Eshoo needs to close loophole in biologics legislation

By Alexander C. Tsai and Nicholas Rosenlicht

Here in San Francisco, one of the initial epicenters of the HIV/AIDS pandemic, we provide critical psychological counseling and support for many patients living with HIV/AIDS as well as many more patients at risk for HIV. We are concerned that new legislation, ALEXANDER C. TSAI, M.D., Ph.D. is a psychiatrist at Langley Porter Psychiatric Institute, University of California, San Francisco and a resident of San Francisco. NICHOLAS ROSENlicht, M.D. is a clinical professor of psychiatry at UCSF, and maintains a private practice in Berkeley, where he resides. They wrote this article for the Mercury News.

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under consideration as part of the health care reform package now weaving its way through Congress, threatens access to new drugs for the most vulnerable in our society.

U.S. Rep. Anna Eshoo, D-Palo Alto, has introduced legislation to establish a generic biologics pathway. Different from chemical compounds such as lopinavir/ritonavir used to treat HIV infection, biologics are complex drugs engineered from human or animal cells using biotechnology. They include many new diagnostic tests and experimental vaccines for HIV that could someday prevent infections and save millions of lives.

Eshoo’s bill establishes a 12-year marketing monopoly for brand-name biologics, apart from patent protection. Even worse, it rewards branded biologic drug manufacturers with additional years of exclusivity if they make slight changes to their existing drugs, a strategy known as “evergreening.” According to the FTC, her bill would stifle innovation by encouraging manufacturers to focus their research efforts on making minor modifications to existing drugs rather than on developing “new inventions to address unmet medical needs.”

As psychiatrists, we are very familiar with how evergreening has adversely affected our patients. The year before Eli Lilly lost its patent protection on Prozac, it repackaged the drug in pink and lavender and spent $33 million promoting its use to women for “pre-menstrual dysphoric disorder,” or severe pre-menstrual syndrome. Same drug, higher price: A typical monthly supply of generic fluoxetine now costs less than $1 per day, whereas Sarafem costs four times as much.

Eshoo has attempted to argue that her bill does not permit evergreening. However, it actually contains a glaring loophole whereby simple, inexpensive modifications to drug structure could trigger additional years of exclusivity.

Given current economic conditions, does it make sense to support a bill that sustains high drug prices, stifles innovation, and reduces our patients’ access to lifesaving drugs in the future? In Eshoo’s own district, one out of every 10 residents under the age of 65 has no health insurance — including one of every 20 children.

Nationwide, one of every five persons living with HIV is uninsured.

Branded biologics can cost more than $20,000 per year.

Eshoo’s bill could ensure that prices remain out of reach for years to come.

As negotiations on the health care reform package continue, Eshoo will have an opportunity to reconcile her priorities with those of the marginalized and excluded — and close her evergreening loophole.

We hope she votes to preserve incentives for innovation and access to lifesaving drugs for all. Our patients deserve that much.