



May, 19, 2009

To the North Carolina Congressional Delegation:

RE: H.R. 1548 (Pathway to Biosimilars Act of 2009)

The House of Representatives is currently considering H.R. 1548, the Pathway to Biosimilars Act, which would create a regulatory approval pathway for biosimilars. These are biologics that are similar to, but not exact copies of, innovator biologics. For the sake of our state's economy and the health of North Carolinians, the undersigned members of the North Carolina Biosciences Organization are asking that you support H.R. 1548.

HR 1548 takes patient safety seriously. Biologics are made from living organisms. As a result, they're significantly more complex than traditional drugs.

In fact, creating biologics is so complicated that they're impossible to duplicate exactly. This is important because even a slight variation in the molecular composition of a medicine can result in unforeseen side effects. Recognizing this, the Pathway to Biosimilars Act -- which creates a legal framework for the approval of attempted copies of biologics -- ensures FDA has the authority to require the appropriate testing of biosimilars so physicians can be sure of a medicine's safety and potency. The legislation appropriately recognizes that biosimilars will not be identical to the innovator product and provides the necessary framework to protect patient safety.

HR 1548 also protects North Carolina's biotech industry. According to an economist at Duke University, it takes about 13 to 16 years of sales for a biopharmaceutical company to break even on new biologics. That's because researching and developing one of these medicines and then bringing it to market is staggeringly expensive, totaling \$1.3 billion on average.

The Pathway to Biosimilars Act allows biotech companies to keep their research data from competitors for 12 years. This gives them the chance to recoup their investment costs and remain economically viable. In North Carolina, protecting the future of biopharmaceutical companies is especially important as the industry accounts for almost 120,000 jobs in the state.

The Pathway to Biosimilars Act lays the foundation for the continued growth of North Carolina's biotech sector while protecting the health of patients everywhere. It warrants your support.

Sincerely,

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