



News Release

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For Immediate Release

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Massachusetts Governor Patrick Signs Bill Granting Patient Access to Interchangeable Biologic Medicines

Transparent Communication Important for Patients and Physicians

San Diego, California (June 25, 2014) – The [Biotechnology Industry Organization](http://www.bio.org) (BIO) and the [Massachusetts Biotechnology Council](http://www.massbiotech.org) (MassBio) commend Massachusetts Governor Deval Patrick for signing legislation yesterday designed to create a pathway for the substitution of interchangeable biologic medicines.

The policies outlined in [House Bill 3734](http://www.mass.gov/hoc/3734) align with [all five of BIO's principles on biologic substitution](#). BIO and MassBio commend Massachusetts's Senate and House of Representatives for passing this legislation earlier this month. Governor Patrick announced yesterday at the [2014 BIO International Convention](#) that the bill had been signed.

"This important legislation enjoys the support of physicians across the country, patient groups, and both biologic and biosimilar manufacturing companies," said Jim Greenwood, BIO's President and Chief Executive Officer. "By signing this bill into law, Governor Patrick added Massachusetts to a growing list of states that have taken a leadership position in allowing retail pharmacies to substitute interchangeable biologic medicines."

"We're so excited that once again Massachusetts is leading the way in adopting policy that not only supports a growing industry, but more importantly allows patients access to the most cutting-edge therapies that have been proven safe and effective," said Robert K. Coughlin, President & CEO of MassBio, the state's life sciences trade association. "We are fortunate to have visionary leaders like Governor Patrick, Senate President Therese Murray and House Speaker Robert DeLeo who are willing to stand up for innovation and patient safety."

While the U.S. Food and Drug Administration (FDA) oversees approval of biologic medicines and designation of interchangeability, policies governing whether one product may be substituted in place of

a doctor's prescription and whether a pharmacist must inform patients and doctors are covered by state law. House Bill 3734 seeks to properly preserve patient access to accurate prescription information, maintains incentives for innovation and promotes a competitive market for biologic therapies. BIO will continue to advocate for full transparency in the substitution process, as patients and their physicians should have the right to know what biologic medicine the patient receives from the pharmacy.

The FDA is currently developing a pathway for the development and approval of safe and effective interchangeable biologic products in the United States. However, there is still a major role for states to play in ensuring substitution practices remain transparent and physicians remain engaged in the process.

“Interchangeable biologics are not generics. Even slight changes to a biologic drug can change its properties entirely,” said Greenwood. “Unlike conventional generic medicines, interchangeable biologics are not the same as the drugs they seek to substitute. In fact, two biologics made using different cell lines and differing manufacturing processes will rarely, if ever, be exactly the same. Those suggesting interchangeable biologics and generics are the same are wrong.”

Patients and physicians managing chronic conditions are generally aware of which biologic treatments work best in their unique circumstances. Communicating with patients and physicians allows everyone involved the opportunity to discuss past treatment experiences so that any possible unexpected issues can be better understood and avoided.

As other states continue to address issues related to biologic medicines, BIO encourages policy makers to continue to put patients first.

About BIO

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO also produces the [BIO International Convention](#), the world's largest gathering of the biotechnology industry, along with industry-leading investor and partnering meetings held around the world. BIO produces [BIOtechNOW](#), an online portal and monthly newsletter chronicling “innovations transforming our world.” [Subscribe to BIOtechNOW](#).

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