MedChi
The Maryland State Medical Society

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MEDCHI APPLAUDS SENATE ACTION TO PROTECT PATIENTS WITH REGARD TO BIOLOGIC DRUGS

ANNAPOLIS, March 8, 2013 – MedChi, The Maryland State Medical Society applauds passage of legislation in the Maryland State Senate to create a process that will make newly-developed biosimilar medications accessible in a safe and transparent manner for state residents. The legislation still has to pass hurdles in the House and be signed by the Governor to become law.

"Biosimilar drugs are now being used in Europe and will soon be authorized for patient use in this country," explained MedChi, CEO Gene Ransom. "Maryland is being proactive in establishing a process by which patients have access to these affordable drugs with provisions to protect their safety."

The committee action fulfills the state's responsibilities under the federal Affordable Care Act (ACA). The ACA empowers states to set the standards by which biosimilars -- reproductions of brand-name biologic medications -- can be substituted for the innovator product. It is expected that biosimilars will be reaching pharmacies as early as 2014.

The State Senate measure, introduced by Sen. Joan Carter Conway, states that biosimilars can only be substituted if the Food and Drug Administration has certified the drugs as interchangeable with the original, brand-name biologic. This standard is made necessary by the fact that, unlike generic versions of conventional drugs, biologics are made from living cells and it is impossible to create exact copies. Even slight variations between the biologic and the biosimilar can make a difference in clinical outcomes.

Ransom explained "Biologics are changing the lives of patients with serious chronic illnesses. Biosimilars will make this improved health financially accessible for more Marylanders, but because of the unique nature of these medications, patient safety must be assured. This committee action provides both accessibility and critical safeguards. This is common-sense, patient-centric legislation."

The State Senate legislation states that patients and physicians must be notified when a biosimilar is substituted. Furthermore, Pharmacists are required under the new law to maintain records of biosimilar substitutions for a reasonable length of time to maintain essential documentation in the event a patient has an adverse reaction to a biosimilar.

About MedChi

MedChi, The Maryland State Medical Society, is a non-profit membership association of Maryland physicians. It is the largest physician organization in Maryland. The mission of MedChi is to serve as Maryland's foremost advocate and resource for physicians, their patients and the public health of Maryland.