



EMPOWERING THE RARE DISEASE COMMUNITY

A PROGRAM OF THE EVERYLIFE FOUNDATION FOR RARE DISEASES

RDLA June 2019 Newsletter

Capitol Hill Updates

Drug Pricing: The House and Senate continue to work to address the growing costs of prescription drugs. On May 23rd, the House passed a package of bills with the goal of lowering drug prices. The bills passed included a ban on “pay-for-delay” deals, a practice where drug manufacturers pay generic drug manufacturers to delay bringing a generic drug to market. Another bill would loosen the rules on the six-month exclusivity sales period that a generic drug manufacturer receives when they are the first company to market a drug after the name brand manufacturer loses its patent protections.

The Senate is working on its own package of health-related bills. The Senate Health, Education, Labor and Pensions Committee plans to mark up their own legislation this summer.

Human Gene Patent Eligibility: In May 2019, Senators Thom Tillis (R-NC) and Chris Coons (D-DE) and Representatives Hank Johnson (D-GA), Steve Stivers (R-OH), and Doug Collins (R-GA) released a draft bill that would rewrite Section 101 of the Patent Act. Section 101 of the Patent Act permits issuing patents on new and useful processes, machines, manufacture, or compositions of matter or any new and useful improvement.

The Supreme Court has held that laws of nature, natural phenomena, and abstract ideas are not patent-eligible under the Patent Act. Most recently in *Mayo Collaborative Services v. Prometheus Laboratories* and *Association for Molecular Pathology v. Myriad Genetics*, the Supreme Court unanimously upheld in separate decisions that a naturally occurring relationship in the blood and then human genes isolated from the body are not patent-eligible. In *Myriad*, the Supreme Court found that patents on human genes isolated from the body would lock up genetic information and prevent scientific and medical work.

The draft legislation rewrites Section 101 of the Patent Act and specifically states that any judicially created exception to patent-eligibility will be abrogated, thereby overturning the decisions of *Myriad* and *Mayo*. This legislation if enacted in its current form would authorize patenting products and laws of nature and abstract ideas, including human genes.

Patient organizations are concerned that making human genes patent-eligible will increase prices for genetic tests and harm innovation and research including preventing discoveries of treatments for countless diseases.

Medical Nutrition Equity Act: Representatives Jim McGovern (D-MA) and Jaime Herrera Beutler (R-WA) reintroduced the Medical Nutrition Equity Act, H.R. 2501, on May 2, 2019. Representatives Brian Fitzpatrick (R-PA) and Joe Kennedy (D-MA) joined as original co-sponsors. The Medical Nutrition Equity Act would provide coverage of medically necessary foods and vitamins for digestive and inherited metabolic disorders under federal health programs and private health insurance.

Autism Collaboration, Accountability, Research, Education, and Support Act: Senators Menendez (NJ) and Enzi (WY) and Representatives Smith (NJ) and Doyle (PA) introduced the Autism CARES Act, S. 427/H.R. 1058, earlier this Congress. The Autism CARES Act would continue the Interagency Autism Coordinating Committee (IACC) which coordinates federal efforts and provides advice to the Secretary of Health and Human Services. The bill also calls for the preparation of a report on the health and well-being of individuals with autism.

Rare Disease Congressional Caucus Update: We are pleased new Members continue to join the Rare Disease Congressional Caucus bringing the total membership of the caucus to 119 Representatives and 18 Senators. The list of members of the caucus can be found at rareadvocates.org/rarecaucus. You can ask your Members of Congress to join the Rare Disease Congressional Caucus [here](#).

Community Action Alerts & Policy Resources

EveryLife Foundation for Rare Diseases: The EveryLife Foundation for Rare Diseases is asking advocates to contact their Members of Congress in support of the Newborn Screening Saves Lives Reauthorization Act. To contact your Representatives to cosponsor H.R. 2507, click [here](#).

National PKU Alliance: The National PKU Alliance is asking advocates to contact their Members of Congress in support of the Medical Nutrition Equity Act, H.R. 2105. H.R. 2105 would provide coverage of medically necessary foods and vitamins for digestive and inherited metabolic disorders under federal health programs and private health insurance. To contact your Representatives to cosponsor H.R. 2105, click [here](#).

Children's Cause for Cancer Advocacy: The Children's Cause for Cancer Advocacy is asking advocates to ask their lawmakers to support the CLINICAL TREATMENT Act, H.R. 913. The CLINICAL TREATMENT Act would require Medicaid to cover routine costs associated with enrollment in approved clinical trials for those with life threatening conditions. To contact your Members of Congress on H.R. 913, click [here](#).

Lymphedema Advocacy Group: The Lymphedema Advocacy Group is asking advocates to contact the Members of Congress to ask Members to cosponsor the Lymphedema Treatment Act

to ensure that patients have access to their doctor prescribed medical compression supplies. To contact your Members of Congress to cosponsor S. 518/H.R. 1948, click [here](#).

Community Events

Below are upcoming policy and advocacy events of interest to the rare disease community. To view more policy and advocacy events for this year and beyond, please visit the [RDLA events calendar](#).

Rare Across America: Rare Disease Legislative Advocates is excited to announce that registration is now open for Rare Across America. Advocates interested in participating should register before July 3rd at www.RareAcrossAmerica.org.

Under the Rare Across America program, RDLA staff organizes meetings for rare disease advocates with their Members of Congress and/or the Member's staff. The meetings take place in the Member's district offices during the month of August, while Congress is in recess from July 29th to September 8th, 2019. The RDLA team prepares advocates for their meetings, provides legislative resource materials, and hosts pre-meeting training webinars. No prior advocacy experience is necessary. The first training webinar for registered advocates, entitled "What to Expect at Your Meetings," will be hosted on July 25th.

RDLA Monthly Webinar and In-Person Meeting, June 13, 2019: The next RDLA Monthly Webinar and In-Person Meeting will take place on Thursday, June 13th. The RDLA Monthly Meetings are an opportunity to educate patient advocates about pressing health policy topics so that they can be successful legislative advocates. The meetings are attended either through a Webinar or in person in Washington, DC. Advocates, staffers, and industry are welcome to join. Register to join on the [RDLA website](#). If you would like to present at the meeting about a current policy issue, please email Shannon von Felden at svonfelden@everylifefoundation.org.

RARE on the Road, a Rare Disease Leadership Tour: The EveryLife Foundation and Global Genes invites rare disease patients, caregivers, and other advocates to attend the RARE on the Road, a Rare Disease Leadership Tour to learn more about rare disease policy, connect with other rare disease advocates, and learn how to tell your story. The last RARE on the Road workshop will be held in Sioux Falls, SD on July 13th. Find out more and register at www.raretour.org.

RareVoice Awards: Please save the date for the RareVoice Awards on December 4, 2019. The RareVoice Awards is an event to educate Congress on rare disease issues and celebrate advocates who give rare disease patients a voice on Capitol Hill.

Stay Connected

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***This E-Blast shares action alerts, legislative, and policy news and events from the patient advocacy community. RDLA does not take positions on the issues herein but serves as a supportive clearinghouse for the rare disease community. Send us an email if you'd like your alerts and/or events included! Email svonfelden@everylifefoundation.org.