BERNARD SANDERS
VERMONT

COMMITTEES:
BUDGET
ENERGY AND NATURAL RESOURCES
ENVIRONMENT AND PUBLIC WORKS
HEALTH, EDUCATION, LABOR, AND PENSIONS
VETERANS' AFFAIRS

United States Senate
WASHINGTON, DC 20510–4504

November 2, 2010

Margaret Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

Thank you for hosting the important Food and Drug Administration hearing on November 2-3, 2010, on the Approval Pathway for Biosimilar and Interchangeable Biological Products.

I write to call your attention and the attention of the hearing's panel members to an important defect in the Biologics Price Competition and Innovation Act of 2009, the first instance of which I am aware of a licensing barrier that, in effect, legislatively mandates that an applicant for marketing approval violate the ethical standards set out in, among other ethical codes to which the United States, its doctors and its researchers adhere, Article 20 of the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects.

I refer to the 12-year period of data exclusivity included in the new law, which would prevent an applicant for marketing approval of a biosimilar or bioequivalent product from relying on existing data establishing the safety and efficacy of the product. Setting aside for the moment the relevant fact that such clinical trial data will likely have been paid for in large part by the taxpayer, my concern is with the ethical implications of such a bar to reliance on the data: an applicant for licensing approval of a bioequivalent or biosimilar product is left with only one option (short of abandoning its product): to repeat clinical trials to answer questions that have already been answered.

Article 20 of the Helsinki Declaration states, in pertinent part, "Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results." Yet a 12-year data exclusivity period by design requires exactly that: the conduct of a clinical trial despite the fact that "conclusive proof of positive and beneficial results" already exists.

By establishing such a de facto requirement, the biologics industry has achieved something quite profound: a virtually absolute bar to competitors for a full 12 years from market entry of a new product, regardless of the patent status of the product and despite that the industry itself reports that R&D costs for biologics are roughly equivalent to those of small molecule drugs for which a 12-year data exclusivity period is not in place. While such a stifling of competition is bad for

our economy and health outcomes, among other things, its implicit requirement that companies, doctors and researchers must conduct unethical clinical trials in order to bring an affordable equivalent product to the market crosses a new line.

My legislation, S. 3921, the Ethical Pathway Act of 2010, would reform this indefensible requirement and is based on a simple premise: The US government should honor and respect international ethical standards for medical research, including the Declaration of Helsinki, by avoiding unnecessary repetition of clinical trials in human subjects. It is pro-patient, pro-research, and pro-taxpayer, while providing for a system of cost sharing for drug registration data that will protect the legitimate financial interests of the innovators. S. 3921 would mandate that applicants for drug marketing approval, including generic and biosimilar producers, be allowed to rely on existing test data when applying for marketing approvals, subject to paying an appropriate share of the costs to rely upon the results of such trials.

I urge the Food and Drug Administration to pay close attention to the ethical implications of the new law it has been charged to implement, and to recommend to Congress that this fundamental flaw be addressed legislatively as soon as possible.

Sincerely,

Bernard Sanders
United States Senator