



MEMORANDUM IN SUPPORT OF S.4788 (Hannon), A.7509 (Gottfried) TO SUPPORT PATIENT ACCESS & TRANSPARENCY FOR INTERCHANGEABLE BIOSIMILAR SUBSTITUTION

We, the undersigned patient advocacy groups and professional societies, strongly support S.4788, A.7509 - an act to amend the education and public health law, a bill which would establish requirements for pharmacies to substitute and dispense interchangeable biological products.

Biologic therapies are successfully treating patients with serious and difficult to treat diseases such as cancer, cardiovascular disease, HIV/AIDS, and various autoimmune conditions such as arthritis, crohn's and colitis, diabetes, lupus, multiple sclerosis, psoriasis, among others. Biologics are often used to treat patients with complex chronic disease and/or critically ill patients that have not been responsive to traditional medical treatments alone.

There are currently more than 200 FDA approved biologic therapies available to patients today - and with continued R&D, we see new frontiers in science being met with more than 900 biologics in development, targeting more than 100 diseases and conditions including: Autoimmune Diseases; Blood Disorders; Cancer and related Diseases; Cardiovascular Diseases; Diabetes; Digestive Disorders; Eye Conditions; Genetic Disorders; Infectious Diseases; Musculoskeletal Disorders; Mental Illnesses; Neurological Disorders; Respiratory Disorders; Skin Diseases; Transplantation; and many others.

While New York State law governs the substitution by pharmacists of generic drugs for their branded counterparts, the existing law has not been updated to allow for the substitution of biologic products with FDA approved interchangeable biologics. This bill will update the law to reflect the growing market of biologic products and increased availability of biosimilar products that are designated as interchangeable by the FDA. Without this change to current law, automatic substitution of biologic products will be prohibited.

Chronic disease is an increasing burden in New York and is a key cause of death and disability to its citizens. Biologic medicines have been developed to treat many of these chronically ill patients, with diseases unresponsive to traditional medicines. For these patients, biologic medicines—drugs created from living cells—are providing new hope for better, healthier lives. ***S.4788, A.7509 updates current NY substitution laws to address biological products while enhancing access to life saving medicines and facilitating communication among patients and their health care providers.***

Enactment of the Affordable Care Act in 2010 created a pathway to allow for the development and manufacture of Biosimilars and Interchangeable Biologics. When interchangeable biologics are approved by the FDA, patients and their providers will need a safe and transparent process by which they can receive access to these medicines to treat their diseases and pharmacists also need a clear standard way to substitute biological products with those that the FDA has deemed “interchangeable” to the products prescribed.

We applaud Senator Kemp Hannon and Assemblyman Richard Gottfried for introducing sound health policy outlining the parameters for substitution of interchangeable biologics that will ensure New Yorkers will have access to high-quality, safe, and - most importantly - effective biologic medicines.

Collectively, we strongly believe that substitution should only occur when the FDA has designated a biologic product as *interchangeable* and proper patient protections are upheld to ensure full transparency including pharmacy-physician communication of the product dispensed through interoperable electronic health records where available. Inclusion of this information ensures that the patient has a longitudinal health record. Given that many patients have comorbidities that require treatment by different health care providers, a complete medical record is essential.

By creating a new pathway for interchangeable biologic substitution where none currently exists in New York, this legislation enhances patient access to new and potentially less costly medications. We, the undersigned, urge the New York State Legislature to act expeditiously on this issue and pass S.4788, A.7509.

Respectfully,

Alliance For Patient Access

Alliance For Safe Biologic Medicine

American Cancer Society - Cancer Action Network, Inc.

American College of Rheumatology

American Liver Foundation

American Lung Association

Arthritis Foundation

Association of Hispanic Mental Health Professionals

BOOM!Health

Cerebral Palsy Associations of New York State

Center for Independence of the Disabled, NY

Crohn's & Colitis Foundation of America

Global Healthy Living Foundation

Harlem United

Hispanic Health Network

ICAN, International Cancer Advocacy Network

Institute for Community Living (ICL, Inc.)

Latino Commission on AIDS

Lupus and Allied Diseases Association, Inc.

Malecare

Mental Health Association in New York State, Inc.

NAMI NYS

New Yorkers for Accessible Health Coverage

New York State Osteopathic Medical Society

New York State Rheumatology Society

NORD (National Organization for Rare Disorders)

Northeast Kidney Foundation

Susan G. Komen Upstate New York

US Pain Foundation