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OPED CONTRIBUTORS

Vital biotech industry under attack in Washington

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The biotechnology industry was born in Northern California. The world's first two biotech companies, Cetus and Genentech, were founded near San Francisco more than 30 years ago. Since then, the life-sciences industry has grown into a vital part of our state economy, and will be a key driver of California's economic recovery — provided Congress doesn't get in the way.

As part of the health care reform legislation, the Senate will soon consider measures that will determine how long the developers of brand name therapeutics called "biologics" can keep their proprietary research data from competitors. When this period of "data exclusivity" ends, outside firms can use this information to make copycat biologic drugs called "biosimilars."

Biologics are among today's most promising treatments for many forms of cancer, Alzheimer's and even HIV/AIDS. The current proposal sets data exclusivity for these cutting-edge drugs at 12 years. But Sens. Chuck Schumer, D-N.Y., and Sherrod Brown, D-Ohio, are threatening to weaken the bill and reduce that period to seven years.

This change puts millions of patients around the world at risk and undermines jobs and investment in the Bay Area. Our state's congressional representatives cannot allow this assault on the life-sciences industry to succeed.

Northern California boasts the highest concentration of life-science companies in the nation — more than 1,377 firms, 95 of which are publicly traded. Together, these firms employ more than 100,000 people.

During a typical year, the industry creates 8,000 to 10,000 new jobs in the region. The five major research universities in Northern California — UC Berkeley, UC Davis, UC San

Francisco, UC Santa Cruz and Stanford — allocate more than \$2 billion to biotech research annually. And the National Institutes of Health pumps more than \$1 billion in funding into local biotech programs.

The Northern California life-sciences industry will continue to perform strongly, improve patient health and drive growth in California only if it's accorded a fair period of data exclusivity for biologics.

Life-sciences companies spend 10 to 15 years and an average of \$1.2 billion to bring new biologics to market. If the data exclusivity period is too short, outside firms will flood the market with biosimilars before innovator companies are able to break even in sales on their massive investment. And if the return on biologics drops dramatically, so will the investment required to create them in the first place.

Northern California is the center of the world's venture capital market. Thirty percent of all active venture capital firms in the U.S. are based here, along with 28 percent of all domestic life-sciences venture capital investments.

If data exclusivity is too short, firms would likely uproot and establish themselves in areas with regulatory environments that better reward innovation. The European Union grants up to 11 years of data protection. Japan and Brazil offer up to 10 years. These are the places where we could lose jobs and investment if data exclusivity is weak.

Proponents of the shortened data exclusivity period claim that bringing biosimilars to market faster will lower health care costs. In fact, the opposite is true.

If life-sciences innovators are to have any hope of recouping their investment costs under a shortened data exclusivity environment, they will need to charge higher prices. Thus, many lifesaving biologic treatments — which are already rather expensive — could become unaffordable for most Americans.

Additionally, shortened data exclusivity incentivizes researchers to pursue only the most profitable medicines and ignore other areas of research, no matter how medically promising. The result would be fewer breakthrough medicines. Patients would suffer.

The goal of providing more patients with lifesaving medicines is righteous. To actually achieve it, Congress needs to provide a sufficiently long data exclusivity period on biologic medicines. That way, Northern California, and America, will continue to attract medical research, and the scientists will continue to produce amazing new treatments,

cures and technologies.

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