December 6, 2019

The Honorable Chuck Grassley
Chairman
Finance Committee
U.S. Senate
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member
Finance Committee
U.S. Senate
Washington, D.C. 20510

Dear Chairman Grassley and Ranking Member Wyden:

The Endocrine Society appreciates the bipartisan commitment that the Finance Committee has shown to reduce the cost of prescription drugs through hearings and bipartisan legislation. Founded in 1916, the Society represents approximately 18,000 physicians and scientists engaged in the treatment and research of endocrine disorders, such as diabetes, hypertension, infertility, obesity, osteoporosis, and thyroid disease. Your work to achieve drug pricing reform is critical to us and the patients our members treat. Our member endocrinologists have difficult conversations every day with their patients who cannot afford the drugs needed to keep them alive or avoid complications.

For the health and well-being of our patients, the Society urges Congress to act now to reduce prescription drug prices, including the price of insulin. As the Finance committee considers revisions to the Prescription Drug Pricing Reduction Act of 2019 (S. 2543), we urge you to include a provision that addresses the high cost of insulin. As you know, the rapid price increases for insulin have made it difficult for many people to afford this medication and effectively manage their diabetes. This has put patient safety in jeopardy as rationing insulin is not an option. Consequently, many patients have opted to forgo other medical care or faced difficult decisions about how to cover other living expenses. The Society has developed a position statement, Increasing Insulin Affordability, that identifies barriers to accessing affordable insulin and potential policy solutions that could address this growing problem. Our efforts are not limited to legislative or policy solutions, but also include member education to help providers work with their patients to identify affordable treatment options.

We support the reforms to the Medicare Part D program, as discussed below, as well as the provisions to increase drug manufacturing price transparency included in the current version of your legislation. We believe that if implemented, these provisions will improve transparency and lower costs to both patients and the health care system, and should be included in the Finance Committee's final legislation. We also encourage the Committee to ensure that any legislation to address drug pricing include provisions that protect patient access to medically-necessary pharmaceuticals and that provide patients transparency on out-of-pocket costs. It is important to include provisions related to pharmacy benefit managers (PBMs) in a final legislative package, since these play an important role in the price of prescription drugs to patients.

Reforms to Medicare Part D

S. 2543 includes substantial revisions to the Medicare Part D benefit design, which would limit spending for consumers will increasing the cost to the drug manufacturers and insurance companies. We were pleased that both the Senate bill and the House bill, H.R. 3, would reduce the share that Medicare pays for the cost of a patient's drug spending that exceeds a "catastrophic threshold" from 80 percent to 20 percent over five years. In the Senate bill, starting in 2022, beneficiaries would have an out-of-pocket spending limit of $3,100 per year; costs over this amount would be covered by drug manufacturers and private insurers that administer Part D plans. The House bill sets the out-of-pocket spending limit at $2,000

Both bills would also reduce the out-of-pocket costs that beneficiaries currently pay for prescription drugs. Seniors would continue to pay the full cost of drugs up to the deductible of $415, and then pay 25 percent of the drug cost until they hit the annual limit ($3,100 in the Senate bill, $2,000 in the House bill). This cap is intended to drastically reduce costs for the sickest patients.

The Society believes it is critical that any legislation to lower prescription drug costs lower patient's out-of-pocket cap. We strongly support the cap of $2,000 included in H.R. 3, which we believe will meaningfully impact the patients treated by our members, particularly those who rely on insulin, and encourage you to include this in your revised legislation.

Drug Manufacturing Price Transparency

The Society supports the provision in S. 2543 to increase drug manufacturer price transparency. It creates a new statutory provision, Social Security Act Section 1128L, effective July 1, 2022, which would require manufacturers to report information to support price increases for prescription drugs and biologics. The Secretary of the Department of Health and Human Services (HHS) would notify a manufacturer within 60 days to identify an applicable drug. After this notification, the manufacturer would have 180 days to provide a price justification to the Secretary, unless the manufacturer reduces the list price so that it no longer meets the qualifying criteria.

The reporting requirements for applicable drugs would apply to three categories:

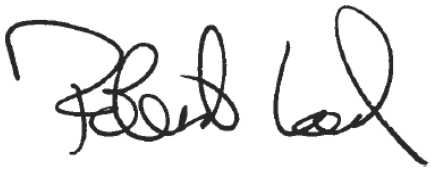
1) Prescription drugs or biologics with list price of at least $10 per dose and price increases of certain percentages over five years;
2) Prescription drugs and biologics in the top 50 percent of net spending per dose in Medicare or Medicaid in at least one of the preceding five years, and the following list price increase of:
    a. 2020: at least 15 percent since enactment of legislation;
    b. 2021: at least 15 percent in the preceding 12 months or at least 20 percent in the preceding two years;
    c. 2022: at least 15 percent in the preceding 12 months or at least 30 percent in the preceding three years;
    d. 2023: at least 15 percent in the preceding 12 months or at least 40 percent in the preceding four years; or
    e. On or after January 1, 2024: at least 15 percent in the preceding 12 months or at least 50 percent in the preceding five years.

3) New drugs with a list price established for the first time, if the list price for a year supply/course of treatment exceeds the gross spending for covered Part D drugs necessary to meet the annual out-of-pocket threshold (approximately $10,000 in 2022).

The Society also supports the provision in S. 2543 that would require HHS to publicize data on its website related to PBMs, including aggregate price concessions, rebates and discounts on prescription drugs. Additionally, this provision would require Part D insurers to conduct financial audits of data related to their PBM contracts, in order to that ensure Part D insurers monitor PBM compliance with contract terms, including with respect to accounting for the net price of Part D covered drugs. The audits would be conducted at least every two years by an independent third party. Insurers would require PBMs to make their rebate contracts with drug manufacturers available for review during the audits and data available within 45 days of the audit request. PBMs that do not comply with insurers' audit requests would be reported to the Secretary and would be subject to civil monetary penalties (CMP) for failing to comply.

Thank you for the opportunity to provide input on this important legislation. We hope you will make insulin a priority as you move forward in finalizing these policies. Should you have any questions, please contact Mila Becker at mbecker@endocrine.org.

Sincerely,



Rob Lash, MD
Chief Clinical and Professional Affairs Officer
Endocrine Society

Cc: Senate Majority Leader Mitch McConnell

Senate Minority Leader Chuck Schumer