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## DAILY NEWS

# Pharmacies, PBMs, Insurers Pan FDA's Biosimilar Naming Proposal

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A group comprising key pharmacy chains, insurers, pharmacy benefit managers and public employee benefit plans is asking FDA to scrap its biosimilar naming plan. The group, which includes the PBM lobby, Academy of Managed Care Pharmacy and Kaiser Permanente, argue biosimilars and their reference biologics should share nonproprietary names, and say FDA's plan to add nonmeaningful suffixes to INNs to distinguish biosimilars from their reference products is “unnecessary and unwise,” in a comments on FDA's naming proposal.

The group says FDA's plan will sow confusion among patients and physicians, and would have the unintended effect of slowing uptake of the products. The group echoes concerns raised by the National Community Pharmacists Association and the Generic Pharmaceutical Association.

FDA proposes that biosimilar products and their reference biologics carry nonmeaningful, four-letter suffixes to prevent inadvertent substitution of products that have not been deemed interchangeable and to help monitor biologics once they're on the market, in draft guidance released in late August. The proposed naming scheme is different from the provisional nonproprietary name given to the first U.S. biosimilar approved in March -- Sandoz's filgrastim-sndz, which hit the market Sept. 3 under the brand name Zarxio. In the provisional name, the suffix "sndz" relates to the sponsor's name, but in the draft guidance FDA proposes using four random letters.

FDA's naming convention seems to strike a middle ground between stakeholders who argued for shared nonproprietary names between biosimilars and their reference products and those who pushed for distinct names for just biosimilars.

But the group argues that a middle ground isn't necessary, In Europe, which has a well-established biosimilars market, biosimilars and their reference products share INNs without problems, the group says in its comments.

“The FDA proposal is a distinction in search of a difference that changes the INN from a system that has a proven track record, of over 60 years, of ensuring patient safety and reducing the potential for confusion,” the group says.

In addition to AMCP and Kaiser Permanente, signatories to the letter include: Blue Cross and Blue Shield Association; Council for Citizens Against Government Waste; CVS Health, Employees Retirement System of Texas; Express Scripts; Illinois Public Pension Fund Association; Kentucky Teachers Retirement System; Missoula County, MT; National Coalition on Health Care; Ohio Public Employees Retirement System; Pharmaceutical Care Management Association; Premier Health Alliance; Prime Therapeutics; Public Sector HealthCare Roundtable; Rite Aid; School Employees Retirement System of Ohio; State Health Plan of North Carolina; UAW Retiree Medical Benefits Trust; and West Virginia Public Employees Insurance Agency.

The group argues that adverse events for small-molecule generics and existing biologic drugs are successfully tracked using the national drug code and lot number. They say the same system can be used for biosimilars if they share the same INNs as their reference products.

“There is no compelling evidence that biosimilars should be handled differently, and to do so risks undermining prescriber confidence in these FDA-approved medicines, and creates barriers to patient access,” the group says.

The groups also contend the agency's proposed naming scheme would create significant burdens for the pharmacy supply chain, noting that the National Council for Prescription Drug Programs has said that existing software would need to be changed.

“These changes will add greater costs to the health care system by treating biosimilar and interchangeable biosimilar products differently from their reference products,” the group says.

Shortly after FDA released its proposal, an industry expert speaking on background raised similar concerns to *Inside Health Policy*. The expert said the agency's plan could wreak havoc with the databases used by clinicians and pharmacists to prescribe and dispense drugs. The expert also questioned whether the people who craft and manage the databases would be able to easily change their systems; and if they could change the systems, if they could do so in time.

"Do all those people know, and are they ready, and can they do?" the expert asked. "And I have to say I expect not. Because if the current system has problems keeping complete and accurate records, to make the system more complicated doesn't tell me that it's going to be more reliable and more accurate.”

The group also argues that FDA has “no realistic approach” for naming interchangeable biosimilars. The agency asked for feedback on whether interchangeable biosimilars should share the same suffix as their reference products or have their own distinct suffixes, saying this is an issue the agency is still grappling with. The agency has yet to issue guidance on interchangeability, and no manufacturer has publicly acknowledged filing an application for interchangeability.

“While the agency has publicly considered multiple options, none avoid additional significant barriers on top of the ones already created by the preliminary proposal,” the group says. -- *Todd Allen Wilson* (*twilson@iwpnews.com*)