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

July 19, 2016

AstraZeneca Pharmaceuticals
Pascal Soriot
Executive Director and Chief Executive Officer
1800 Concord Pike
P.O. Box 15437
Wilmington, DE 19850-5437

Dear Mr. Soriot:

We would like to better understand AstraZeneca's position that generic competitors to Crestor® should be delayed from entering the market. The Food and Drug Administration (FDA) recently granted AstraZeneca seven year exclusivity for Crestor under the Orphan Drug Act for the express purpose of treating children for a rare pediatric genetic disorder. As we understand it, AstraZeneca does not dispute that, on the face of the Orphan Drug Act, this seven year exclusionary period only applies to the orphan indication affecting approximately 300 U.S. patients. Despite this, AstraZeneca filed a Citizen Petition seeking to block the FDA from approving any generic version of Crestor, effectively expanding exclusivity to cover 20 million U.S. prescriptions.

As we understand it, AstraZeneca believes that because of the pediatric exclusivity, the FDA cannot approve a generic version of Crestor unless it creates a different label for the generic version that does not include the protected pediatric indication that exists on the current approved brand name label. AstraZeneca then argues that the FDA cannot approve one label for generic Crestor *without* the pediatric indication and another label for brand name Crestor *with* the label for the protected pediatric indication, and consequently, no generic can be approved. Apparently on these grounds, AstraZeneca has brought suit in U.S. District Court seeking to enjoin the FDA from approving a generic version of Crestor until the period of pediatric exclusivity expires. We question whether AstraZeneca's apparent position implements the longstanding public policy goal of Congress to allow exclusivity for a defined period of time in exchange for investment in innovative new medications.

We have a system that rewards innovation and allows the discovery of new medicines, as well as new uses for existing medicines, that save and improve lives. We applaud AstraZeneca for its work in seeking the pediatric indication of Crestor for children with this rare genetic disorder. While we understand the important role of labeling, we are concerned that AstraZeneca's interpretation of FDA's regulations and congressional intent behind the entry of generic medications into the market could lead to substantial harm to patients and taxpayers. Obtaining approval for the treatment of additional indications as a means to hinder the market entry of generics, which would be approved for the treatment of other conditions, is troublesome because a competitive generic marketplace is imperative in order to curtail skyrocketing health care and prescription drug costs.

The lawsuit filed by AstraZeneca against the FDA does not provide the information we need to understand how the public interest would be advanced by creating an additional exclusivity period for 20 million U.S. prescriptions based on a pediatric indication that serves approximately 300 U.S. patients. Further, we would like to better understand why AstraZeneca believes the Food, Drug, and Cosmetic Act and FDA's regulations compel the conclusion that AstraZeneca be allowed to maintain market exclusivity for all populations being prescribed Crestor, not just the pediatric population. We ask that you provide this briefing to Aging Committee staff by July 27, 2016. Please contact Olivia Kurtz with the Majority staff at (202) 224-5364 and Phylicia Woods with the Minority staff at (202) 224-0185.

Sincerely,

Susan M. Collins
Chairman
U.S. Senate Special Committee on Aging

Claire McCaskill
Ranking Member
U.S. Senate Special Committee on Aging