



January 26, 2015

Ms. Elizabeth Giaquinto
Center for Drug Evaluation and Research
Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Delivered electronically through <http://www.regulations.gov>

Reference: Docket No. FDA-2014-D-1891

Dear Ms. Giaquinto:

We appreciate the opportunity to provide comments on the proposed rule, "How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD."

The Ohio Public Employees Retirement System (OPERS) provides comprehensive health care coverage, including prescription drug coverage, to almost 230,000 retirees. Our gross prescription drug spend in 2014 was \$680 million and in that same year, we saved an additional \$32 million because of increased generic drug utilization. Generic and biosimilar drugs are an integral part of OPERS' strategy to improve access to safe and affordable prescription drugs for our retirees.

That is why we wholeheartedly support the FDA's proposal and its efforts to ensure that Risk Evaluation and Mitigation Strategies (REMS) programs are not misused for anticompetitive purposes.

As you know, certain reference brand drug manufacturers have used the fact that one or more of their reference listed drugs (RLDs) are subject to a REMS program with "elements to assure safe use" (ETASU) to deny samples of their RLDs to generic drug manufacturers that wish to conduct necessary bioequivalence (BE) studies to support an Abbreviated New Drug Application (ANDA).

By preventing or delaying access to RLDs, reference brand drug manufacturers maintain artificially high prices for drugs that could otherwise be transitioning off patent protection,

resulting in millions of dollars in lost savings for consumers, payors and state and local governments. According to one study, the ongoing abuse of REMS and REMS-like programs, such as limited distribution, is costing the American health care system and patients as much as \$5.4 billion annually.¹ There is also some concern that this behavior is in direct violation of the Food and Drug Administration Amendments Act of 2007, which precludes an innovator (RLD sponsor) from using the REMS programs to stifle competition.²

We applaud the FDA for taking helpful steps to address, and hopefully limit, scenarios in which some reference brand drug manufacturers misuse REMS programs to prevent competition with more affordable generic drugs.

The guidance provides helpful step-by-step actions that a prospective ANDA applicant can take in order for the RLD sponsor to receive a letter from the FDA clarifying that 1) the Agency has determined that protocols, informed consent documents and informational materials contain safety protections comparable to those in the applicable REMS ETASU, and 2) the Agency will not consider it a violation of REMS for the RLD sponsor to provide a sufficient quantity of drug product to the potential ANDA applicant.

Our only concern is that the letter from the FDA to RLD sponsors cannot legally require the sponsor or wholesaler or specialty distributor authorized by the sponsor to provide samples to the potential ANDA applicant. That said, we appreciate the FDA's input into this process and urge the agency to continue to do everything within its authority to oppose the abuse of the REMS program.

OPERS is encouraged that this issue has also drawn the attention of the FTC, which has documented concern over "the possibility that procedures intended to ensure the safe distribution of certain prescription drugs may be exploited by brand companies to thwart generic competition,"³ as well as several members of Congress. For instance, in 2014, Congressmen Steve Stivers (R-OH) and Peter Welch (D-CT) co-introduced the "Fair Access for Safe and Timely Generics Act". This important legislation effectively prohibits companies from restricting access to RLDs in order to avoid generic competition, and is expected to be reintroduced in the current Congress.

¹ Matrix Global Advisors, Lost Prescription Drug Savings for Use of REMS Programs to Delay Generic Market Entry, July 2014

² 21 USC 355-1(f)(8), "No holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection to block or delay an approval of an application under section FDC Act 505(b)(2) or to prevent application of such element under subsection FDC Act 505-1(i)(1)(B) to a drug that is subject of an abbreviated new drug application."

³ FTC Brief as Amicus Curiae, Actelion Pharmaceuticals Ltd. Pharmaceuticals Ltd. v. Apotex Inc., (No. 1:12-cv-05743-NLHAMD), (DNJ March 2013), www.ftc.gov/os/2013/03/130311actelionamicusbrief.pdf



In summary, we support the FDA's proposal and see it as an important part of a collaborative effort to prohibit abuse of the REMS program. We urge the FDA to use its full authority to oppose this anticompetitive practice, and to support the efforts of other agencies or interests that favor fair drug development practices.

If you have questions or would like additional information regarding OPERS' comments, please contact Brian Pack, OPERS' Health Care Finance and Policy Officer, at (614) 225-1858.

Sincerely,

A handwritten signature in black ink, appearing to read "Marianne Steger".

Marianne Steger, MS, CEBS
OPERS Health Care Director