United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510–6400
(202) 224–5364

September 10, 2019

The Honorable Norman Sharpless, M.D.
Acting Commissioner
United States Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Acting Commissioner Sharpless:

The FY2019 Consolidated Appropriations Act directs the FDA to assess potential impacts of polypharmacy, which might help inform the design of clinical studies. For older adults, the risk of an adverse drug interaction as a result of polypharmacy is high. Frequently prescribed psychoactive drugs such as opioids, benzodiazepines, selective serotonin reuptake inhibitors, and anticonvulsants can trigger side effects like vision disturbances, orthostatic hypotension, confusion, and sleepiness, increasing the risk of falls in older adults.

Since June, the Senate Aging Committee has received significant stakeholder feedback on the tools, resources, and implementation of evidence-based practices to prevent falls and fall-related injuries, and what they perceived as policy gaps. Polypharmacy has emerged as a key factor related to falls risk. To better understand these policy gaps, we respectfully request written responses to the following questions by September 26, 2019:

- What is the FDA's process for evaluating drug to drug interactions (DDI) in the development of new medicines and the post-marketing of products?
- What additional information is the FDA providing on minimizing the risk of polypharmacy, improving educational resources, labeling, and ensuring regular medication review and recommendations?
- How does FDA plan to increase research on specific drug combinations and fall risk in older adults?

We look forward to your responses. If your staff have questions, they may contact [redacted] from Chairman Collins' Office at [redacted] or [redacted] from Ranking Member Casey's Office at [redacted]

Sincerely,

Susan M. Collins
Chairman

Robert P. Casey, Jr.
Ranking Member