

April 26, 2017

Secretary Tom Price Department of Health and Human Services

Dear Secretary Price,

On behalf of the Endocrine Society members and leaders, I write to offer our assistance as you lead the Department of Health and Human Services (HHS) in developing and implementing programs impacting practicing endocrinologists and basic and clinical scientists.

The Endocrine Society is the oldest and largest global professional membership organization representing the field of endocrinology. We are dedicated to advancing hormone research and excellent care of patients with diabetes, obesity, osteoporosis, infertility, rare cancers, thyroid conditions and other endocrine disorders. Our more than 18,000 members include scientists, physicians, educators, nurses, and students, in 122 countries around the world.

Because hormonal issues underlie nearly all chronic diseases, Endocrine Society members are indispensable to other physicians, patients, and policymakers, who rely on their unique expertise. Historically, breakthroughs such as the discovery of insulin, cortisol, and the estrogen receptor shaped treatments that enhance the lives of millions of patients worldwide.

Below, we highlight some of our policy priorities we hope to work with you on:

Ensuring access to affordable health care: We ask that HHS continue to support a health care system that ensures patient access to care that is continuous, high-quality, adequate, and affordable. Without affordable insurance that covers their needs, many Americans skip or delay health care. We need a system that leads to healthier and more productive lives.

We appreciate President Trump's commitment to maintaining important 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 year¹. By reducing financial burden, insurance coverage promotes treatment adherence and reduces complications.

Policies that expand access to coverage are critically important, but alone do not ensure meaningful access to health care. We offer to work with you and your team to ensure that our patients' needs are fully considered as the health care and insurance systems are reevaluated.

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Addressing the global epidemic of diabetes and obesity: More than 26 million Americans have diabetes and more than 1/3 are obese. Diabetes leads a list of just 20 diseases and conditions that account for more than half of all spending on health care in the United States. US spending on diabetes diagnosis and treatment totaled \$101 billion in 2013, and has grown 36 times faster than spending on heart disease, the country's No. 1 cause of death.²

Access to preventive care, intensive behavioral counseling and the necessary treatments are crucial to improve early diagnosis and to begin effective treatment before these conditions worsen or costly complications develop. Provider and patient education must be prioritized to reduce hypoglycemic events, a significant driver of diabetes spending. Because people with diabetes are at risk for costly comorbidities, such as heart disease, stroke and kidney failure, the US must continue researching and building effective multidisciplinary care team models.

We urge the Administration to support:

- Increased funding for the National Diabetes Prevention Program, a proven behavioral intervention that reduces the risk of progressing from prediabetes to diabetes by 71 percent in the Medicare population;
- Coverage for evidence-based obesity treatments; and
- Reauthorization of the Special Diabetes Program at \$300 million to fund type 1
 diabetes research at the National Institutes of Health (NIH) and treatment,
 education, and prevention programs for American Indian and Alaska Native
 populations, who are disproportionately affected by Type 2 Diabetes.

Recognizing the value of endocrinologists: Care by endocrinologists is associated with lower morbidity rates, fewer readmissions, and lower healthcare costs. Endocrinologists provide this cost- and time-effective treatment without the use of unnecessary diagnostic testing and procedures. Endocrinologists also improve quality and reduce costs by coordinating care for patients with co-morbidities. Approximately 40 percent of the total US population has at least one chronic disease and 30 percent of Medicare beneficiaries with diabetes have 5 or more chronic conditions, including osteoporosis and thyroid disease. Endocrinologists are often the primary care provider, as these conditions and associated complications are often too complex for a general practitioner to treat.

Despite the vital role of endocrinologists in the care of patients with these chronic diseases, there are currently fewer than 4,000 clinical endocrinologists in the United States to care for the 100 million potential patients that suffer from diabetes and prediabetes alone. These workforce shortages can be partially attributed to the low compensation for endocrine care and the administrative burden associated with practice. Compensation is similar to that of primary care physicians, as over 90 percent of endocrinologists' charges are evaluation and management (E/M) codes. Currently, these codes do not account for the non-face-to-face services that cognitive specialists provide to patients with chronic conditions. **We have requested that CMS conduct a comprehensive review to understand care required by**

² Dielman JL, et al. US Spending on Personal Health Care and Public Health, 1996-2013. JAMA. 2016;316(24):2627-2646.



the chronically ill patient. Such data will allow for more accurate reimbursement and reduced documentation for services that cognitive specialists provide. We look forward to working with CMS to increase payments for services that are shown to improve outcomes with lower costs.

Women's health care: 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. Should the ACA be repealed or modified, we strongly urge that preventive health services, including hormonal and other contraception, continue to be covered at no cost to the patient.

Endocrinologists prescribe hormonal contraception to treat a myriad of conditions; 58 percent of oral contraceptive (OC) users cite non-contraceptive health benefits, such as reduced menstrual bleeding or pain, and acne, as reasons for using the method.³ In fact, 1.5 million women (14 percent of OC users) use this method exclusively for non-contraceptive purposes⁴. Hormonal contraception also can reduce a woman's risk of developing ovarian or endometrial cancer, and may protect against osteoporosis. We believe that all women should have access to contraception, both for health reasons and to control when they choose to have children.

As the Administration considers changes to or replacement of the ACA, we strongly urge that preventive health care, including contraception, continue to be covered at no cost.

Federal funding for biomedical research: Endocrine scientists funded by the National Institutes of Health (NIH) continue to make remarkable contributions in areas of critical national interest, including diabetes, obesity, the microbiome, cancer, bone health, and fertility.

President Trump has emphasized the importance of the United States maintaining its place as the global leader in all sectors. Biomedical research is an area where the country is losing its place as the top generator of scientific discovery. The lack of sustained federal support compounded by austerity measures such as sequestration has created a "brain drain," as gifted scientists pursue other careers or leave the US to develop important breakthroughs and therapies elsewhere, while young people opt out of biomedical research careers. Without increased federal support for biomedical research and the NIH, other countries will fund groundbreaking new cures and treatments and replace the United States as the global leader in biomedical research.

Future opportunities to cure many diseases will decrease as the government's investment in biomedical research declines. For FY 2017, we have urged Congress to pass a final spending package that provides at least \$34 billion for the NIH. For FY 2018, we support an increase of \$2 billion over the final FY 2017 budget to make up for years of flat and underfunding, and to maintain America's status as a leading research engine.

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³ Jones RK, *Beyond Birth Control: The Overlooked Benefits of Oral Contraceptive Pills*, New York: Guttmacher Institute, 2011.

⁴ Ibid.



Sex as a biological variable: To ensure that there are appropriate therapies to treat both women and men, females must be included in all phases of biomedical research to evaluate sex-specific effects and enhance rigor and completeness of studies. Research by NIH should consider sex as a biological variable where appropriate; all studies funded or conducted by the NIH and those reviewed by the FDA should report data by sex.

Reducing harmful exposure to endocrine disrupting chemicals (EDCs): EDCs are present in everyday products and throughout the environment; they harm human health by interfering with hormones in the body. However, there is no comprehensive, coordinated approach to regulating EDCs in the US. Policies based on comprehensive data covering low and high-level exposures would have significant economic and health benefits.

We urge the Administration to support coordinated regulatory oversight of EDCs based on scientific evidence, including data developed by academic researchers, and continued support of the National Institute of Environmental Health Sciences to build the scientific basis for such regulation.

Regulatory burdens in research: Clinical and basic scientists receiving federal support are often negatively impacted by the time and effort required to comply with administrative requirements imposed by granting agencies and their home institutions. For example, grant forms are often not standardized across agencies, creating redundancies, and there can be multiple layers of administrative approval for forms, necessitating advanced due dates.

In addition to the burden on investigators, the excessive administrative burdens waste taxpayer dollars and delay the completion of lifesaving research. The high expense of these administrative and regulatory tasks also results in an increasingly unequal playing field for biomedical researchers at many institutions across the country. **As the Administration examines opportunities to reduce federal regulations, we encourage you to consider opportunities to reduce onerous regulatory burdens faced by researchers.**

We look forward to engaging with your agency on many health and research issues. If we can be of assistance, please do not hesitate to contact me or Mila Becker, JD, Chief Policy Officer, at mbecker@endocrine.org when our expertise may be of value.

Sincerely,

Barbara Byrd Keenan

Chief Executive Officer, Endocrine Society

cc: Administrator Seema Verma

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Director Francis Collins