



June 25, 2016

Honorable Andrew M. Cuomo
 Governor
 Executive Chamber
 State Capitol
 Albany, N.Y. 12224

Dear Governor Cuomo-

We are writing this letter on behalf of the 36 organizations listed below and the millions of New Yorkers we represent who struggle daily to manage complicated, multi-system diseases. The Lupus Agencies of New York State, the U.S. Pain Foundation, the New York State Rheumatology Society, the New York State Academy of Family Physicians, the Association of Hispanic Mental Health Professionals, the Association of Black Cardiologists, the Global Healthy Living Foundation, the American Autoimmune Related Diseases Association, the Scleroderma Foundation Tri-State Chapter, the Sjögren's Syndrome Foundation, the Northeast Kidney Foundation, the International Institute for Human Empowerment, the National Multiple Sclerosis Society – New York MS Coalition Action Network, the National Psoriasis

Foundation, the Latino Commission on AIDS, the Hispanic Health Network, the Mental Health Association in New York State, the New York State Rare Disease Alliance, the 1 in 9 The Long Island Breast Cancer Action Coalition, the NAACP New York State Conference, the Digestive Disease National Coalition, the Crohn's & Colitis Foundation of America, the Gay Men's Health Crisis, the Sisterlink Collaborative, the Institute for Community Living, the Arthritis Foundation, the Hispanic Federation, the Hepatitis Foundation International, the American Behcet's Disease Association, the New York Association on Independent Living, the Bleeding Disorders Advocacy Network, the Harlem United, and the International Foundation for Autoimmune Arthritis strongly support **A.2834-D / S.3419-C** an act to amend the insurance law and the public health law in relation to expedited utilization review of prescription drugs and to regulate insurance companies, health maintenance organizations, and utilization review agents who impose step therapy protocols on patients. The legislation would also provide for an expedited appeals process for health care professionals and patients to override such protocols. This bill would guarantee the health and safety of consumers by ensuring timely access to life-saving medications and providing necessary patient protections.

Establishing fail first or step therapy policies requiring that the least expensive drug in any class be prescribed to a patient first has dire implications as well as dangerous consequences for consumers and our health care system. Delaying patient access to medicines denies care. Patients and their providers need open access to all medications in order to maintain consistent disease management. Disrupting continuity of care can result in detrimental life-threatening consequences to the individuals who are the most vulnerable and can actually lead to increased symptoms, more medical complications, and higher health care costs.

Basing treatment decisions on cost rather than clinical considerations ignores important variations that can exist among patients in terms of safety, efficacy, and tolerability in drug classes. New scientific research shows there are gender, racial, and ethnic differences in responses to treatments, and limiting access will greatly widen already existing health disparities. The determination of the most appropriate medication for a particular individual with complex chronic or rare conditions or the recipient of an organ donation/transplant must be made on the basis of patient acceptability, prior individual drug response, side-effect profile, and long-term treatment planning – not on cost. Many of these individuals already face tremendous challenges in their daily lives and do not need another roadblock to further complicate their medical care.

Individuals with multifarious conditions and those with autoimmune diseases such as lupus, rheumatoid arthritis, inflammatory bowel disease, scleroderma, sjögren's syndrome, multiple sclerosis, psoriatic arthritis – require individually tailored treatments. Many of these individuals have multiple co-morbid conditions that require unencumbered access to the full array of treatments. Individuals with complex care needs (e.g., mental health and multiple chronic diseases) require unique strategies to manage their health care.

There is ample evidence that innovative medicines such as biologics or plasma-derived therapies offer some therapeutic advantages over conventional medicines but usually cost more than older treatments because they are produced in lesser quantities and not yet available as lower cost versions. The newer medications can reduce the severity and frequency of disease activity and decelerate its progression, enabling patients to lead more productive lives. For example, older immunosuppressive therapies attacked a patient's entire immune system; causing detrimental side effects, while newer therapies

target a particular cell or biomarker making the treatment much more efficient and safer. Forcing patients to fail treatments first, exclusively based on cost, will discourage and stifle drug research and development especially for diseases of unmet need with limited therapies. Drug research and development needs to be encouraged and payer protocols must be regulated in order to keep pace with biomedical innovation.

It is imperative that the relationship between individual patient and provider remain intact so that only health care professionals familiar with a patient's personal medical history and uniqueness are making treatment decisions. The provider-patient relationship is undermined when these decisions are solely driven by cost. Limiting access to vital life-saving medications will disrupt continuity of care and result in driving up costs in the long run by increasing the number of unnecessary hospitalizations and emergency room visits. Patients also endure physical, emotional, and financial distress due to delays in proper treatment, disease instability, increased symptomology, intolerable side effects from inadequate medicine, and initial cost-sharing for ineffective treatment and medical visits.

Limited therapies exist for individuals with autoimmune conditions and other diseases of unmet need since few, if any, drugs have been developed specifically for these conditions. Health providers know best what treatments they intend to use to balance the various therapeutic and safety concerns in complex patients with limited treatment choices. The entire patient profile needs to be considered including: unique bio-chemical needs, individual compliance, side effect tolerability, and limited heterogeneity. There is no single medication that patients respond to—treatment is highly individualized and no two people are alike. Immunosuppressive drugs are not always equivalent nor interchangeable; what is tolerable for one individual may not be in the next.

We thank Assemblyman Titone and Senator Young for their efforts to ensure the health and safety of consumers by requiring that the standards used by an insurer to establish step therapy protocols cannot be driven exclusively by cost and are recognized evidence-based and peer-reviewed clinical review criteria that takes into account the needs of atypical patient populations and diagnoses. This bill improves the safety and efficiency of such protocols by establishing guidelines to guarantee health care providers have an expeditious process to override step therapy when it is not in the best interest of the patient to require failure on an alternative treatment with **A.2834-D / S.3419-C**.

This bill allows the prescribing provider, who is acutely aware of the individual patient's needs, to follow a standardized and expedited appeals process to override step therapy protocol when based on sound clinical evidence and in his/her professional medical judgment the preferred treatment by the insurer is not the most suitable therapy for the complex, atypical patient. The determination of appropriate medical treatment is best accomplished by open and transparent communication between the patient and the health care provider who is educated and ethically bound to treat them. It is imperative that we protect consumers and preserve providers' rights to make medical decisions in the best interest of their patients and ensure ethical responsibilities are being met.

For the above reasons, we the undersigned representatives of the listed organizations, strongly support this legislation and passionately urge you to sign it into law. Please contact Kathleen Arntsen at lupuskaa@aol.com or 315-264-9101 if you have any questions.

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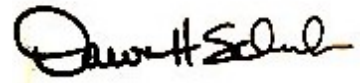
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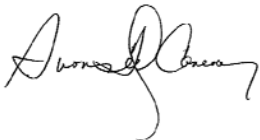
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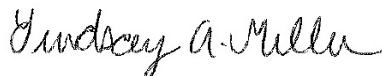
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