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Editorial

A Patient's Voice

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Having read the related article[1] and editorial[2] in this issue of *The Journal of Pediatric Pharmacology and Therapeutics* I felt there was one perspective

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missing in this controversy – the perspective of the patient. In the spring of 1980 I was diagnosed with epilepsy. Over the years I have been prescribed six anticonvulsants. Today, my seizures are controlled on a brand formulation. If I were newly diagnosed with epilepsy I would have no problem beginning with a generic formulation. Likewise, if I were to have a seizure today, I would have no problem transitioning to a generic product, provided I received the same brand of generic each month. But I have not had a seizure and am controlled on a brand anticonvulasnt. For this reason, I feel that I represent one of the groups with a stake in the brand-to-generic anticonvulsant substitution controversy – I am the stable, controlled patient who adheres to her anticonvulsant regimen.

For many stakeholders the debate is as simple as the cost of a brand formulation. I appreciate the cost incurred by both the patient and payers and am fortunate to have insurance. However, one cannot discount the direct and indirect financial costs to all stakeholders should a seizure occur. Although brand formulations are more expensive to the healthcare system, the literature suggest that brand-to-generic substitution of anticonvulsants does not automatically reduce overall healthcare costs and may even increase costs during periods of generic anticonvulsant use.[3-6] Studies have found an increase in physician visits and hospitalizations during a period of transition. This increase in cost has been consistently reported across studies in different countries (i.e., Canada and the US) and in individuals with both stable and unstable epilepsy.

The issues for a stable patient extend beyond the cost of the anticonvulsant. For many diseases, a change in efficacy may or may not affect one's quality of life, but a seizure for those whose epilepsy is controlled may significantly impact quality of life. For me, the issue is reduced to the consequences that accompany a "loss" of control following a single seizure.

Epilepsy is a unique disorder. There are few other diseases where a loss of control can result in an increase in morbidity and mortality to not only the patient, but to someone else as well. Although the likelihood is small, I am not willing to knowingly assume the risk of harming another person due to a seizure that occurs during transition to a generic product. Even if I were willing to assume the personal risk of a seizure, who would bear the legal consequences if injury or death occurs during a time of switching from a brand to generic or from generic to generic?

There are other consequences associated with a loss of seizure control. The loss of control may present as status epilepticus. For those whose are stable, the recurrence of a seizure and initiation of the same anticonvulsant regimen does not guarantee that adequate control will return. Fi-

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nally, few other diseases are associated with legal restrictions that are linked to control of disease. For example, driving privileges may be lost for 6-12 months if a seizure occurs and depending on the state where one resides there may be no opportunity for appeal to a medical board. Unless you have lost driving privileges and have been dependent upon the generosity of others, I am not sure you can understand the impact this can have ones quality of life. If there were an appeal to reinstate driving privileges following a seizure that occurred during transition to a generic formulation, I would be more willing to consider a change in formulation as a "tolerable" risk. Without that caveat, it will forever be an unacceptable risk to me.

As a pharmacist, I understand evidence-based medicine and the issues surrounding this particular controversy, but as a patient the possibility of the above consequences makes any variable that increases the risk of a seizure and loss of control unacceptable.

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