

Invite to Sign-On to Investor Statement on Board Oversight of Biosimilar Issues: Global Health Concerns and Corporate Political Lobbying

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The UAW Retiree Medical Benefits Trust invites you to sign-on to the *Investor Statement on Board Oversight of Biosimilar Issues* that will be transmitted to the top 25 pharmaceutical companies. The deadline for signatories is **May 30, 2014**. Attached is the statement. Background on the issue and a summary of the Statement's key points to directors is provided below as well as the list of the companies. **Your fund does not need to have investments in the top 25 pharmaceutical companies to sign-on.**

Background

There has been a new development in the overlap of health care and corporate lobbying expenditures that pose new risks to investors, payors and patients as well as healthcare markets globally.

At the heart of the issue is the use of investor dollars by certain pharmaceutical companies to lobby U.S. state legislatures and federal agencies on policies that would impede patients access to biosimilars. Biosimilars are less costly alternatives to specialty drugs known as biologics. Biologics treat life-long chronic illnesses such as cancer, rheumatoid arthritis and multiple sclerosis and have revolutionized medical treatment but at a cost that is unsustainable and can be as much as 22 times more than ordinary drugs.

Evolution of biosimilar regulation: Global reference product possible in EU, US, and Japan



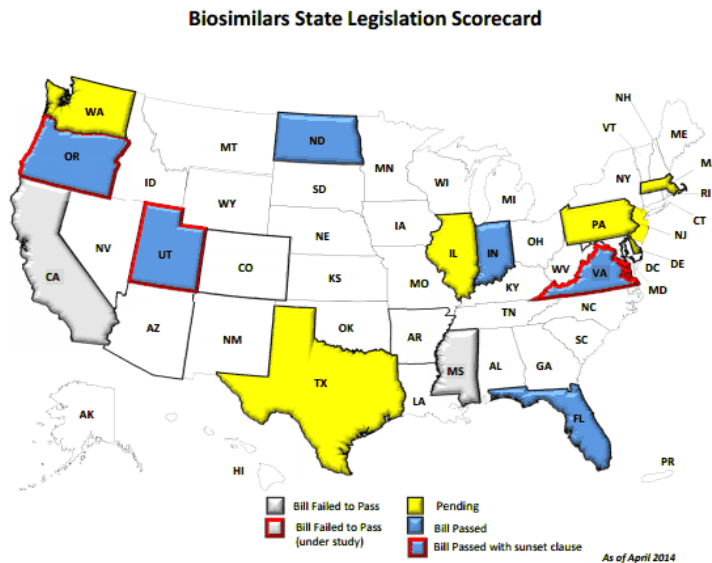
Biosimilars have yet to be approved in the U.S. but currently over 14 biosimilars have been approved and marketed in the EU, Japan, Canada, India, France and South Korea. Data compiled by the European Medical Agency and several companies that sell biosimilars in the EU have no recorded patient problems. The map (left) shows biosimilar market and regulatory developments around the world. Currently, biosimilars are used in over 50 countries.

Source: Sandoz Biopharmaceuticals, Biosimilars World 2013

Despite studies in the EU biosimilar markets that show the patient safety efficacy of these drugs, pharmaceutical companies have chosen to use safety issues to slow down the approval process in the U.S. and to lobby for laws at the state level that require administrative burdens on pharmacists and

doctors. These requirements are viewed as a scare tactic to thwart market competition and innovation that may threaten the profitable biologics market, facing \$70 billion in patents expiring in 2018.

The pharmaceutical industry has long been significant contributors to political lobbying in the U.S., spending over \$140 million in federal lobbying in 2013 according to Open Secrets. In the case of biosimilar legislation, the legislation has been controversial and given that state level contributions are less transparent to investors, it is difficult to discern total expenditures on a specific issue or more importantly if such actions are aligned with investor interests.



The Biotechnology Industry Organization, currently under fire for its lobbying efforts related to labeling of genetically modified foods, is the leading trade association that has developed model legislation on the biosimilar issue that contains the provisions that will thwart patient access and have a potentially chilling affect on industry innovation and competition. The legislation has been introduced in 18 states and failed to pass in 12. Source: FDALaw Blog

The Investor Statement : The investor statement calls on boards to adopt three principles when taking actions on biosimilars:

- 1) Policy and educational information provided on biosimilars should be balanced, accurate and informed by the patient safety experience of biosimilars in the European Union and other biosimilar markets.
- 2) Lobbying expenditures for federal and state activities related to biosimilars should be fully disclosed and boards should ensure that political activities are aligned with investor and other stakeholder interests.
- 3) Key information about any partnership or business deal related to biosimilars should be fully disclosed to investors, including information about the value, terms and duration of the deal.

The 25 companies include: JNJ, Roche-Genentech, Novartis, Pfizer, Merck, Sanofi, Glaxo, Novo Nordisk, Gilead, Amgen, Bristol-Myer SQB, AstraZeneca, ABBVIE, Eli Lilly, Biogen, Abbott, Celgene, Teva, Valeant, Allergan, Takeda, Actavis, CSL TD, Regeneron Pharm, Shire PLC