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In the Case of Epilepsy, Generic Drugs and Random Product Substitution are Not Always “Good Medicine”

Nisola LLC Launches Campaign for Stricter Regulatory Approval Requirements and Continuity of Product Supply

New York (May 27, 2009) – A recent report released by Wolters Kluwer Health predicts that by the end of the year, nearly two-thirds of all drug prescriptions will be filled with generic drugs. This march to generics is fueled by several factors, which include the current economy, ever-increasing co-payment requirements for brand name drugs and pharmacies’ desire to increase their profits by filling prescriptions with high margin generics versus lower margin brand name medicines.

This reliance on generics is generally considered a positive shift in healthcare as the vast majority of patients see significant cost savings without any noticeable change in their treatment. However, in the case of many neurological disorders, especially epilepsy, switching from a brand to a generic or between generics can be extremely dangerous.

The primary problem with random product substitution is that the Food and Drug Administration (FDA) does not require generic drugs to definitively demonstrate therapeutic equivalence to their brand name counterparts (i.e., the same clinical efficacy and safety profile). In fact, for approval, the FDA only requires that the generic be bioequivalent (i.e., within a certain range of a brand name drug’s potency as measured by single-dose blood tests in healthy volunteers). Additionally, pharmacies, in their quest for profits, not only push patients to switch from brand name drugs to generics, but often switch from one generic manufacturer to another. Most alarmingly from an epilepsy patient’s perspective, this means that one can receive a different generic brand every time they refill their prescriptions. This is understandably a nightmare for a patient trying to regulate their medications to avoid both seizures and/or side effects.

“Generic drugs can vary between 80% and 125% of the potency of the original brand they’re modeled on,” explains Eric Liebler, CEO of Nisola LLC, a neurological advocacy and business strategy consulting firm. “While that may not be an issue for a person using generic Vicodin to occasionally treat an achy back, for a patient with life-long epilepsy, that 45% variance can mean the difference between a normal, seizure-free life and dealing with the risk of breakthrough seizures, brain damage and even death.”

Urging the healthcare community to strive for “Good Medicine,” Liebler, a longtime supporter of best practices in the treatment of neurological diseases, announced today that Nisola is calling for a coordinated awareness campaign to educate patients, healthcare professionals and policymakers about the risks involved when switching from branded Anti-Epileptic Drugs (AEDs) to generics. Furthermore, the campaign aims for strengthened regulations and practices, to ensure that patients receive consistently safe and effective AEDs throughout the course of their treatment.

Nisola’s “Good Medicine” campaign seeks:

1. Extensive & Appropriate Clinical Testing – The FDA should reconsider its generic approval protocol with regard to generic AEDs so that they are proven to be therapeutically equivalent, not just bioequivalent, to the innovator drug.

“For the treatment of many neurological diseases and epilepsy in particular, the FDA should make the generic manufacturers prove their products are safe and effective rather than placing the burden on doctors and patients to prove that they aren’t safe,” said Liebler.

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2. Prudence & Patience – Before approving any more generic AEDs, Liebler suggests that the FDA wait on a study currently being planned by the National Institute for Neurological Disorders and Stroke (NINDS), which will examine the issue of therapeutic equivalence versus bioequivalence as well as the potential dangers when switching from a brand name to a generic or being subject to the random substitution of one generic for another. The study is expected to begin shortly, and when it is completed it will enable the FDA to apply the most definitive data to its generic approval process for AEDs.

“The FDA has acknowledged that current studies gauging the therapeutic equivalence of many generic AEDs are inconclusive. These studies show that certain drugs are chemically similar to the original brand, but do not prove that they are effective. It is risky for the FDA to approve generic drugs without complete data, so it makes sense that they wait for conclusive information to become available. Given the pending NINDS research project, the good news is that they won’t have to wait long,” said Liebler.

3. Continuity – To make certain that epilepsy patients receive the economic benefits of generic pharmaceuticals, pharmacies, insurance companies and health service providers must work together to create a system – similar to that in Europe – whereby they guarantee that the patient will receive the same generic medication throughout the course of their treatment.

“We can save the patient money and protect their health by always providing them with the same generic medication, month after month,” said Liebler.

Nisola’s “Good Medicine” campaign, though in support of stricter regulations, is not against the development of generic AEDs. Nisola supports drugs that are affordable and, more importantly, safe for everyone. However, Liebler notes, “Until we can be certain that generic medications are proven *as safe and effective* as the originator brand, or that pharmacies can ensure the drug’s continuity, patients should stick to the drug in which they have confidence. No cost is too great when it comes to your health.”

Nisola’s “Good Medicine” campaign goals to improve the testing protocols used to approve generic AEDs and to eliminate the random switching of generics are shared by the Epilepsy Foundation, American Epilepsy Society and the American Academy of Neurology (AAN). The Epilepsy Foundation, which just recently launched its own campaign to raise awareness of these issues, has more than 1,000 stories to share about the needless suffering of people with epilepsy due to current testing and regulatory policies. Says Liebler: “If we don’t improve this situation immediately there could, unfortunately, be thousands more stories to tell.”

Recently honored at AAN’s annual meeting with the AAN Foundation’s prestigious Chair’s Award, Liebler has positioned himself and Nisola as advocates for “Good Medicine” in the field of neurology. His 20-plus years of experience in the neurological community have provided him with exceptional insight on the important needs of the professionals and consumers who are concerned with the health and safety of epilepsy patients.

Epilepsy is a chronic neurological disorder affecting nearly three million Americans. Each year, approximately 200,000 people in the U.S. are diagnosed with epilepsy. Although initial onset can occur at any age, epilepsy most commonly arises in either early childhood or old age.

Nisola LLC (www.nisola.com) is an advocacy and business strategy consulting firm that is focused on serving clients interested or involved in the field of neurology. The company’s core area of strength is its experience and understanding of the interplay between science, clinical medicine, product development and commercialization. Nisola works closely with clients to accelerate and enhance their ability to understand and interact with the relevant medical and patient constituencies. For more information on epilepsy or how you can help the campaign for “Good Medicine,” please contact Nisola at (908) 437-1320 or by email at lieblier@nisola.com.

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