**Tuberous Sclerosis Alliance**

**Government Relations Committee Meeting Minutes**

**December 21, 2017**

**DRAFT**

**In Attendance:**

**Committee Members (Voting):** Debora Moritz (Chair), Sara Chieffo

**Committee Members (Non-Voting):** Julie Blum, Will Cooper, Sr., Ted Mastroianni, John Richards

**Staff:** April Cooper, Jaye Isham, Kari Rosbeck, Katie Smith

**Guest:** Mark Vieth

Debora Moritz called the meeting to order at 4:04 pm.

**Approval of the Minutes from October 12, 2017**

A quorum of voting members was not present. Therefore, notes will be reviewed at a future meeting.

**Status of FY18 Appropriations**

The Republicans have been focused on their recently passed tax plan and FY18 appropriations are not yet done. There is a Continuing Resolution (CR) until Friday, December 22 at midnight. Congress is likely to pass the next CR to avoid a government shutdown before they leave for the holidays.

Right after this call, the House approved a clean CR (that does not include the full Defense Appropriations Act) and sent to the Senate, which is expected to clear it before a government shutdown. The CR funds government operations at existing FY17 levels through January 19.

**Planning for FY19**

*Dear Colleague Letter Sponsors*

All of our FY18 Dear Colleague Letter Sponsors are still in office next year and friendly to our cause. Mark Vieth will circle back with all the offices about FY19 in January. Representative Ileana Ros-Lehtinen (R-FL) will be retiring from Congress after next year and we will need to identify future Republican House and Senate Sponsors.

*March on Capitol Hill Messaging and Authorization Act Language*

The Armed Services subcommittees should be targeted during the March on Capitol Hill. The Defense Health Research Consortium (DHRC) has some talking points on authorization language. We should continue to keep military relevance as part of the ask. We can also include testimony from TSCRP funded researchers.

**Patient Assistance Program (PAP)**

*Overview*

The TS Alliance emailed and put a statement on social media (see below) about changes that have been made to Patient Assistance Programs (PAP) and co-pays.

Recently, we were made aware that there would be stricter enforcement of the anti- kickback statute between industry and patient assistance charities. This article provides an overview of the changes and enforcement – <https://www.bna.com/hhs-yanks-compliance-n73014472593/> . The article refers to a Nov. 28 action by the Department of Health and Human Services Office of Inspector General that affects the Caring Voice Coalition (CVC), a charity that subsidizes medical costs for Medicare beneficiaries and other patients. Specifically, the OIG rescinded an advisory opinion that had protected CVC from any federal anti-kickback law enforcement.

Due to the stricter enforcement, industry has started stepping back from charity run co-pay programs. Some pharmaceutical companies also have PAPs. Lundbeck is also making changes their SHARE PLUS patient assistance program and their ability to offer co-pay assistance and UCB is will no longer be accepting new applicants into their patient assistance program for Keppra and Keppra XR.

At the same time, Lundbeck’s Sabril exclusivity ended last April and generic forms of vigabatrin are being made available. Currently Par Pharmaceutical makes a generic sachet, Teva is expected to release a generic vigabatrin in both sachet and pill form soon, Upsher-Smith and at least one other company are also developing generics.

*California Law*

California recently passed a new law impacting co-pay programs that will take effect on January 1, 2018. The new law prohibits drug manufacturers from offering discounts on patients’ out-of-pocket expenses for prescription drugs when a lower cost generic drug is available that the Food and Drug Administration approves as having the same treatment response as the brand name drug and that drug is covered under the individual’s health insurance on a lower cost-sharing tier.

Under this law, no discounts, repayment, product vouchers or any reductions in out-of-pocket costs may be given by the manufacturers. The exception is “independent charity patience assistance programs” provided by outside foundations to help with patient costs and/or free product provided by manufacturer. For more information, we are providing a link to a very helpful article provided by *Hogan and Lovells:* <https://www.lexology.com/library/detail.aspx?g=5bad7782-3316-4a19-8b56-c94b5d0ede99>.

Massachusetts has passed a similar law and other states may follow suit. This is of particular concern to those who have been on Sabril or achieved seizure control on brand name antiepileptics that now have a generic version available.

The Department of Justice and the Internal Revenue Service and several states’ District Attorneys are looking into these compliance issues.

The TS Alliance is working to compile a list of resources and participating independent charity patient assistance programs that may be helpful to families.

*Next Steps*

Document what is happening and the impact on our constituents. Find out what they have experienced and when it happened. This documentation can be taken to a future meeting with the House and Senate Labor HHS and Energy and Commerce committees. We need to be mindful about advocating for the need for accessible treatment without endorsing specific companies.

The Committee recommended reaching out to other epilepsy organization including CURE, the Epilepsy Foundation and Infantile Spasms Awareness Network (ISAN) to build a coalition around this issue. The Epilepsy Foundation has information on their website- <http://advocacy.epilepsy.com/medication-access>.

**Other Items**

Kari Rosbeck formally thanked Debora Moritz for her tremendous contributions as Government Relations Committee Chair.

The meeting adjourned at 4:57 pm.

Respectfully submitted,

Katie Smith, Manager, Research and Global Affairs

**IMPORTANT MESSAGE ABOUT PATIENT ASSISTANCE AND**

**PATIENT CO-PAY ASSISTANCE PROGRAMS**

**FOR USERS OF SABRIL**

**Changes already in effect**

The Tuberous Sclerosis Alliance (TS Alliance) has been contacted by several constituents experiencing challenges with changes in patient assistance programs for Sabril. We also know there have been additional challenges in filling prescriptions now that new generic Vigabatrin products are coming to market. Therefore, we want to provide information and some tips in dealing with these challenges.

**Changes to Sabril Patient Assistance Programs:**

1. For any questions regarding changes to the Sabril Patient Assistance or Co-Pay programs, please contact SHARE PLUS. They may also be able to provide a list of additional resources of independent charity patient assistance programs to assist you with covering out-of-pocket costs. Please be aware SHARE PLUS hours will be 8 a.m. to 8 p.m. ET Monday to Friday only. There will be no weekend hours moving forward. The support center can be reached at 888-457-4273.
2. There are hospitals stocked with Sabril in case of a weekend emergency. Those can be found at <https://www.vigabatrinrems.com/#Pharmacy/Lookup>.
3. If you encounter any challenges in seeking information, please let us know immediately by contacting TS Alliance Vice President of Support Services, Dena Hook, at dhook@tsalliance.org or 301-562-9890 x 215.

**Tips for Navigating this Changing Environment:**

1. When you receive a call from your specialty pharmacy for refill, be sure to ask if it will be filled with brand or generic.
2. If you wish to remain on brand, you may need to contact your physician to request a new prescription. This also may depend on your insurance carrier. You will want your physician to be sure to write “dispense as written” if you wish to remain on brand and qualify for coverage, although this is no guarantee.
3. Be sure to confirm your prescription is being shipped timely. This may require you to place an additional call to the specialty pharmacy (even if you have been told it’s shipping on a particular day) with enough time so you do not miss a dose.
4. If you have any issues with timely delivery of drug after speaking with your specialty pharmacy, please contact TS Alliance Vice President of Support Services, Dena Hook, at dhook@tsalliance.org or 301-562-9890 x 215.

You may wonder why all of these changes are taking place. There are stricter enforcements within the definitions of charitable patient assistance programs under the anti-kickback statute. The regulatory and legal environment is shifting, and many companies are taking a more conservative approach. With the introduction of multiple new generics for Vigabatrin over the next year, patient assistance programs are changing and will be different from company to company. And wherever government funding is involved, such as Medicaid, regulations have an impact on what manufacturers are able to do. The TS Alliance is most concerned with ensuring access to critical medications, and we will continue to work to compile additional resources we can share with you in the future.

**FOR USERS OF KEPPRA AND KEPPRA XR**

**Changes in effect as of January 1, 2018**

The TS Alliance has been informed about a change to the UCB Patient Assistance Program. Beginning January 1, 2018, KEPPRA and KEPPRA XR will no longer be available to ***new applicants*** to the UCB Patient Assistance Program. UCB sent a letter stating, “We are committed to ensuring continuity of care for all patients. ***This change will affect only new*** applicants for KEPPRA and/or KEPPRA XR. No other medication in the program will be affected.”

Any patients currently approved and enrolled in the Patient Assistance Program for KEPPRA and KEPPRA XR will continue to receive medication, if they remain qualified and have a valid prescription.

If you have further questions, please contact the UCB Patient Assistance Program customer service department at (877) 785-8906. Representatives are available between 8 am and 5 pm CT Monday through Friday (excluding holidays).

**FOR CALIFORNIA RESIDENTS**

**New California law goes into effect on January 1, 2018**

The TS Alliance has recently become aware of a new California law (AB-265) that will go into effect on January 1. The law will impact co-pay assistance programs and will likely require families on such assistance to pay greater out-of-pocket expenses. We wanted to share this information with you immediately.

The new law prohibits drug manufacturers from offering discounts on patients’ out-of-pocket expenses for prescription drugs when a lower cost generic drug is available that the Food and Drug Administration approves as having the same treatment response as the brand name drug and that drug is covered under the individual’s health insurance on a lower cost-sharing tier.

Under this law, no discounts, repayment, product vouchers or any reductions in out-of-pocket costs may be given by the manufacturers. The exception is “independent charity patience assistance programs” provided by outside foundations to help with patient costs and/or free product provided by manufacturer. For more information, we are providing a link to a very helpful article provided by *Hogan and Lovells:* <https://www.lexology.com/library/detail.aspx?g=5bad7782-3316-4a19-8b56-c94b5d0ede99>.

**NEXT STEPS**

The TS Alliance is in the process of gathering a list of resources and participating independent charity patient assistance programs that may be helpful to families. We are also discussing next steps with our Government Relations Committee in trying to address these difficult changes in a meaningful way.