COMMITTEE ON
ENERGY & COMMERCE
CHAIRMAN FRANK PALLONE, JR.

MEMORANDUM

July 24, 2020

To: Subcommittee on Health Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Hearing on "Improving Access to Care: Legislation to Reauthorize Key Public Health Programs"

On **Wednesday, July 29, 2020 at 10 a.m. (EDT), via Cisco Webex online video conferencing,** the Subcommittee on Health will hold a legislative hearing entitled, "Improving Access to Care: Legislation to Reauthorize Key Public Health Programs."

I. H.R. 2075, THE SCHOOL-BASED HEALTH CENTERS REAUTHORIZATION ACT OF 2019

A. Background

School-based health centers (SBHCs) serve as the primary point of care for many students and their families, providing an array of essential health services. While service models vary by site, many SBHCs provide mental and behavioral health services, dental health services, health education and promotion, case management, and nutrition education.[1] SBHCs often operate as partnerships between schools and a community health organization ((i.e., a community health center (CHC), a hospital, or a local health department)).[2] Nearly 2,000 SBHCs currently operate nationwide,[3] and are funded by a combination of patient revenue from billed services, government grants (state, local, and federal), partner contributions, and private sector grants.[4] The program's statutory authorization expired in 2014.[5] While SBHCs are eligible to apply for grants through the Health Resources and Services Administration (HRSA)

[1] Health Resources and Services Administration, School-Based Health Centers (www.hrsa.gov/our-stories/school-health-centers/index.html) (accessed July 21, 2020).

[2] *Id.*

[3] *Id.*

[4] School-Based Health Alliance: Redefining Health for Kids and Teens, Who Pays for SBHCs? (www.sbh4all.org/school-health-care/school-based-health-care-financing/) (accessed July 21, 2020).

[5] *Id.*

and CHC funding, they have not received any direct appropriations since the Affordable Care Act (ACA) in 2010.

B. Legislation

H.R. 2075, the "School-Based Health Centers Reauthorization Act of 2019," introduced by Reps. Sarbanes (D-MD), Tonko (D-NY), Stefanik (R-NY), and Upton (R-MI), would reauthorize funding for the program through Fiscal Year (FY) 2024, and make technical changes, including allowing more health centers serving medically underserved children and adolescents to qualify for funding.

II. H.R. 4078, THE EARLY ACT REAUTHORIZATION OF 2019

A. Background

In 2009, Congress passed the "Young Women's Breast Health Education and Awareness Requires Learning Young Act of 2009."[6] This legislation created an outreach and education campaign through the Centers for Disease Control and Prevention (CDC) that highlights breast cancer risks for young people and those at increased risk of developing the disease. The funds authorized through this bill support CDC's work in identifying breast cancer risk knowledge gaps among young women and education gaps among health care providers. It also supports young survivors through grants to organizations focused on helping those coping with breast cancer-related challenges. The program's statutory authorization expired in 2019. However, it has continued to receive annual appropriations.

B. Legislation

H.R. 4078, the "EARLY Act Reauthorization of 2019," introduced by Reps. Wasserman Schultz (D-FL) and Brooks (R-IN), reauthorizes the "Young Women's Breast Health Education and Awareness Requires Learning Young Act of 2009." This program was authorized and funded at $4.9 million each year from FY 2015 through FY 2019. The bill would increase the authorization to $9 million each year from FY 2020 through FY 2024.

III. H.R. 4439, THE CREATING HOPE REAUTHORIZATION ACT

A. Background

The Rare Pediatric Disease Priority Review Voucher (PRV) Program was originally created in 2012, as part of the Food and Drug Administration (FDA) Safety and Innovation Act, and was later reauthorized for four years as part of the 21st Century Cures Act in 2016.[7] The program, intended to create an incentive for drug manufacturers to develop therapies for rare pediatric diseases that affect neonates, infants, children, and adolescents, provides for an award

[6] Pub. L. No. 111–148 (2010), Sec. 10413.

[7] Pub. L. No. 112-114 (2012); Pub. L. No. 114-255 (2016).

of a PRV to the sponsor of a drug application that receives FDA approval to treat a rare pediatric disease. A rare pediatric disease is defined as a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years. A PRV can be used by a drug manufacturer to speed FDA review times for another drug application from the standard ten-month review period to six months. A PRV can also be sold to other drug manufacturers for their use on any drug application of their choosing. The PRV does not need to be redeemed on an application for a drug to treat a rare disease. To date, 22 vouchers have been awarded under this program.[8]

A Government Accountability Office (GAO) report published in January 2020, analyzed the effectiveness of the Rare Pediatric Disease PRV Program and the two other PRV programs at FDA.[9] While GAO noted that studies have indicated that PRV programs have little or no effect on drug development, pharmaceutical developers reported that PRVs were a factor in making drug development decisions.[10] Looking across all three PRV programs, most vouchers have been awarded under the Rare Pediatric Disease PRV Program.[11] In a previous GAO audit of the Rare Pediatric Disease PRV Program, prior to the 2016 reauthorization, FDA expressed concerns that the program negatively affected FDA's ability to set public health priorities and argued that it was a strain on agency resources.[12]

B. Legislation

H.R. 4439, the "Creating Hope Reauthorization Act," introduced by Reps. Butterfield (D-NC), McCaul (R-TX), Speier (D-CA), Kelly (R-PA), Engel (D-NY), Bilirakis (R-FL), Kelly (D-IL), Hudson (R-NC), and Rush (D-IL), would permanently reauthorize the Rare Pediatric Disease PRV program.

IV. H.R. 4764, THE TIMELY REAUTHORIZATION OF NECESSARY STEM-CELL PROGRAMS LENDS ACCESS TO NEEDED THERAPIES ACT OF 2019 (THE "TRANSPLANT ACT OF 2019")

A. Background

[8] *Regulatory Explainer: Everything You Need to Know About FDA's Priority Review Vouchers,* Regulatory Focus (Feb. 25, 2020) (www.raps.org/regulatory-focus/news-articles/2017/12/regulatory-explainer-everything-you-need-to-know-about-fdas-priority-review-vouchers).

[9] Government Accountability Office, *Drug Development: FDA's Priority Review Voucher Programs* (2020).

[10] *Id.*

[11] *Id.*

[12] Government Accountability Office, *Rare Diseases: Too Early to Gage Effectiveness of FDA's Pediatric Voucher Program* (2016).

The C.W. Bill Young Transplantation Program helps patients suffering from leukemia, lymphoma, sickle cell anemia, and certain other immune system disorders and in need of a potentially life-saving bone marrow or umbilical cord blood transplant.[13] For some patients, these transplants may come from an unrelated donor. The program's purpose is to assist these transplant patients by providing additional information about bone marrow and cord blood transplants, maintaining an efficient process for identifying donor matches, increasing the number of unrelated donors available for transplant, and collecting data and expanding research to improve patient outcomes.[14]

The National Cord Blood Inventory (NCBI) receives government funding for the collection and storage of at least 150,000 cord blood units, which are then made available through the C.W. Bill Young Transplantation Program.[15]

B. Legislation

H.R. 4764, the "Timely ReAuthorization of Necessary Stem-cell Programs Lends Access to Needed Therapies Act of 2019," or the "TRANSPLANT Act of 2019," introduced by Reps. Matsui (D-CA), Bilirakis, and Pingree (D-ME), reauthorizes the C.W. Bill Young Transplantation Program at level funding of $30 million each year from FY 2021 through FY 2025. The legislation also requires HRSA's Advisory Council on Blood Stem Cell Transplantation to meet at least twice a year and requires the Department of Health and Human Services to review the state of the science related to adult stem cells and birthing tissues for the purpose of potentially including these innovative therapies in the Program. In addition, the legislation also reauthorizes the cord blood inventory program under the Stem Cell Therapeutic and Research Act of 2005 at level funding of $23 million for each year from FY 2021 through FY 2025.

V. H.R. 5373, THE UNITES STATES ANTI-DOPING AGENCY REAUTHORIZATION ACT OF 2019

A. Background

The U.S. Anti-Doping Agency (USADA) is the national anti-doping organization in the United States for Olympic, Paralympic, Pan American, and Parapan American sports.[16] USADA, which was created as an independent body in 2000, was given authority by Congress to

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[13] Health Resources and Services Administration, Blood Stem Cell, About (bloodstemcell.hrsa.gov/about) (accessed July 22, 2020).

[14] *Id.*

[15] Health Resources and Services Administration, Blood Stem Cell, About, Contracts, National Cord Blood Inventory Contract Summary (NCBI) (bloodstemcell.hrsa.gov/about/contracts/national-cord-blood-inventory-contract-summary-ncbi) (accessed July 21, 2020).

[16] U.S. Anti-Doping Agency, About USADA (www.usada.org/about/) (accessed July 21, 2020).

manage a comprehensive anti-doping program, including in-competition and out-of-competition testing, results management processes, drug reference resources, and athlete education for all United States Olympic & Paralympic Committee recognized sport national governing bodies, their athletes, and events.[17] The organization also engages with other national anti-doping organizations globally to advocate for integrity in sport on behalf of clean athletes. Through its TrueSport program, it works to educate young athletes and promote positive youth sport experiences.[18] USADA's authorization expires at the end of FY 2020.

B. Legislation

H.R. 5373, the "United States Anti-Doping Agency Reauthorization Act of 2019," introduced by Reps. Thompson (D-CA), Johnson (R-OH), and DeGette (D-CO), authorizes the USADA through the end of FY 2027. The FY 2020 authorization is set at $14.8 million. In anticipation of hosting the 2028 Olympics in Los Angeles, this bill steadily increases the authorization to $22.8 million by FY 2027. The bill also directs USADA to promote positive youth sports experiences by using a portion of its funding to provide educational materials on sportsmanship, character building, and healthy performance for those participating in youth sports. It also directs the Department of Justice, the Department of Homeland Security, and FDA to coordinate with USADA efforts to prevent the use of performance-enhancing drugs or prohibit performance-enhancing methods by sharing all information in their possession that may be relevant to preventing the use of such drugs or prohibiting such methods.

VI. WITNESSES

The following witnesses have been invited to testify:

Robert Boyd, MCRP, MDiv
President
School-Based Health Alliance

Linda Goler Blount, MPH
President and CEO
Black Women's Health Imperative

Nancy Goodman, MPP, JD
Founder and Executive Director
Kids v. Cancer

Aaron Seth Kesselheim, MD, JD, MPH
Professor of Medicine
Harvard Medical School

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[17] *Id.*

[18] U.S. Anti-Doping Agency, TrueSport (www.usada.org/choose-usada/choose-usada-truesport) (accessed July 21, 2020).

Brian Lindberg
Chief Legal Officer and General Counsel
National Bone Marrow Donor Program

Travis T. Tygart
Chief Executive Officer
U.S. Anti-Doping Agency