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November 23, 2015

**VIA ELECTRONIC SUBMISSION**

Dr. Stephen Ostroff, M.D.
Acting Commissioner
Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Route 20161 (HFA-305)
Rockville, Maryland 20852

**Re: Citizen Petition on Biosimilar Labeling**

Dear Dr. Ostroff:

## I. Introduction

The undersigned institutional investors respectfully submit this Citizen Petition to the Food and Drug Administration ("FDA") to require all biosimilars to have the same labeling as their reference drugs[1] and to conduct a public hearing so that stakeholders can express their views, which will lead to a more comprehensive public record prior to any proposed rulemaking or draft guidance.

The funds signing on to this Citizen Petition are both diverse and sizeable with assets from public sector, labor-management, faith-based, sustainability, and global pension and health care plans. These signatories have broad public equity exposure to health care companies in the domestic and global markets, including stock holdings in companies that produce both biologics and biosimilars.

In our view, biosimilars and interchangeable biologics represent an attractive investment opportunity as well as a safe alternative to specialty drugs whose cost threatens the financial sustainability of the

[1] This Citizen's Petition is submitted under 21 CFR §10.25 and 10.30, section 2101 (n) and 502(a) of the Federal Food, Drug and Cosmetic Act (FDCA) §351 of the Public Health Service (PHSA), as amended by the Biologics Price Competition and Innovation Act (BPCIA), and sections 4(e) and 10 of the Administrative Procedure Act (APA) related to a Part 15 hearing under 21 CFR § 15.

markets in which our companies operate.[2] Several studies, including a report from Rand Corporation, show that biosimilars have the potential to lead to significant reductions in spend on biologic specialty drugs. [3] Express Scripts projects that from 2014 to 2024, the U.S. healthcare system could save $250 billion if biosimilars were substituted for the eleven most widely used biologics.[4]

Consistent with our request for all biosimilar labels to have the same labels as their reference drugs, we support the FDA's "same labeling "approach used for Sandoz, Inc.'s Zarxio™. This approach is critically important in boosting investor confidence, signaling market certainty, and upholding the role of the FDA in determining biosimilarity and interchangeability.

This petition below is prepared by the UAW Retiree Medical Benefits Trust and on behalf of the undersigned parties.

## II. Action Requested

This petition asks the FDA to require that all approved prescription drug labeling for biosimilar and interchangeable biological products follow the "same labeling" approach the agency applied to Sandoz, Inc.'s Zarxio™ and to hold a Part 15 public hearing on this issue as well as any other related issues being debated by the FDA and connected to biosimilars. The Part 15 hearing is requested to address the following issues:

a. The implications of labeling rules for biosimilar innovation and investment in the U.S.;
b. The European experience with biosimilars, including "same labeling," "patient tracking," and patient safety; and
c. Stakeholder views on how different approaches to labeling may affect prescribing, dispensing, and patient use of biosimilars and interchangeable biologic products.

## III. Discussion

**The Implications of Labeling Rules on Biosimilar Innovation and Investment in the U.S.**

As providers of capital to FDA-regulated companies, we have a strong interest in supporting and promoting biosimilar policies that enhance competition and innovation in our healthcare marketplace and that open up affordable, safe and accessible treatment options for serious illnesses including

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[2] "Biosimilars: Real, Dangerous, Coming Soon: A Disruptive Innovation Whose Time has Come: Winners, Losers," Citi Research Equities (February 9, 2015) (Exhibit A) ; see also: "Pharma Sector Update: Pfizer Acquires Hospira: Emphasis on Generic Injectable and Biosimilars for Future Growth, Business Wire (February 6, 2015) (Exhibit B), available at http://www.businesswire.com/news/home/20150205005368/en/Pfizer-Acquire-Hospira#.Vh0dBHbD_rc.

[3] Andrew W. Mulcahey, Zachary Predmore, and Soreen Mattke, "The Cost Savings Potential of Biosimilar Drugs in the United States," Rand Corporation (2014)(Exhibit C), available at: http://www.rand.org/pubs/perspectives/PE127.html; see also: Bruno Calo-Fenrandez and Juan Leonardo Martinez-Hurtado, "Biosimilars: Company strategies to Capture Value form the Biologics Market," Pharmaceuticals (Volume 5, Issue 12, Debaser 12, 2012) (Exhibit D) available at http://www.mdpi.com/1424-8247/5/12/1393/htm.

[4] Steve Miller, "The $250 Billion Potential for Biosimilars," Express Scripts (May 22, 2013)(Exhibit E), available at: http://lab.express-scripts.com/insights/drug-options/infographic-two-biosimilars-to-save-227-billion

cancer, rheumatoid arthritis, and multiple sclerosis. To that end, we believe it is important for investors to share with the FDA their perspective on the impact that technical issues such as labeling can have on the potential for biosimilar growth in the U.S. marketplace. Policies that would hamper the introduction or wide acceptance of biosimilars would discourage entities that develop medications from developing biosimilars and, instead, encourage them to place their focus elsewhere. Consequently, investors would lose out on the investment opportunity of biosimilars.

The undersigned investors support the FDA's decision to approve the first label for a U.S. licensed biosimilar, Zarxio™, as containing the same information as the label of its reference product Neupogen®. This decision confirms the safety and efficacy of the FDA approval process for biosimilar biologics and at the same time provides the prescriber and patient with the information needed to make an informed treatment decision while excluding additional, confusing information that does not help in decision-making.

Accordingly, we request that the FDA reject proposals to require that biosimilar and interchangeable biologic product labels include information about the clinical trials conducted by the biosimilar sponsor and the licensure pathway under which the drug was approved.[5] We believe that a differentiated labeling approach for biologics and biosimilars will send an inaccurate message to prescribers that biosimilars and interchangeable biologics, are more dissimilar than highly similar to each of their reference products, raising the specter of safety issues.

We also note that additional information about any FDA licensed biologic is available from a multitude of other sources including the Purple Book[6], FDA's own documents regarding licensure of the product, and published peer-reviewed literature (e.g., describing confirmatory clinical trials conducted by the biosimilar or interchangeable biologic sponsor).

**The European Experience with "Same Labeling" and Patient Safety**

In Europe, where biosimilars have been approved since 2006, biosimilars use the "same label" as their reference products (excepting minor differences such as presentations). With over 20 biosimilars on the market in Europe, despite extensive use, there are no reported immunogenicity issues,[7] an assertion affirmed by member states of the European Union and the European Medicines

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[5] AbbVie Citizen Petition dated June 2, 2015, and Supplement to Citizen Petition dated August 10, 2015, docket number: FDA-2015-P-2000, available at: http://www.regulations.gov/#!docketDetail:D=FDA-2015-P-2000 (accessed September 28, 2015).

[6] FDA website: "Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations," updated July 27, 2015, available at: http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm411418.htm (accessed October 1, 2015).

[7] Sumant Ramachandra, MD, PhD, Senior Vice President, Chief Scientific Officer, Hospira, " Lessons for the United States: Biosimilar Market Development Worldwide" presented at the FTC Follow-on Biologics Workshop: Impact of Recent Legislative and Regulatory Naming Proposals on Competition, Washington D.C. February 4, 2014 (Exhibit F) ; and Mark McCamish MD PhD, "Effect of Naming on Competition and Innovation," Global Head of Biopharmaceutical Development, Sandoz , presented at FTC Biosimilar Workshop on Naming Proposals and Impact on Competition, Washington, DC, December 10, 2013 (Exhibit G).

Agency.[8] Companies that market biosimilar products, with hundreds of millions of patient days combined, have published safety profiles that are comparable to or better than the reference drug. These safety records are also recognized by industry analysts and researchers.[9]

As investors in companies that have global biosimilar experience, we believe that comparison and consideration of the European biosimilar experience is important in the context of patient safety and in efforts to maintain consistent policies and regulations across global markets. One of the key principles in an *Investor Statement on Board Oversight of Biosimilar Issues* developed by many of the signatories to this Citizen's Petition, calls on boards and directors of pharmaceutical companies to consider the European biosimilar experience in business and policy decisions.[10] Eli Lilly, Amgen, Hospira, Novartis and Walgreens signed on to these principles.

**The Need for Stakeholder Views on Labeling**

We believe that the FDA would greatly benefit from hearing views from all stakeholders on the labeling issue prior to issuing proposed regulations. At that hearing, the FDA may wish to consider other, related issues to the introduction of biosimilars and interchangeable biologics into the U.S. markets. To date there has not been an opportunity for this kind of discourse.

Stakeholders that order, prescribe, and dispense should be invited to share their views as well as patients, who are dependent on the potential of these drugs to provide affordable and accessible treatment options. Given the biosimilar track record in Europe noted above, the FDA may wish to devote part of the hearing to a review of that experience. This part of the hearing will allow not only the FDA to review the European experience on labeling, which it may already have done, but also allow other stakeholders to hear that experience.

Investors concerned about the need for a robust biosimilar market and the attendant opportunities such a market would present for innovation, should also be able to share their views. As noted above, the investor community has a stake in the ongoing opportunity for investment that biosimilars represent.

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[8] What You Need to Know about Biosimilar Medicinal Products" European Commission Consensus Information Paper (2013) (Exhibit H), available at: http://www.egagenerics.com/index.php/biosimilar-medicines/information-about-biosimilars/398-ec-consensus-information-document and "What's Keeping Less Expensive Biologic Drugs from the U.S. Market," PBS Newshour (April 19, 2014) (Exhibit I), available at http://www.pbs.org/newshour/bb/whats-keeping-generic-version-biologic-drugs-u-s-market/.

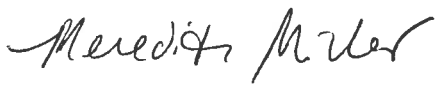
[9] Frances Megerlin et al, "Biosimilars and the European Experience: Implications for the United States," Health Affairs (October 2013) (Exhibit J).

[10] Investor Statement on Board Oversight of Biosimilar Issues (Exhibit K), available at http://www.uawtrust.org/AdminCenter/Library.Files/Media/501/In%20the%20News/Investor_Statement_on_Board_Oversight_of_Biosimilar_Issues_August_2014.pdf.

## IV. Certification

I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: June 2, 2015. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: UAW Retiree Medical Benefits Trust. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.

Respectfully Submitted,



Meredith Miller
Chief Corporate Governance Officer
UAW Retiree Medical Benefits Trust

Signatories,

AFL - CIO
Daughters of Charity, Province of St. Louise
Hermes Equity Ownership Services
Marco Consulting Group
Massachusetts Laborers Benefit Funds
Mercy Health
Mercy Investment Services, Inc.
Middletown Works Hourly & Salaried Union Retirees Health Care Fund
Northwest Coalition for Responsible Investment
Portfolio Advisory Board of the Adrian Dominican Sisters
Seventh Generation Interfaith Coalition for Responsible Investment
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Trinity Health
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