, and affordable, but to enhance the current law. We want to stress the importance of maintaining insurance market reforms, including the guarantee of health insurance with no annual or lifetime caps or pre-existing condition exclusions, and the opportunity for children to be covered by their parents' insurance until age 26. The ACA has allowed many of these people to obtain affordable insurance coverage; without it, many Americans cannot afford the cost of care for diabetes, which averages \$13,700 per year. We also stress the importance of reinstating Title X protections for reproductive health and contraceptive health care, which are critical to women's health.

In conclusion, the Endocrine Society shares many issues with the Administration's health agenda. The list above reflects our priorities and interwoven in these issues is the pressing need to address COVID-19 and our commitment to diversity, equity, and inclusion. We have appreciated our previous work with you on transgender and diabetes prevention when you served as Pennsylvania's Physician General and Secretary of Health and look forward to working with you in your new role. Our members can provide expertise in several key health areas and we stand ready to assist you in any way we can. We hope to meet with you to discuss these issues and policies and will have our staff contact your scheduler. In the meantime, if you have any questions or would like additional information, please have your staff contact our Chief Policy Officer Mila Becker at mbecker@endocrine.org. We look forward to working with you to protect the public's health.

Sincerely,

Caral H Hugham

Carol H. Wysham, MD President Endocrine Society