

**Congress of the United States**  
**House of Representatives**  
Washington, DC 20515

March 19, 2018

The Honorable Tom Cole  
Chairman  
Labor-HHS-Education and Related Agencies  
Subcommittee on Appropriations  
2358-B Rayburn House Office Building  
Washington, D.C. 20515

The Honorable Rosa DeLauro  
Ranking Member  
Labor-HHS-Education and Related Agencies  
Subcommittee on Appropriations  
1016 Longworth House Office Building  
Washington, D.C. 20515

Dear Chairman Cole and Ranking Member DeLauro:

As you consider the Fiscal Year 2019 Labor, Health and Human Services, Education and Related Agencies Appropriations bill, we respectfully request that you consider the addition of report language that reflects the importance of access to safe and efficacious off-label medications for children with autoimmune diseases such as inflammatory bowel disease (IBD) by encouraging the development of a pediatric IBD safety registry.

An estimated 1.6 million Americans are living with IBD (Crohn's disease and ulcerative colitis), with nearly one in four patients diagnosed under 20 years of age. The vast majority (an estimated 80 percent) of medications prescribed by physicians to treat children with IBD are not approved by the Food and Drug Administration (FDA) for the indication at the time they are given, meaning they are not approved by the FDA for use in children. Medications used to treat IBD are first approved in adults, and approval for children may come many years later, if at all. During this time, these highly effective medications are prescribed "off-label" to children without any mechanism to monitor safety.

In addition to monitoring the safety of these medications, there is a desperate need to expedite approval of pediatric indications for FDA-approved drugs for the treatment of IBD. The greatest obstacle to getting drugs approved for pediatric indications is the lack of transparent information sharing. A public-private safety registry would capture data on off-label use of FDA-approved medications for the treatment of IBD in children. The FDA could use this data to expedite the approval process for drugs to treat IBD in the pediatric population and to do so with the confidence that the drugs are safe. Currently, due in part to the lack of data sharing, it takes an average of 10 years for the FDA to approve pediatric indications for drugs previously approved for use in adults.

Proprietary, single-product registries exist for IBD treatments, but information collected by these registries may not be made public and lack uniformity of data collection. A single national safety registry will, among other things, allow for the identification of potentially dangerous drug-to-drug interactions. For example, two medications approved for treatment of Crohn's disease in adults has been found to

cause a rare but fatal lymphoma in boys who received the medication in combination with another Crohn's treatment. A national safety registry might have identified this problem much earlier.

Through a federally-led initiative, private IBD registries would share data points with the public IBD registry which could connect to an existing registry for pediatric rheumatology (CARRA – Childhood Arthritis and Rheumatoid Research Alliance). Connection to the CARRA registry would benefit both pediatric IBD and rheumatology patients because these auto immune diseases are often treated with the same medications. CARRA was started with a \$7.5 million grant in 2009 as a result of funding through the American Recovery and Reinvestment Act. Building on this federally-funded registry would encourage data sharing, extend the government's return on investment, and allow federal regulators and researchers to access data without having to rely on propriety registries.

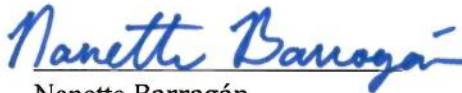
For the above stated reasons, we respectfully ask for the inclusion of the following language in the report to accompany the FY 2019 Labor, Health and Human Services, Education and Related Agencies Appropriations bill:

***Pediatric IBD Safety Registry*** – The vast majority (an estimated 80 percent) of medications prescribed by physicians to treat children with inflammatory bowel disease (IBD) are prescribed “off-label” without any mechanism to monitor safety. The Committee recognizes a need for a national pediatric IBD population-based database to capture information on evidence-based health outcomes related to specific therapies and interventions, including concomitant medications and adverse events, and to make data accessible to physicians, patients, industry, researchers, and federal agencies. The Secretary, acting through the National Institutes of Health, and in consultation with the Food and Drug Administration, is encouraged to enter into cooperative agreements with public or private entities for the collection, analysis, and reporting of data on pediatric IBD.

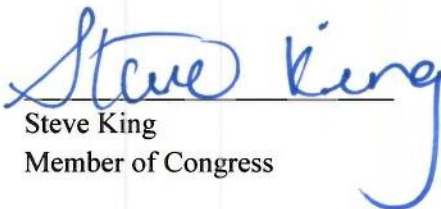
Sincerely,



Dave Trott  
Member of Congress



Nanette Barragán  
Member of Congress



Steve King  
Member of Congress



John K. Delaney  
Member of Congress



Jeff Denham  
Member of Congress



Debbie Dingell  
Member of Congress



Leonard Lance  
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