

VIA EMAIL: PartDImprovements@mail.house.gov

June 06, 2019

To: The Honorable Richard E. Neal
Chairman, House Ways and Means Committee

The Honorable Frank Pallone, Jr.
Chairman, House Energy and Commerce Committee

The Honorable Kevin Brady
Ranking Member, House Ways and Means Committee

The Honorable Greg Walden
Ranking Member, House Energy and Commerce Committee

RE: Response to Solicitation for Feedback on Draft Medicare Part D Legislation

Mallinckrodt Pharmaceuticals appreciates the opportunity to comment on the House Energy and Commerce Committee and Ways and Means Committee joint discussion draft on Medicare Part D. We appreciate the bipartisan approach to this issue and look forward to working with the Committees on this important topic.

Mallinckrodt is a global business consisting of multiple wholly owned subsidiaries that develop, manufacture, market and distribute specialty pharmaceutical products and therapies. The company's Specialty Brands reporting segment's areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; analgesics and gastrointestinal products. Its Specialty Generics reporting segment includes specialty generic drugs and active pharmaceutical ingredients.

Mallinckrodt supports efforts to lower the out-of-pocket (OOP) costs patients pay for their medications. We have worked with stakeholders in the patient advocacy community to help address cost concerns to ensure patients receive timely and affordable access to their treatments. In particular, Part D beneficiaries who reach the catastrophic phase of the benefit generally represent patients with the highest healthcare needs, including those with rare diseases. Ensuring timely access to critical medications helps improve health outcomes and reduce overall healthcare expenditures through other avoided health interventions.

Mallinckrodt appreciates the challenges in assessing how best to apply an OOP cap for patients in the highly successful Part D program and we appreciate the Committees' call for feedback on how to structure such a change. As set out in the Discussion Draft, the Committees propose a phased-in approach to change the current reinsurance subsidies, by shifting financial responsibility from the government to insurers as follows:

- 2019: 80 percent
- 2020: 70 percent
- 2021: 60 percent
- 2022: 40 percent
- 2023 and beyond: 20 percent

As the Committees consider these issues, we recommend the following:

- Consider a reasonable cap on patient OOP spending not to exceed a defined threshold. We urge the Committees to ensure that patients are not required to spend more OOP overall to reach that cap than under the current benefit.
- At the same time, the Committees should ensure no corresponding changes are made that would impede patient access, such as increasing flexibility for plans to employ additional utilization management tools, adopt narrow formularies, or limit the ability of physicians or beneficiaries to appeal for necessary medications for their patients. Efforts to decrease beneficiary spending would be undercut if, at the same time, patients are required to face additional hurdles in securing the appropriate treatment for their health condition.
- Additionally, the Committees must consider the potential impacts of any efforts to create an OOP cap on premium spending.
- We would be concerned with any effort to eliminate the availability of manufacturer discounts in the coverage gap, which help reduce beneficiary spending and promote adherence to medicines.
- Consider the application of any OOP cap on patients receiving low-income subsidies. These patients already receive significant assistance with their OOP obligations, and thus, may be appropriate to exclude from any new OOP cap for all Part D beneficiaries.

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Mallinckrodt appreciates the opportunity to comment on the draft bill to help lower health care costs. We look forward to continuing to work with you to address these issues. Please contact Kendra Martello, Executive Director, Public Policy (kendra.martello@mnk.com or 202-459-4145) if you have any questions or wish to discuss.

Sincerely,



Mark Tyndall
Senior Vice President, Government Affairs