ENDOCRINE SOCIETY
Hormone Science to Health

June 4, 2019

The Honorable Lamar Alexander
Chair, HELP Committee
US Senate
Washington, DC

The Honorable Patty Murray
Ranking Member, HELP Committee
US Senate
Washington, DC

Re: Opportunities to reduce health care costs

Dear Senators Alexander and Murray:

On behalf of the Endocrine Society, I am responding to the Health, Education, Labor, and Pensions (HELP) Committee's request for comments on the Lower Health Care Costs Act of 2019. The Endocrine Society is the world's largest professional organization of endocrinologists, representing the interests of over 18,000 physicians and scientists engaged in the treatment and research of endocrine disorders. Endocrine researchers have discovered many effective treatments for costly diseases and endocrinologists use their expertise in treating endocrine conditions to avoid costly complications and unnecessary tests. Our comments focus on the following areas:

- Sec. 209—Streamlining the Transition of Biological Products
- Sec. 306—Health Plan Oversight of Pharmacy Benefit Manager Services
- Sec. 403—Guide on evidence-based strategies for state health department obesity prevention programs
- Sec. 406-Innovation for maternal health
- Sec. 410—Integrated services for pregnant and postpartum women

Sec. 209—Streamlining the Transition of Biological Products

The cost of insulin has nearly tripled in the past fifteen years, making it difficult for many of the over 7 million people who use insulin to afford this medication and effectively manage their diabetes. This has put patient safety in jeopardy as patient self-rationing of their insulin may lead to unnecessary hospitalizations, complications or death and should not be a cost-savings approach that people with diabetes are forced to choose. The issue of insulin affordability is a top priority for the Endocrine Society and one we hear frequently about from our members, many of whom have conversations daily with their patients about their ability to afford their insulin.

Competition from multiple medications in a class typically drives down price, but this has not been the case with insulin. The price of modern insulins has continued to increase despite the availability of multiple competing brands on the market. Currently, no interchangeable biosimilar version of

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insulin is available due to the complexity of biologically replicating a human hormone and the strict FDA review process for the approval of biosimilars. Congress recognized the need for a less arduous approval process for biosimilars with the passage of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The abbreviated licensure pathway set to go into effect on March 23, 2020 will allow for the development of interchangeable medications at a lower cost and will likely encourage new manufacturers to enter the insulin market. However, we are concerned that manufacturers may be holding applications for insulin biosimilars until March 23, 2020 because they expect that the application would not move through the approval process by that date, in which case they would be required to resubmit the application after March 23, 2020, starting the review process over again. The impact that high insulin prices are having on patients makes any action that would reduce their out-of-pocket costs urgent and should be prioritized.

Sec. 306-Health plan oversight of pharmacy benefit manager services

There are many stakeholders across the drug supply chain who influence rising costs, including wholesalers, PBMs, pharmacies, health plans, and employers. While manufacturers establish the list price, each of these players impact the out-of-pocket cost to a patient on insulin or other prescription medicine through a complex series of negotiations and rebates that are not transparent to the public. The lack of transparency makes it difficult, if not impossible, to understand how much each stakeholder gains when costs to the patient increase. While we support the intent of Sec 306(a) to provide more transparency regarding medication costs of a health plan's beneficiaries, we are concerned that limiting public access to this information will not achieve the goal of making the supply chain more transparent to the patient. We recommend that a subset of the information that the pharmacy benefit manager would be required to submit to the health plan be made available to plan beneficiaries.

In general, we support efforts to eliminate rebates that artificially inflate drug prices or policy changes that pass the rebates on to patients at point-of-sale. We urge the Committee to modify Sec. 306(d) to pass the rebates to the patients rather than the health plan. Despite significant financial incentives negotiated between the stakeholders in the supply chain, most of these savings are never shared with the consumer. As such, an individual's cost is largely based on the list price. As list prices grow at double-digit rates, people with high-deductible plans, co-insurance, or no insurance suffer the effects.

Sec. 403—Guide on evidence-based strategies for state health department obesity prevention programs

Obesity prevention is critical in reducing the incidence of chronic diseases in America, particularly in addressing the diabetes epidemic. As the Senate HELP Committee moves forward in requiring HHS to develop and disseminate a guide on evidence-based obesity and control strategies for State and local health departments, and Indian tribes and tribal organizations, we would recommend building on the successes of two programs: the National Diabetes Prevention Program (NDPP) and

the Special Diabetes Program for Indians (SDPI). Both of these programs provide evidence-based lifestyle intervention programs that have proven effective in weight reduction and diabetes prevention.

NDPP, an evidence-based lifestyle intervention program funded through the NIH, has demonstrated that a 5-7 percent weight loss could reduce the risk of developing diabetes by 58 percent.[1] Among seniors, the program was even more successful, reducing the risk by 71 percent.[2] In 2018, Medicare began covering the benefit but more needs to be done to address barriers to expanding the program and ensuring access. The Medicare Diabetes Prevention Program (MDPP) should be aligned with the Centers for Disease Control and Prevention's Diabetes Prevention Recognition Program guidelines to ensure that DPP suppliers do not need to meet two different sets of standards. We are also concerned that there is a once-per-lifetime limit for MDPP as some beneficiaries may require multiple attempts to achieve successful weight loss. Virtual programs should also be covered under MDPP for individuals who may not be able to attend in person.

Through the Special Diabetes Program for Indians (SDPI), more than 400 evidence-based treatment and education programs on type 2 diabetes have been implemented in American Indian/Alaska Native (AI/AN) communities, who have the highest prevalence of diabetes. SDPI Community-Directed Diabetes Programs provide funds to the Indian Health Service's (IHS) Tribal and Urban Health Programs in all 12 IHS areas to begin or enhance local diabetes treatment and prevention programs. The SDPI Diabetes Prevention and Health Heart Programs translate current science on diabetes prevention and cardiovascular disease risk reduction to AI/AN communities.

These programs have implemented proven lifestyle change interventions that lower body weight and reduce the risk of diabetes in those at the greatest risk for being diagnosed. In fact, in the AI/AN communities, obesity and diabetes rates in youth have not increased in more than 10 years, while diabetes rates have not increased in adults since 2011. As a result, the SDPI has successfully reduced A1c levels, cardiovascular disease, and promoted healthy lifestyle behaviors. Diabetic eye disease was decreased 50%, reducing vision loss and causing blindness. Kidney failure rates have decreased by 54%, reducing the need for dialysis. Data has shown that these positive clinical outcomes in program participants has reduced the risk for blindness, amputations, kidney failure, as well as preventing the onset of type 2 diabetes. However, funding for the SDPI (and its sister program the Special Type 1 Research Program, which together comprise the Special Diabetes Program) is scheduled to expire on September 30 if Congress fails to act. If the program is not reauthorized, we risk going in the wrong direction for this patient population. In addressing obesity prevention in vulnerable populations, we urge you to consider these important programs.

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[1] National Institute of Diabetes and Digestive and Kidney Diseases. Diabetes Prevention Program. https://www.niddk.nih.gov/aboutniddk/research-areas/diabetes/diabetes-prevention-program-dpp

[2] Ibid.

Sec. 406-Innovation for maternal health

We commend the Committee for prioritizing opportunities to improve maternal and fetal health and support the use of grants to identify and spread best-practices. However, one of the most important ways to improve maternal and fetal health is to guarantee access to care for reproductive health planning. Title X grantees provide contraceptive counseling and services, pregnancy testing and counseling, preventive health screenings, infertility services, and health education, primarily to low income women and adolescent girls who typically are uninsured or on public health insurance. While some may argue that Title X funders do not provide maternal and fetal health care, healthy pregnancies start with healthy mothers who have chosen to get pregnant. Despite the critical importance of equitable access to family planning services for all people, regardless of their income or insurance status, Title X remains woefully underfunded. In 2016, researchers from the Centers for Disease Control and Prevention, the Office of Population Affairs, and George Washington University estimated that Title X would need $737 million annually to deliver family planning care to all uninsured women with low incomes in the United States.[3] We urge the Committee to provide additional funds to Title X to allow continued access to care for millions of women and adolescent girls in convenient locations.

Sec. 410—Integrated services for pregnant and postpartum women

Under this section, the HELP Committee is proposing to authorize HHS to grant states to establish or operate evidence-based or innovative, evidence-informed programs that deliver integrated health care services to pregnant and postpartum women. The Society believes there is an opportunity to improve the maternal and fetal health outcomes associated with diabetes in pregnancy through telehealth, particularly in the Medicaid population. Patients with diabetes who become pregnant are at a significantly greater maternal and fetal risk, particularly if their diabetes is uncontrolled. As a result, these individuals often require insulin therapy and frequent visits to an endocrinologist or high-risk obstetrician (every 1-2 weeks in addition to routine OBGYN appointments, which are typically monthly). During these visits, the physician will review blood glucose logs and adjust insulin doses as needed. Members of the care team and/or the physician may also provide diabetes education to the patient. Telemedicine could be utilized for a significant proportion of these visits as blood glucose log review and therapy adjustment can be conducted remotely. Patients who require visits weekly could see their endocrinologists or high-risk obstetrician every other week and utilize telemedicine (telephone or video visit) for the remaining visits from their home. Patients who require bi-weekly visits can utilize telemedicine visits once per month. The Society believes that the use of telehealth in this population would ease the burden on patients who would find it difficult to be absent from work each week. Easing this burden would

[3] Euna August, et al, "Projecting the Unmet Need and Costs for Contraception Services After the Affordable Care Act," *American Journal of Public Health* (February 2016): 334-341.

reduce the high rate of noncompliance in this patient population and avoid costly complications, unnecessary hospitalizations and c-sections, and improve outcomes in their babies

Thank you for considering our comments. We appreciate that the Committee is looking at ways to reduce health care costs. This is important work and will have an impact on individuals and the country. We look forward to working with you as you pursue legislative solutions to the rising health care costs. If we can provide any additional information, please contact Stephanie Kutler, Director of Advocacy and Policy at skutler@endocrine.org and Meredith Dyer, Director of Health Policy at mdyer@endocrine.org.

Sincerely,

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President
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