We very much appreciate the time and interest of you and your colleagues on the follow-on biologics matter. As we discussed, BIO would like to submit to the docket the three attached papers that we recently provided to you. They are:

· Benjamin N. Roin, Academic Fellow, Petrie-Flom Center for Health Law Policy, Biotechnology & Bioethics: *Unpatentable Drugs and the Standards of Patentability* (May 1, 2008).

· Henry Grabowski, Professor of Economics and Director of the Program in Pharmaceuticals and Health Economics, Duke University; Joseph DiMasi, Director of Economic Analysis, Tufts Center for the Study of Drug Development, Tufts University: *Biosimilars, Data Exclusivity, and the Incentives for Innovation: A Critique of Kotlikoff's White Paper* (February 2009).

· Joseph Golec, Finance Department, University of Connecticut; John A. Vernon, Department of Health Policy and Administration, University of North Carolina; Ted Buckley, Director of Economic Policy, Biotechnology Industry Organization: *Data Exclusivity Period Length and Federal Government Savings from Enactment of the Biologics Price Competition and Innovation Act of 2007* (January 28, 2009).

These papers provide further support regarding the need for a substantial period of data exclusivity to enable biologics to have parity with small molecule drugs and provide an environment that is conducive to investment in, and development of, biotech drugs. Note that the Grabowski response to Brill (already in the docket) (**http://www.econ.duke.edu/Papers/PDF/Data_Exclusivity_Periods_for_Biologics.pdf**) confirms that an exclusivity period of only seven years would result in a break-even point of 50 years for an innovator biologic, even in light of the CBO figures on market entry. We believe that, in the years after the CBO scoring window ends, the possibility exists for more robust competition in the FOBs space than predicted by the CBO in the scoring period.

You also had asked about the power of PBMs and health insurance plans to influence prescribing in a competitive FOBs marketplace. While we cannot predict the specific impact of such activities with respect to an evolving FOBs regulatory and market regime, note that both PBMs and health insurance plans have grown substantially in their ability to influence the price and choice of biopharmaceuticals that doctors prescribe and that patients take. Some facts for your consideration:

· From 2000-2004, the PBM industry grew approximately 30 percent, so that about 200 million people (68 percent of the U.S. population) were in private plans with pharmacy benefit management.

· PBMs and health insurance plans often have patients pay different out of pocket amounts in order to steer the patients towards certain pharmaceuticals.

· In early 2000, 80% of managed care plans with drug benefits offered three-tier co-payment options, compared with only 36% in 1998.

Finally, please note that the final Vernon paper (we cited the draft working paper in our December 22, 2008 comments) should be out any day now. Please let us know if you have any questions or if we can provide additional information.

Best regards,

Sandi

Sandra J.P. Dennis
Deputy General Counsel for Healthcare
Biotechnology Industry Organization (BIO)
1201 Maryland Avenue, S.W.
Suite 900
Washington, D.C. 20024
202-962-6673 (ph)
202-962-9201 (fax)
sdennis@bio.org