

**STATE OF MARYLAND**  
OFFICE OF THE GOVERNOR



**MARTIN O'MALLEY**  
GOVERNOR

December 31, 2008

The Honorable Steny H. Hoyer  
U.S. House of Representatives, Majority Leader  
H-107, The Capitol  
Washington, D.C. 20515

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TTY USERS CALL VIA MD RELAY

Dear Majority Leader Hoyer:

I am writing to convey our Administration's perspective on what has been termed "follow-on biologics" (FOBs; also referred to as "biosimilars" or "biogenerics") – particularly in regards to legislative initiatives which were considered by Congress this past year and are likely to reappear before the 111<sup>th</sup> Congress.

This critically important issue has a direct impact on our nation's economic future, its ability to promote biomedical innovation and discovery, and its ability to make health care more affordable to all Americans.

There is no doubt that biologics-based therapeutics, many of which derive from young risk-taking small- and medium-sized biotechnology companies, will play an increasingly significant role in producing positive health care outcomes. Other promising candidates come from public and private research investments and technology transfer initiatives in the life sciences programs of higher education institutions in Maryland and across the nation. They, in turn, rely on subsequent commercialization by private industry.

These FOBs - complex protein molecules - unlike conventional small molecule drugs, pose considerable R&D, manufacturing, and clinical trial challenges that can drive up their development costs in addition to lengthening their time to market. The risks taken by so-called "innovator" companies involve more failures than successes, all of which are underwritten by venture capital investment or the public markets. The high cost of development is reflected in their cost of delivery. Many are under development for deadly or debilitating diseases in patient populations so relatively small that, even if 100% were treated, reimbursement would not cover the costs of development.

Moreover, the inherent complexity of a biotherapeutic raises concern over the true interchangeability of such molecules (original "reference" and "similar" FOB) in humans with regard to the need for demonstrable safety and efficacy. In fact, the FDA has not yet determined how interchangeability can be established for such complex proteins. Unlike small molecule drugs, the manufacturing of biologics can introduce significant variability in the end-product. Often the manufacturing process itself requires proprietary development and is patent protected. It is for these reasons that, for the foreseeable future, the FDA should caution patients against using FOBs unless expressly prescribed by a knowledgeable physician.

Legislation introduced this past year by Rep. Anna Eshoo (D-CA) and Rep. Joe Barton (R-TX) entitled the Pathway for Biosimilars Act (H.R. 5629) would develop such a regulatory pathway for approving FOBs. The bill includes most of the essential elements to ensure that any such pathway follows two critical principles: protecting patient safety and ensuring



continued innovation. Absent compelling data, the pathway also establishes a mechanism for the FDA to advise whether it is feasible, based on current science, to make a determination that a follow-on product is interchangeable with an innovator's biotherapeutic. This approval pathway for FOBs would include thorough regulatory standards to assure patient safety and demonstrate product effectiveness.

It is important, as with provisions in the Drug Price Competition and Patent Term Restoration Act of 1984 (usually referred to as the Hatch-Waxman Act), for small molecule drugs, to assure additional data exclusivity for innovator derived drugs. Long development times (12-15 years) and cost recovery periods (2-5 years once marketed) for any particular drug reach the edge of patent expiration. Moreover, only 3 of 10 approved drugs recoup their development costs. Thus, the Pathway for Biosimilars Act seeks to provide innovators with at least 12 years of non-patent data exclusivity to promote continued innovation, a balance between providing incentives for innovation and follow-on product entry. Non-patent exclusivity maintains effective market protection to attract the hundreds of millions of dollars of investment necessary to research and develop additional innovative biotherapeutics.

Timely resolution of patent disputes is also essential to the implementation of an FOB approval pathway. The Pathway for Biosimilars Act includes balanced procedures for the resolution of patent-related disputes that may occur with respect to FOBs. These provisions allow for resolution of patent disputes before the expiration of the innovator product's market exclusivity period and hence make it more likely that such disputes can be fairly resolved prior to market-entry of the FOB. An additional outcome of such a pathway is a predictable market entry point for generics companies, with a defined transition of innovator information and barriers to both innovator and generics' misuse of patent extending or evading variants. Such clear transitions would mitigate the hundreds of millions of dollars spent each year by both sides in patent litigation and realize potential savings to patients. Therefore, it is possible, through legislation, to support the valuable role of the generics industry already recognized by the FDA, health care payors, and consumers.

In Maryland, we view advances in the biosciences as key not only to unlocking our economic potential as a State (and indeed as a country) but in allowing us to exercise moral leadership in this world – to proliferate what Dr. Jeffrey Sachs refers to as “weapons of mass salvation” – the sciences and technologies of healing.

As we seek to develop a new generation of cures, treatments and technologies, it is incumbent on all of us in public life to recognize that the discovery process is driven by intensive risk capital and years of trial and error. It is therefore essential to balance the moral obligation we all share to make new cures affordable and accessible with the understanding that the costs involved should be spread among various sectors in society, not solely upon those who deliver biomedical innovation.

It is my sincere hope that we are able to work together in this upcoming Congress to support legislation such as the Pathway for Biosimilars Act. I ask you to help maintain Maryland's leadership role in scientific innovation and grow its leadership role in the delivery of lifesaving therapeutics around the world.

Sincerely,



Martin O'Malley  
Governor