



# Why Neurologists and Their Patients Must Be Informed When Pharmacists Switch Biologics

BY DAVID CHARLES, MD, FAAN

Over the past several years, in response to campaigns by the AAN and state neurology societies, a growing number of states have passed laws prohibiting pharmacists from substituting one generic version of an antiepileptic drug (AED) for another without notifying the physician. The subtle but potentially critical differences among generic versions of the same AED support the case for making physician notification mandatory. With regard to this class of therapies, it is clearly in the patient's interests that pharmacies inform the patient's doctor when a substitution is made so that a blood level can be ordered if necessary.

This is the same principle at stake in a policy debate taking place in state legislatures over the substitution of biologic medicines or biologics. These new medications are fundamentally expanding our ability to treat neurologic conditions such as multiple sclerosis (with interferon beta-1a and natalizumab, for example) and movement disorders, as well as helping other specialty physicians treat conditions such as rheumatoid arthritis and some forms of cancer.

Unlike conventional drugs that are synthesized on a foundation of basic

chemical reactions, biologics are manufactured through highly complex steps beginning with or derived from cells or other living matter. The process of creating a biologic medicine is far more complex than copying a small molecule drug. It is so complex that processes can't be precisely duplicated from one manufacturer to another and variations in the process most often mean variations in the safety, efficacy, dosing, and side effects.

While this makes generic versions of biologics impossible, the Food and Drug Administration (FDA) is encouraging the development of biosimilars, also known as follow-on biologics. These are biologics created to duplicate the therapeutic benefits of brand name biologics as closely as possible after the patent expires on the brand name biologic.

Beginning in 2010, the FDA created a pathway for approval of biosimilars. It is a complex pathway that includes clinical testing, but the idea is to encourage the marketing of biosimilars as lower cost options to brand name biologics.

I have yet to meet a physician who was not in favor of making drugs more affordable for patients. Biosimilars might

do this for biologics just as generics have for conventional drugs. In both cases, though, this goal has to be met without jeopardizing the well-being of our patients. And with biologics and conventional drugs, patient safety requires that physicians be notified before a drug they have prescribed is replaced with a substitute. The stakes are even higher with biologics since there are no generic biologics.

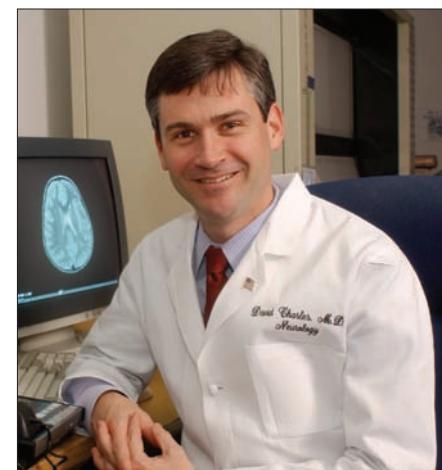
To realize the full potential of biologic medicines, the entire medical profession needs to get behind a public policy campaign to insist on notification of physicians when a substitution is made for any biologic. Furthermore, the privilege to order "dispense-as-written," when deemed necessary by the physician, must be maintained for biologics.

We need a clear national requirement that each biosimilar comes to market with a unique name, distinct from any other biosimilars and the name brand, even if the FDA deems them interchangeable. Allowing multiple biosimilars to have the same name would impair safety efforts in the event of product contamination or manufacturing defects.

These issues carry enormous significance for our patients. There is already an unfortunate example in recombinant erythropoietin of how minor changes in a biologic can have unexpected and devastating consequences. As was reported in 2004 in the *New England Journal of Medicine*, following a minor change in the manufacturing process, more than 150 patients suffered pure red cell aplasia leading to death in some cases. As more and more biologics come to market to help our patients with multiple sclerosis, neuromuscular diseases, and movement disorders, we must not allow policy makers to forget patient safety.

Lastly, clearly differentiated biosimilar names and physician notification on substitutions will expedite the rational use of biologics and help more people experience the benefits of these game-changing medicines.

I have seen those benefits first-hand in my own practice treating patients with movement disorders. Similarly, biologics have helped thousands of patients suffering from multiple sclerosis convert this disease into a manageable chronic



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condition instead of a relentless physical deterioration leading to early disability and death.

To see more results like that, we need to win the battle for physicians' and patients' right to know when it comes to biologics. •

*Dr. Charles, a neurologist practicing and conducting research in Nashville, has chaired both the Public Policy Committee of the American Neurological Association and the AAN Government Affairs Committee. He is also national chairman of the Alliance for Patient Access.*



## LETTERS TO THE EDITOR

### UnitedHealthcare: Why Clinicians Should Fight Back

Regarding "Medicare Advantage Loses its Advantage: UnitedHealthcare Responds by Dropping Providers," (Feb. 20; <http://bit.ly/1fuslwZ>), I have been thinking a lot about the battles we are all fighting with the insurance carriers over the cost of multiple sclerosis (MS) medications. We must collectively fight back.

UnitedHealthcare, for example, demonizes physicians when, in fact, they should be castigating the actuaries. What inexpensive treatments are there for MS? None. The insurers know that. I challenge UnitedHealthcare to outline to the community of neurologists an evidence-based strategy for inexpensive care of MS. In order to cover

for its own miscalculation of costs, the insurance industry blames the physicians as being the drivers of costs, justifying their position for firing doctors.

The battles today are frankly between the insurance carriers (public and private) and the pharmaceutical industry. The patients and the health care providers (formerly known as physicians) are caught in the crossfire.

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### LINK UP FOR MORE INFORMATION:

- Bennett CL, Luminari S, Nissenson AR, et al. Pure red-cell aplasia and epoetin therapy. *N Engl J Med* 2004;351:1403-1408.
- Reingold SC, Steiner JP, Polman CH, et al. The challenge of follow-on biologics for treatment of multiple sclerosis. *Neurology* 2009;773:552-559.
- Alliance for Patient Access: <http://allianceforpatientaccess.org>