



December 11, 2019

The Honorable Diana DeGette
U.S. House of Representatives
Room 2111 Rayburn HOB
Washington, D.C. 20515

The Honorable Fred Upton
U.S. House of Representatives
Room 2183 Rayburn HOB
Washington, D.C. 20515

Subject: Response to Request for Input on Cures 2.0

Dear Representative DeGette and Representative Upton:

Thank you for the opportunity to provide comments on your proposal to develop Cures 2.0 legislation. 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 like diabetes, obesity, osteoporosis, thyroid disease, and infertility. Below please find two proposals for consideration in the Cures 2.0 legislation.

Establishing Telehealth Coverage for Pregnant Women with Diabetes in Medicaid—Women with diabetes who become pregnant have a significantly greater maternal and fetal risk, particularly if their diabetes is uncontrolled. Risks to the fetus include infant death and miscarriage (spontaneous abortion), birth defects, larger than average weight, and others. The mother will need to take insulin, which can result in hypoglycemia or ketoacidosis if not properly dosed and managed. She is also at risk for having labor difficulties, cesarean delivery, heavy bleeding during delivery, and preeclampsia. There is an opportunity to improve the health outcomes in pregnant women with diabetes through telehealth visits in the Medicaid population. These patients 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 the office visit, the endocrinologist or high-risk OBGYN 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. Telehealth 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 originating site requirement would need to be waived. The use of telehealth to manage patient's diabetes would ease the burden on patients who would find it difficult to be away from work or home each week. Easing this burden would reduce the high rate of non-compliance with their diabetes treatment and care to better control their blood sugar. It would also help avoid costly complications, unnecessary hospitalizations and CEsarian-sections, and improve outcomes in their babies.

Extending Regenerative Medicine Innovation Project to Find a Cure for Diabetes—The 21st Century Cures Act allocated \$30 million toward the Regenerative Medicine Innovation Project (RMIP) to accelerate the field by supporting clinical research on adult stem cells while promoting standards for scientific research and patient safety. However, funding for the RMIP expires in 2020. We ask Reps. DeGette and Upton to consider extending this important program, which has funded projects spanning science and new technologies and advancing the understanding of and identifying regenerative



approaches for treating a number of diseases including hemophilia, age-related macular degeneration, ischemic heart disease, emphysema, chronic leg ulcers and Type I diabetes. We believe that the field of endocrinology is particularly primed for using regenerative medicine because cell-based therapies are the “lowest hanging fruit” (as opposed to tissue- and organ-based therapies) and could result in finding a cure for diabetes. RMIP also includes a 1-to-1 funding requirement from external sources like academic centers, industry, and private organizations that are ready to pay and ready to play, in part due to the approval and successes of regenerative therapies like CAR T cells. Extending RMIP is particularly important for endocrinology, where a beta or adrenal cell can be removed, the mutation repaired, and placed back into the patient to cure or treat various conditions, including diabetes. We urge you to extend the RMIP and prioritize a focus on endocrine research areas like islet cell transplantation and others. We hope that this focus will help find a cure for the 114 million Americans living or at-risk for developing diabetes. Should you have any questions on this, we would be happy to set up a call or meeting with one of our member experts to discuss this issue more in-depth.

Should you have any questions or need experts to discuss these issues with, please don't hesitate to contact Meredith Dyer, Director of Health Policy, at mdyer@endocrine.org.

Thank you,

A handwritten signature in blue ink that reads "E. Dale Abel".

E. Dale Abel MB.BS., D.Phil. (M.D., Ph.D.)
President Endocrine Society