



THE AIDS INSTITUTE



July 13, 2009

The Honorable Edward M. Kennedy, Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
428 Dirksen Senate Office Building
Washington, DC 20510

RE: Support for 12 Years of Data Exclusivity for Biologics

Dear Chairman Kennedy,

As advocacy organizations for people living with and affected by HIV/AIDS specifically, and as advocates for patients living with and suffering from any disease or illness generally, we commend President Obama and members of Congress who are working to make health care affordable and available to all Americans. We commend those members who are diligently working to draft a healthcare reform bill that will provide quality health care for those who cannot afford it.

We are grateful also for the commitments that members of Congress secured from the pharmaceutical industry to reduce the price of certain prescription drugs for Medicare beneficiaries. This is good news for the thousands of disabled and elderly people living with HIV/AIDS who rely on Medicare Part D for their life-saving prescription drugs. We know this will be effective only if meaningful health reform passes this year. It is our hope that it does. We call on Congress to include language as part of health reform that would allow ADAP funds to count as true out of pocket expenses (TrOOP), so the coverage gap can be filled, and ADAP funds can be stretched to cover more HIV+ patients. This provision is included in the House Democrat's HCR discussion draft.

While we applaud the aforementioned aspects of the legislation, we are concerned that it may also include language that will serve to block the flow of innovative drugs for the treatment of not only HIV/AIDS, but other diseases and conditions. Since 1987, approximately 32 drugs have been developed to treat HIV/AIDS. These innovations have turned what was once a terminal illness into a potentially chronic, manageable condition. Technology, research, and innovation have expanded the horizon of possibilities for saving lives. The new frontier is in the area of biologics. We are already beginning to see these compounds emerge on the market to treat conditions in more effective ways. We have witnessed the transformation of HIV/AIDS care and treatment for one drug (AZT) to over 32 drugs in just the past 22 years. We have seen the HIV drug regimen transformed from upwards of 10 to 15 pills a day to just 1 a day. And now we stand as witnesses to what biologics can do. Two such biologics, Procrit and Aranesp, are being used to effectively treat HIV-related anemia as well as anemia related to kidney failure and chemotherapy. All of these life-saving drugs were developed with private investment and it is our opinion that this was only possible because pharmaceutical and biotechnology companies were able to recoup their investment in the extensive clinical research and clinical trials required to make these drugs available to the people that need them. We look to biologics to move forward as quickly as HIV medications have.

We believe health care reform should improve quality and reduce costs, but it must be crafted in such a way as to strongly support continued medical innovation. That is why we strongly urge you to include a period of data exclusivity relative to biologics of 12 years. During the 110th Congress, there was unanimous and bipartisan support for legislation (S. 1695) that provided biologic innovators parity with drug manufacturers. We believe the goal should be to achieve a balanced approach that would act as an incentive for companies who develop innovative products without retarding the development of the generic drug and biosimilar industry. We firmly believe that the only way for people living with HIV/AIDS and other diseases to benefit from groundbreaking treatments is to preserve the strong incentives that made these lifesaving treatments possible in the first place.

Best regards,

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