



Politico

Prescription Pulse

A weekly briefing on pharmaceutical policy news

By Brett Norman

05/31/16 12:01 PM EDT

A NEW WRINKLE FOR CURES: USP EXEMPTION FOR BIOLOGIC DRUGS DRAWS

CRITICISM — Several groups sounded the alarm last week over a little-noticed provision in the Senate innovation package that would exempt biologics and biosimilars from requirements that they adhere to U.S. Pharmacopeia quality standards, as required of other drugs. The measure was not publicly debated while the legislation was being developed but was included in the unrelated FDA and NIH Workforce Authorities Modernization Act. It was “quite a surprise,” said Mary Jo Carden of the Academy of Managed Care Pharmacy, which asked HELP leadership last week to pull the measure. The provision “would have potentially grave consequences for public health and would hinder, rather than support, our shared goal of getting safe and effective biosimilars to market,” states the letter from AMCP and several other groups. <http://bit.ly/27UpVvT>