of pediatric homozygous familial hypercholesterolemia ("pediatric HoFN"), a rare, severe generic disorder that heightens cholesterol levels and can cause premature death.[164] The Orphan Drug Designation provided Crestor with an additional seven years of marketing exclusivity, but only for that orphan use. Notably, it is not as if it was found that Crestor has a unique effect on treating HoFN – AstraZeneca simply found that it could reduce cholesterol as the drug was generally intended to do, which could then mitigate the effects of HoFN.[165] AstraZeneca, in essence, was collecting additional exclusivities for confirming that a drug used for reducing cholesterol could help treat a pediatric disease marked by high cholesterol. We do not intend to denigrate the real therapeutic benefit that Crestor may have on patients with pediatric HoFN, but the finding was not particularly novel – it is not as if AstraZeneca suddenly discovered that Crestor had therapeutic effects not related to lowering cholesterol levels. Plus, the study suspiciously (as always) did not begin until years after Crestor was first approved in 2003.[166] Numerous commentators have expressed concerns about pharmaceutical companies' attempting to game the Orphan Drug Act by getting approval for their otherwise very popular drugs to treat rare diseases long after the drugs are first approved.[167]

AstraZeneca filed a supplementary new drug approval application to gain full marketing approval for the pediatric use, which was granted in May 2016, just a little more than a month before generics would have otherwise entered the market.[168] This allowed information about the orphan pediatric use of the drug to be included on a revised label.

Here is where matters get tricky. As we explored in the Skelaxin snafu, labeling information generally can be carved out unless it pertains to the safety and efficacy of the drug. By adding information about a pediatric, orphan drug use to the label, AstraZeneca argued in a citizen petition that this information was safety related and may not be carved out for any reason, in part because physicians might overtreat children by prescribing too high of a dose if the pediatric labeling information is removed while the adult labeling information remains.[169]

[164] Ed Silverman, *AstraZeneca Sues FDA to Prevent Generic Versions of Crestor*, STAT (Jun. 28, 2016), www.statnews.com/pharmalot/2016/06/28/astrazeneca-fda-crestor/.

[165] AstraZeneca Petition, *supra* note 163, at 1.

[166] *Ibid*. at 3.

[167] *See, e.g.*, Feldman, *Regulatory Property: The New IP*, *supra* note 134.

[168] Silverman, *AstraZeneca Sues FDA to Prevent Generic Versions of Crestor*, *supra* note 164.

[169] AstraZeneca Petition, *supra* note 163, at 13–14. In a twist that makes this even more confusing, AstraZeneca also argued that pediatric HoFN patients could be *undertreated* using a generic because Crestor is also approved for the treatment of another pediatric disorder, *HeFN*. That labeling information, however, is not exclusivity-protected, but it suggests a lower dose than would be needed for pediatric *HoFN*. Thus, AstraZeneca presented the concern that physicians could become confused, which, given those head-spinning sentences, may be true. *Ibid*.