MYLAN

May 2, 2008

The Honorable Frank Pallone
Chairman
Committee on Energy and Commerce
Health Subcommittee
United States House of Representatives
316 Ford Office Building
Washington, DC 20515

The Honorable Nathan Deal
Ranking Member
Committee on Energy and Commerce
Health Subcommittee
United States House of Representatives
316 Ford Office Building
Washington, DC 20515

Dear Chairman Pallone and Ranking Member Deal:

As a leading global manufacturer of generic and specialty pharmaceuticals based in the United States and with operations in over 90 countries, Mylan greatly appreciates the opportunity to provide our input on the establishment of a legislative pathway for the United States Food and Drug Administration to approve generic versions of biologic products.

Mylan supports initiatives around the world that will enhance patient access to pharmaceutical care. Recent examples clearly show that the pharmaceutical science exists to create an appropriate pathway to allow for the approval of generic biologic products. Undoubtedly, legislation that provides our industry with clear and unequivocal pathways to facilitate cost-effective products to patients and medical care providers after patent expiry is paramount in this effort. A pathway for the approval of generic biopharmaceuticals will greatly increase access to these medicines, which are currently still often unaffordable for many Americans.

Mylan has been actively engaged with policy makers and regulators around the world, including the European Medicines Agency (EMEA) and Health Canada on the development and marketing of generic versions of biologics. Recently Health Canada reached out to stakeholders in a consultation process and Mylan played an active role in this process and submitted extensive comments. Additionally, as a member of the Board of Directors of the Generic Pharmaceutical Association (GPhA), Mylan played an important contributing role in GPhA's response to your Committee. We support the input that GPhA will give to your Committee and have therefore

decided to refrain from sending you detailed answers to your questions that would have been largely reiterating GPhA's input.

We would like to emphasize that Mylan globally supports the establishment of a pathway that is based on sound science. Two elements are of particular interest to Mylan.

First, we strongly support a robust pathway that is guided by sound science and regulatory process to assure safety, quality and purity of generic versions of biologics. At the same time we do believe that a pathway for approving generic versions of biopharmaceuticals should not include unnecessary clinical trials and should allow for the possibility of interchangeability between the originator product and a generic. Only then will patients have meaningful access to generic versions of biologic products. Therefore we encourage the Committee to give as much deference, flexibility and scientific discretionary power to the United States Food and Drug Administration, one of the premier drug regulatory agencies around the world, as they have the expertise to make decisions on a case-by-case basis. This is especially important as science in the biotechnology area continues to evolve each day.

Second, with respect to the identification and enforcement of intellectual property (e.g., patents) Mylan strongly believes that there should be no patent linkage that delays the regulatory approval of generic versions of biologic products. Under the Agreement on Trade-Related Aspects of Intellectual Property Rights it is well accepted that patent linkage is not a requirement and the majority of the countries around the world do not require linkage. In addition, because of the voluminous amount of process and manufacturing patents that can be obtained by the originator, requiring a generic applicant to challenge each patent prior to market entry can significantly delay access to these valuable medicines. However, Mylan may support the listing of relevant patents in an Orange Book type of document that can assist both the brand company and generic applicant to identify the most pertinent patents. The listing of a patent in an Orange Book should be limited to patents that cover the use of the product. In addition, the listing of a patent in an Orange Book type of a document should be accompanied by a strong certification subject to verification by the patent holder and marketing authorization holder listing the patent. Also, the generic applicant should have the ability to file an independent claim challenging the listing of any patent in the Orange Book type of document irrespective of the originator or patent holder filing a patent infringement suit.

In conclusion, it is Mylan's belief that the pharmaceutical science is available to establish a regulatory pathway for the approval of generic biopharmaceuticals. The healthcare of the American public can significantly progress with the arrival of cost-effective alternatives to existing products.

We are at your disposal for further information and support in this important effort.

Sincerely,

Robert J. Coury
Vice Chairman and Chief Executive Officer