

pediatric Tourette’s, so carving out that part of the label leaves no indication related to Tourette’s. For Crestor, eliminating the pediatric HoFN designation still leaves the adult HoFN dosage on the label, and AstraZeneca argued that this presents a potential safety problem in accidentally overtreating children.¹⁸³

In July 2016, after several senators, representatives, and the Department of Justice weighed in to support generic approval,¹⁸⁴ AstraZeneca lost all of its labeling-related challenges. The FDA denied the citizen petition in a ruling very similar in structure to its letter denying Otsuka’s challenges, finding that the adult HoFN dosing information is not “significantly different” from the carved-out pediatric HoFN information, and reiterating its interpretation of § 355A(o).¹⁸⁵ A federal judge also denied an injunction that would have prevented generic sales.¹⁸⁶

That finally brings a conclusion to the sagas of Crestor and Abilify. If anything, these two complex scenarios show the lengths that brand-name companies are willing to go to block generics in Generation 3.0 of pharmaceutical delay, combining exclusivities with citizen petitions, lawsuits, and issues of statutory interpretation. They are perhaps the best example of legal resources being deployed in place of research and development, as brand-name pharmaceutical companies turn to obstruction and delay tactics that attempt to distort regulatory processes.

¹⁸³ AstraZeneca Petition, *supra* note 163, at 11–12.

¹⁸⁴ Ed Silverman, *Sanders, Other Lawmakers Urge FDA Approval of Generic Crestor*, STAT (Jul. 7, 2016), www.statnews.com/pharmalot/2016/07/07/bernie-sanders-fda-generics-cholesterol/.

¹⁸⁵ Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., to Joseph A. Cash, Jr., AstraZeneca Pharm., Re: No. FDA-2016-P-1485, at 15 (Jul. 19, 2016), www.regulations.gov/document?D=FDA-2016-P-1485-0007 (denying AstraZeneca’s citizen petition).

¹⁸⁶ Ed Silverman, *AstraZeneca Loses Court Battle to Prevent Generic Versions of Crestor*, STAT (Jul. 20, 2016), www.statnews.com/pharmalot/2016/07/20/astrazeneca-generics-crestor-fda/.