Is it the Hard Knock Life for the Orphan Drug Industry or Will the Sun Come Out Tomorrow?

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Many of us remember the comic strip-turned Broadway musical turned-movie-turned movie, about little orphan Annie. My 8-year old daughter, Kayla, reminds me every day as she sings (on key), "It's The Hard Knock Life" and "Tomorrow." The lyrics, "'stead of treats, we get tricked, 'stead of kisses, we get kicked," come to my mind when I read the Food and Drug Administration's (FDA) "clarification policy" regarding orphan drug exclusivity, published in a Federal Register notice, dated December 23, 2014. While some in industry might have hoped that FDA could change its orphan drug policy in light of a recent court decision challenging the agency's decision on a particular product, the agency said, in keeping with the holiday season, bah humbug. As will be discussed, FDA said the court decision was case-specific, and its policy remains the same.

In a Bulletin, dated October 28, 2014, we discussed the Depomed case, where the U.S. District Court for the District of Columbia ordered FDA to recognize orphan drug exclusivity of Gralise® (gabapentin tablets) "without requiring any proof of clinical superiority or imposing any additional conditions on Depomed."[1] We will not re-review the court decision here, except to note that many readers of the holding wondered whether FDA would revise its clinical superiority requirement. The agency has responded – no.

In the Federal Register notice, FDA said that it interprets the Depomed decision to be limited to Gralise only. Thus, it does not intend to revise its clinical superiority regulatory framework, at this time. FDA stated:

> In consideration of any uncertainty created by the court's decision in Depomed, the Agency is issuing this statement. It is the agency's position that, given the limited terms of the court's decision to GRALISE, FDA intends to continue to apply its existing regulation in part 316 to orphan-drug exclusivity matters. FDA interprets section 527 of the FD&C [Federal Food, Drug, and Cosmetic] Act and its regulations (both the older regulations that still apply to original requests for designation made on or before August 12, 2013, as well as the current regulations) to require the sponsor of a designated drug that is the 'same' as a previously approved drug to demonstrate that its drug is 'clinically superior' to that drug upon approval in order for the subsequently approved drug to be eligible for orphan-drug exclusivity.

AGG Observations

- For now, to quote The Who – "Meet the new boss – same as the old boss." Nothing has changed, at least for now, with the FDA's orphan drug requirements or interpretation.
- Another lawsuit, particularly if FDA loses again, might prompt a change. But don't expect the sun (of change) to come "tomorrow."
- For those expecting a potential "treat," where FDA would reconsider its orphan drug policy, they might feel "tricked," but FDA's statement is not entirely surprising. The agency is not inclined to change, en masse, rules it has had for years because of an interpretation (namely the clinical superiority element) of a lone court decision. It typically takes a few losses in court before FDA reverses course.
- We will continue to follow orphan drug developments.

1 Click http://www.agg.com/Orphan-Drug-Exclusivity-Criteria-Clarified-in-Court-Decision-10-28-2014/ to access the Bulletin.

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