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Pfizer makes a statement regarding Dilantin

The Foundation has received reports on breakthrough seizures from the changes Pfizer made on the manufacturing of Dilantin. Below is a statement from Pfizer regarding this issue.

"Last fall, Pfizer sent a letter to health care professionals informing them that the FDA had approved manufacturing changes for Dilantin® (phenytoin sodium). Because Dilantin® has been continuously produced since 1938, some aspects of its manufacture did not reflect the latest technological advances. The FDA requested that Pfizer update its manufacturing processes and make procedures consistent, and Pfizer agreed with that request.

"As a result of this updated manufacturing method, Pfizer discontinued manufacturing Dilantin® Kapseals® (extended phenytoin sodium, USP) 100 mg capsules and began manufacturing and distributing Dilantin® 100 mg Extended Oral Capsules. It's important to note that Dilantin® Capsules contain the same active (100 mg extended phenytoin sodium) and inactive ingredients (lactose monohydrate, NF;

confectioner's sugar, NF; talc, USP; and magnesium stearate, NF) as Dilantin® Kapseals®.

"Pfizer conducted two bioequivalence studies comparing the rate and extent of absorption of Dilantin® Kapseals® and Dilantin® Capsules. Bioequivalence is recognized by the FDA and is considered worldwide to be a valid substitute for therapeutic equivalence. The bioequivalence studies conducted by Pfizer showed that the Dilantin® Capsules met FDA standards for bioequivalence to the Dilantin® Kapseals®, and FDA granted Pfizer the authorization to market Dilantin® Capsules.

"While the products are 'pharmaceutical equivalents,' phenytoin sodium is a drug product that has a narrow therapeutic index (NTI). Due to the NTI, therapeutic drug monitoring is essential for any patient during treatment with phenytoin sodium. For

this reason, patients transitioning to Dilantin® Capsules should continue to have therapeutic drug monitoring. This monitoring should be done according to the judgment of the physician. Patients taking phenytoin should be advised to inform their physician of any change in seizure control, any new clinical condition or any new medication.

"Dilantin is an important medicine that helps patients with a serious medical condition. Pfizer is committed to ensuring the availability of a product that is safe and efficacious for patients and that complies with FDA's current Good Manufacturing Practices standards."

For more information, please visit: http://www.pfizer.com/products/rx/rx_product_dilantin.jsp or ask your physician.

Expressions of Courage® Art Contest is underway!

The Expressions of Courage®, for the 6th consecutive year, is a great opportunity for those with epilepsy to highlight and show off their creative talents. Also, although the Epilepsy Foundation did not receive funding from Ortho-McNeil Neurologics, Inc., another purpose of this contest is to help eliminate the stigma of epilepsy by raising awareness. The success of this program in the past was due to your work to spread the word and we'd like to request your efforts again this year! Forms can be downloaded off of www.expressionsofcourage.com or by calling one of our offices. Good Luck!



Expressions
of Courage®
ART BY PEOPLE
WITH EPILEPSY

EFA's No More Seizures Campaign Offers Hope and Support

Efnj is proud to announce Epilepsy Foundation's launch of the No More Seizures campaign. Certainly, not everyone will achieve the goal of no more seizures or side effects, but far too many could if we could reach them with basic education and empowerment messages. This is what the No More Seizures campaign is all about. Through our affiliates, website, and toll-free information line, people with epilepsy can get up to date information on epilepsy and treatment options.

The campaign has two primary elements: the *Treating Epilepsy and Seizures—What Can YOU Do?* and the website, NoMoreSeizures.org. The brochures have been sent to all member of the American Academy of Neurology to put in their waiting rooms. It is not intended for those actively seeking information, but rather to raise questions to motivate those with epilepsy and their caregivers to become more aware and empowered. The website, NoMoreSeizures.org, provides basic information, but also ties into the national website to encourage viewers to seek more and more information in greater depths. Visit NoMoreSeizures.org for more information and to find out what YOU can do.

Final Epilepsy Session Held in Vineland



From left to right, Dr. Mark Mintz, Micah Brown

The final of a series of three statewide Epilepsy Sessions was held on June 18th in Vineland, New Jersey. Micah Brown, EEG Technology Specialist and Dr. Mark Mintz, President and CEO of The Center for Neurological and Neurodevelopmental Health in Voorhees presented. Dr. Mintz talked about the latest in Epilepsy clinical research, and Mr. Brown addressed using new technology for Epilepsy diagnosis and treatment.

Appreciative attendees were able to discuss questions and concerns with the expert presenters in an intimate setting, grateful for the information they were able to take away. We hope to be able to do more events in the South Jersey area in the near future.

Valeant's Mysoline® (primidone) 250 mg Tablet Design Changes

Due to manufacturing changes, Mysoline 250 mg tablets are changing in appearance. Other dosages of Mysoline (such as the 50 mg tablets) have not changed. The new version of Mysoline is FDA-approved and bio-equivalent to the older version of Mysoline. It still has the same amount of the active ingredient primidone as the previous version, although its inactive ingredients vary from the current tablet. Because the tablet is essentially the same medicine as before, your insurance coverage should not change.

If patients have any questions regarding this change, they should speak with their pharmacist and/or health care provider. Above all, people with epilepsy and/or seizure disorders should not change their medication or stop taking it without consulting their health care providers.

Veterans Affairs Epilepsy Centers of Excellence Act Passed

On June 24, the House unanimously passed the VA Epilepsy Centers of Excellence Act (H.R. 2818). The bill, championed by Rep. Ed Perlmutter (D-CO), was designed to address critical issues facing veterans who have experienced traumatic brain injuries that often develop into epilepsy. The House bill was amended in committee to establish five epilepsy treatment centers co-located at the VA Polytrauma Centers in Palo Alto, CA, Minneapolis, MN, San Antonio, TX, Richmond, VA and Tampa, FL, to lead the way in epilepsy diagnosis, research, treatment and surgery.

The House bill differs from the Senate bill which calls for six competitively bid centers that would not be co-located with polytrauma centers. Hill staff and advocates for the bill are meeting this week to discuss strategy for the best final outcome. A date for a conference committee to convene to discuss the differences between the bills has not yet been set.

American With Disabilities Act Amendment Act Passed!

The *ADA Amendments Act of 2008* sailed through the House on Wednesday June 25 passing by a vote of 402-17 (234 Democrats and 199 Republicans). The bill, carefully negotiated by the disability and business communities, overturns several Supreme Court decisions issued in the last decade thus restoring the bill to its original congressional intent. The overwhelming majority vote in the House was even stronger than the vote to pass the original ADA in 1990 and sends a strong message that

discrimination against people with disabilities including epilepsy, diabetes, cognitive disabilities and many other conditions will not be tolerated. Attention now shifts immediately to the Senate where it is expected that the bill as passed by the House (H.R. 3195) will be introduced after the July 4th recess. Now is the time to ask your Senators support the *ADA Amendments Act of 2008*, we encourage all affiliates and their advocates to contact their Senators via the Speak Up Speak Out network: [http://capwiz.com/efa/issues/alert/?](http://capwiz.com/efa/issues/alert/?alertid=11549051)

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Everyone is also encouraged to contact their Representative to thank them for their vote, or to encourage them to support the legislation if it would come back to the House for conference. You can send a message that will automatically determine if your Member of Congress supported H.R. 3195 at: <http://capwiz.com/efa/issues/alert/?alertid=11549306>