DRAFT

Investor Statement on Board Oversight of Biosimilar Issues

The pharmaceutical industry represents important investments for our portfolios and important producers of life-altering medicines. We greatly value pharmaceutical companies' commitment to innovation and patient safety. As long-term investors in pharmaceutical firms, we have a strong interest in the financial sustainability of these companies and the healthcare systems within which they operate.

Pharmaceutical industry innovation has produced treatments for diverse conditions in the form of biologics—medical products whose active substance is made by or derived from a living organism. We recognize the important role biologics play in treating cancer, rheumatoid arthritis, anemia, multiple sclerosis and many other conditions. But we believe costs for biologics are on an unsustainable trajectory, with some biologics costing as much 22 times more than ordinary drugs. [1] U.S. national spending on these medications has increased 15-20% each year and is not expected to slow down any time soon.[2] These costs could, we believe, impede access for patients and acceptance by providers and insurance companies.

Providers do consider cost when making prescribing decisions. For example, in 2012, three oncologists at Memorial Sloan-Kettering Cancer Center published an op ed in *The New York Times* explaining that they were refusing to prescribe a new biologic for metastatic colon cancer, which cost more than twice as much as another agent for the same condition. They stated, "When choosing treatments for a patient, we have to consider the financial strains they may cause alongside the benefits they might deliver." [3] Recently, the American Society of Clinical Oncology, the American College of Cardiology, and the American Heart Association announced that they would consider costs in treatment decisions, reflecting a broader concern for the financial viability of the U.S. healthcare system.[4]

Biosimilars--lower cost follow-on products that are comparable to biologics--hold the promise of lowering costs for treating conditions for which biologics are indicated or prescribed off-label. The recent adoption of a pathway to approval of biosimilars in the U.S. market (pending final FDA rules), and the continued growth of biosimilars in the European Union, Japan, Canada, Australia and South Korea, pose a challenge for companies that market biologics. Financial experts project that biosimilars have the potential for significant market penetration and attractive returns.[5]

The development of the biosimilar market has implications for access to critical medicines that extend beyond the U.S. borders to include underserved populations.[6] For example, hepatitis C virus infection

[1] Anthony D. So and Samuel L. Katz, "Biologics Boondoggle," New York Times (March 7, 2010) at http://www.nytimes.com/2010/03/08/opinion/08so.html?_r=0
[2] "A Shifted National Focus Toward Specialty Meds," Health Insights from the Express Scripts Lab (July 29, 2013).
[3] See op ed at http://www.nytimes.com/2012/10/15/opinion/a-hospital-says-no-to-an-11000-a-month-cancer-drug.html?_r=0
[4] Andrew Pollack, "Cost of Treatment May Influence Doctors," New York Times (April 4, 2014).
[5] "Biodynamism: Insights into the Biosimilars Market: An Overall Perspective," Grant Thornton (2013).
[6] Timothy Ken Mackey, MAS and Professor Bryan A Liang, MD PhD, "Promoting Access to Biosimilars: a Public-Private Partnership Model for Biosimilar Development in Underserved Populations," Generics and Biosimilars

affects up to 180 million people, killing 350,000 with the greatest incidence in developing countries. It has been reported that some drug companies are marketing hepatitis C biologics at the same market price for both developed and developing markets. These high costs have spurred a search for alternative therapies, including biosimilars.[7]

In addition to cost pressures for alternatives to biologics, market opportunities for biosimilar manufacturers will open up when biologic products accounting for $70 billion of sales go off patent by 2017.[8] However, companies' ability to bring biosimilars to market in the U.S. may be stymied by several factors that are of concern to institutional investors.

First, the information that is being disseminated in the state and federal policy debates related to the dispensing, naming and oversight of the biosimilar market is imbalanced. Noticeably absent is the safety record of the 14 biosimilars that have been marketed in the European Union (EU) since 2006.[9] Data from companies that currently market biosimilars in Europe show no immunogenicity issues;[10] an assertion affirmed by member states of the EU and the European Medicines Agency.[11] Companies that market biosimilar products, with hundreds of millions of patient days combined, have published safety profiles that are comparable or better than the reference drug. These safety records are also recognized by industry analysts and researchers.[12]

Companies seeking to downplay the patient safety record of European biosimilars have also challenged the capacity of the FDA to promulgate rules and determine when biosimilars may be substituted for biologics even though federal law stipulates that such drugs may not be dispensed unless they meet scientifically rigorous standards for approval. These companies advocate that it is not enough for the FDA to determine if a biosmilar drug is safe for substitution, biosimilars should be assigned a different nonproprietary name.

In our view, assigning different names communicates to providers that the biosimilar is less effective, causing providers not to prescribe it and ultimately making it difficult for pharmacists to dispense. As well, different names could lead to prescribing errors.[13] Biosimilar company data based on experience in

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Initiative (April 14,2014) at http://gabi-journal.net/promoting-access-to-biosimilars-a-public%E2%88%92private-partnership-model-for-biosimilar-development-in-underserved-populations.html

[7] "Improving Access to HCV Treatment in Developing Countries," Generics and Biosimilars Initiative (January 31, 2014) available at http://www.gabionline.net/layout/set/print/Biosimilars/Improving-access-to HCV

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

[9] "Biosimilars Approved in Europe," Generics and Biosimilars Initiative (January 31, 2014) at http://www.gabionline.net/Biosimilars/General/Biosimilars-approved-in-Europe

[10] 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; 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.

[11] "What You Need to Know about Biosimilar Medicinal Products" European Commission Consensus Information Paper (2013) at http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/biosimilars_report_en.pdf and "What's Keeping Less Expensive Biologic Drugs from the U.S. Market," PBS Newshour (April 19, 2014) at http://www.pbs.org/newshour/bb/whats-keeping-generic-version-biologic-drugs-u-s-market/

[12] See Mergerlan et al above.

[13] "Biosimilar Suffix Naming Idea Trips on Dispensing Problem," The Pink Sheet (May 21, 2012).

the EU showing that biosimilars can be safely tracked when on the market using nonproprietary names should be considered.[14]

Second, investors' dollars are being used to fund controversial state legislation related to biosimilars. The state legislative efforts have been expansive, with bills imposing requirements on pharmacists dispensing biosimilars introduced in 18 states. Policy makers have objected to the bills as likely to impede patient access to biosimilars by imposing overly burdensome record keeping and communications requirements. These bills failed in 11 states.

Specific political contributions to legislators acting on behalf of pharmaceutical companies have been widely reported by state and national press.[15] These articles show direct contributions to legislators who sit on key committees that are influential in the passage of legislation related to pharmacy dispensing issues. Companies seeking to pass this legislation also wield influence through the lobbying arm of their trade associations.

Investors are faced with a lack of transparency of these expenditures and therefore a diminished ability to evaluate whether boards of directors are effectively exercising oversight over these activities to protect against reputational risk. Many companies do not fully disclose lobbying expenses associated with trade association membership and there are no uniform reporting requirements or format for state level contributions. This issue has been among the top priorities for investors when engaging with pharmaceutical companies.[16]

Investors concerned that controversial political activities may harm companies' reputations point to the characterization in news articles of companies supporting this state legislation as naysayers against biosimilars in order to protect market shares of existing biologic revenue streams or to narrow the number of fellow competitors entering the biosimilar field. In our view, by engaging in activities that signal broad patient safety concerns about biosimilars and the capabilities of the FDA to protect against these risks, companies create market uncertainty, dampen competition, and misconstrue the biosimilar safety record in European and other markets.

Finally, investors seek to understand the business partnerships and deals that may arise with the introduction of biosimilars in the U.S. in order to determine if there are potential legal or other risks. It is expected that the U.S. markets will spawn several partnerships and deals similar to the "pay for delay" deals we have seen with branded and generic drugs.[17] These deals have come under scrutiny as a result of a recent Supreme Court decision that allows the Federal Trade Commission (FTC) to challenge these

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[14] Sumant Ramachandra M.D. Ph.D.,
What's in a Name? The Importance of Biosmilar Nonproprietary Names for Healthcare Innovation," Hospira Policy Paper; and Mark McCamish et al, "Biosimilars by Name and Biosimilar by Nature," Elsevier Business Intelligence (July/August 2013).

[15] Andrew Pollack, "Biotech Firms, Billions at Risk, Lobby States to Limit Generics," New York Times (January 28, 2013); and Ed Silverman, "Controversial Biosimilar Legislation Heats Up in California" Forbes (August 22, 2013); and "Biotech lobbyists Bring Battle to State Level," Posted at Daily Progress (February 15, 2014).

[16] "Statement of Principles and Recommended Corporate Practices to Promote Global Health," Interfaith Center for Corporate Responsibility (March 2014) at http://www.iccr.org/iccrs-statement-principles-and-recommended-corporate-practices-promote-global-health-0

[17] Health Policy Brief, Health Affairs (October 10, 2103).

agreements on anti-trust grounds. The FTC announced this month that it is seeking $1 billion in a patent settlement involving a pay for delay arrangement.[18]

The patent-challenge process established for small molecule drugs under the Hatch-Waxman Act and the requirement that pay for delay arrangements be disclosed to the FTC do not apply to biologics and biosimilars. Investors fear that without full disclosure of the value, terms and duration of these arrangements, investors and analysts will not be able to evaluate the risks associated with the transactions.

In sum, we urge boards of directors to use the following principles to guide decision-making related to biosimilars:

- 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.
- 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.
- 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.

Thank you for consideration of this important issue.

Sincerely,

Investor Signatories:

[18] "US Sues Drugmakers $1 Billion for Upping Prices," Reuters (March 28, 2014) at http:///www.cnbc.com/id/101535013.