House Committee on Energy and Commerce
Subcommittee on Health
Improving Access to Care: Legislation to Reauthorize Key Public Health Programs
July 29, 2020
10:00 AM, Virtual Hearing via Webex

Purpose
*The purpose of this hearing was to discuss five pieces of legislation to reauthorize key public health programs***:** *H.R. 2075, the "School-Based Health Centers Reauthorization Act of 2019"***,** *H.R. 4078, the "EARLY Act Reauthorization of 2019"***,** *H.R. 4439, the "Creating Hope Reauthorization Act"***,** *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"***,** *H.R. 5373, the "United States Anti-Doping Agency Reauthorization Act of 2019"*

Members Present
Chairman Eshoo, Ranking Member Burgess, Representatives Pallone, Sarbanes, Walden, Upton, Butterfield, Guthrie, Matsui, Griffith, Castor, Brooks, Cardenas, Mullin, Sarbanes, Gianforte, Kennedy, Ruiz, Bilirakis, Kuster, Carter, Blunt Rochester, Rush, Barragan, Johnson, and O'Halloran

Witnesses
Robert Boyd, MCRP, MDiv, President, School-Based Health Alliance
Linda Goler Blount, MPH., President and CEO, BlackWomen'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
Brian Lindberg., Chief Legal Officer and General Counsel, National Bone Marrow Donor Program
Travis T. Tygart., Chief Executive Officer, U.S. Anti-Doping Agency

Opening Statements
(3:50) Chairman Eshoo said that today, this subcommittee meets to discuss five important pieces of legislation to reauthorize key public health programs. While so much focus has been placed on COVID-19, this committee cannot lose sight of its prior responsibilities. Pediatric cancer is the number one disease killer of children in the United States. Unfortunately, there are not enough incentives in place to encourage pharmaceutical manufacturers to develop treatments and cures. H.R. 4439 seeks to solve this problem. Meanwhile, H.R. 4078 is an important bill to help young women reduce their risk of developing and dying from breast cancer. Today this subcommittee will also discuss school based health centers. It has become clear that these health centers are important pillars of health in all communities. This committee has a duty to address the issues facing the country. The programs being considered today should all be reauthorized.

(9:15) Ranking Member Burgess said that today's hearing is very important. All five of the bills being discussed today provide tools to help individuals stay healthy. Reauthorizing support for school based health centers is vitally important. Now is not the time to be reducing access to care for vulnerable students. Schools are a familiar and comfortable setting and serve as vital healthcare access points. The EARLY Act should also be reauthorized to protect the health of women and reduce the incidence of breast cancer. This committee must also promote the stem cell program and incentivize bone marrow and blood transplants. Over the years, this program has been championed by both Republicans and Democrats. The Anti-Doping Agency is also a pillar of international health and helps to protect the sanctity of sport. It should not be forgotten that one of the first acts of Russian interference was to meddle with the anti-doping program in 2018. The Creating Hope Act should also be reauthorized.

(14:20) Chairman Pallone said that today this committee continues its work to deliver change to the American people. This committee must work to expand access to care for all Americans. All of the bills being considered today would reauthorize programs that are essential to the nation's public health infrastructure.

(17:50) Rep. Sarbanes said that the School-Based Health Center Reauthorization Act must be passed by Congress. Students need to have access to timely, culturally appropriate care. This can be delivered in school-based health centers. It is known that this will lead to improved education outcomes.

(19:45) Rep. Walden said that reauthorizing the funding of these public health programs could literally be life saving for Americans. These bills should swiftly be moved through Congress.

<u>Testimony</u>

(25:30) Ms. Blount said that Black women develop breast cancer on average 5-7 years younger than white women. Until recently, the good news was Black women got breast cancer at lower rates than white women, but as of 2015 that is no longer the case. But that's where the good news ends. Black women are 40% more likely than white women to die of breast cancer. This is in part for three reasons. First, Black women are more likely than other racial/ethnic groups to have aggressive breast cancer subtypes; second, they are less likely to receive the most effective therapeutics for their cancers. The first is an issue of biology and the second, an issue of behavior. The third reason that Black women die at such high rates is because their breast cancers are too often detected at late stages when treatment of any kind is less effective. Researchers know that most breast cancers are detectable long before a woman gets a mammogram. The EARLY Act would reauthorize and increase funding originally authorized in 2010, giving needed attention to the education of younger and higher risk women about their breast health. The program not only educates women age 45 and younger on breast cancer risks, but it supports initiatives and research to help identify high-risk women, collect family histories and educate healthcare providers. The EARLY Act has already benefitted women. Mortality rates from breast cancer have dropped in the past 10 years in large part due to early detection.

(30:50) Mr. Boyd said that school-based health centers have been located in public schools since the early 1970's. Schools are pillars of community-- whether located in large cities, suburbs, or rural America. For millions of low-income students, school-based health centers are their sole source of healthcare. They allow parents to remain at work and students to stay in school while getting the healthcare they need. Now, the data is clear: healthy kids learn better. Healthy kids earn higher grades and achieve higher promotion and graduation rates. Healthy kids grow up to be healthy adults. School-based health centers sit at the critical intersection of education and health. Many people may not realize

it, but even during the pandemic, many school-based health centers are still delivering ongoing care. Throughout the pandemic, school-based health centers have continued to provide health services to K-12 students directly: on site in a school, at school-linked clinics, via mobile vans, and even drive-through visits in school parking lots. Some students have been able to receive life-saving medications, immunizations, and even participate in socially-distanced counseling sessions. Unfortunately far too many have not. Going forward, telehealth will remain an important strategy for increasing access to care, allowing Health Centers to reach the students and families with the greatest needs, including the almost one-third of school-based health centers located in rural communities. Telehealth is not a substitute for in-person care. It is a technological enhancement in the tool chest of healthcare providers. The mental and emotional health of students is an issue that has too often been overlooked in the current debate about re-opening school buildings. It is more important than ever that we think comprehensively and act with urgency: we must treat this pandemic as we would a mass incident like tornados, hurricanes, or school shootings that wreak multiple levels of havoc on an entire community.

(36:20) Ms. Goodman said that on September 30, 2020, the pediatric voucher program is scheduled to expire. Since the passage of the Creating Hope Act in 2012, the pediatric voucher program has approached a sunset date and been reauthorized three times. Now, to address this fourth sunset date, the Creating Hope Reauthorization Act (HR 4339) permanently reauthorizes the pediatric voucher program. The first measure of success of the pediatric voucher program is that the program has mobilized well over $1 billion in incentives for pediatric drug development in the form of payments for vouchers. A second measure of success is the increase in the number of new drugs that have been approved for rare pediatric diseases before the passage of the Creating Hope Act and after. A third measure of success is the increased number of rare pediatric disease drugs that are in the drug development pipeline. But perhaps the most important, long-term impact of the Creating Hope Act has been to change the risk/return calculation of biotech and pharmaceutical companies such that they are increasingly interested in pediatric rare disease drug development. Kids V Cancer urges Congress to pass the Creating Hope Reauthorization Act.

(42:10) Dr. Kesselheim said priority review vouchers were devised in 2007 as a way of incentivizing private investment in research and development for neglected tropical diseases. A drug maker that gets FDA approval for a neglected tropical disease indication earns a voucher that entitles it to have one of its otherwise unremarkable and not clinically innovative drugs—that would have been reviewed by the FDA on a standard timeline of 10 months—to be reviewed on the 'priority review' timeline of 6 months. This faster-to-market potential was estimated to be worth over $300 million to drug makers. The voucher program was extended to include drugs treating rare pediatric diseases in 2012 and drug treating medical countermeasures in 2016. Since that time, there has been no evidence that priority review vouchers have stimulated development of new treatments for any of the diseases to which they apply. The voucher incentive's economic value was substantially overestimated, and in recent years has dropped to about $80-110 million in part because of numerous vouchers on the market arising from all the types of drugs that can now earn them. The program also does not assure access to drugs that earn the voucher, which are often priced at extremely high levels by their manufacturers. Vouchers are potentially dangerous because they force the FDA to accelerate review of drugs that are otherwise unremarkable and/or non-innovative, which increases the risk of problematic regulatory decisions relating to these products. The FDA has also reported that the voucher strains its limited resources and disrupts its public health-based approach to prioritizing drug reviews. Thus, the priority review voucher program was ill-conceived and in the 14 years since it was devised, there has been no systematic, rigorous evidence that it has proven useful in achieving its goals. It is time to let the rare pediatric

disease priority review voucher sunset, and instead direct efforts towards better solutions with a known track record in successfully leading to transformative drugs for medical conditions for which current market incentives have proven inadequate.

(48:20) Mr. Lindberg said the C.W. Bill Young Cell Transplantation Program was first established through a partnership with the Navy in 1986, transferred to the NIH for oversight the following year, then authorized by this committee in 1990 and has been reauthorized in 1998, 2005, 2010, and 2015. Today, the Be The Match Registry includes more than 22 million selfless volunteers who stand ready to be a life-saving bone marrow donor. It also includes more than 300,000 cord blood units, 110,515 of which are in the National Cord Blood Inventory. This valuable source of cells also is reauthorized by H.R. 4764. Through international relationships, NMDP/Be The Match has access to more than 35 million potential donors and 783,000 cord blood units worldwide. H.R. 4764 also authorizes our work in support of patients and families through the Office of Patient Advocacy. This legislation also will continue the work of the SCTOD, a remarkable data resource that allows doctors and researchers significantly impact survival for blood cancer and other diseases while also improving the quality of life for thousands of transplant patients. Finally, this legislation is fundamental to vision to ensure that every patient in need of a lifesaving transplant has access to a matched donor regardless of ethnic, racial, or socioeconomic background.

(54:25) Mr. Tygart said USADA is charged with implementing a robust, fair anti-doping program, which includes in and out-of-competition testing, results management, and athlete education for all US Olympic, Paralympic and Pan American athletes. In the late 1990s, Congress, together with the United States Olympic and Paralympic Committee (USOPC), took action and put a stake in the ground to establish, through a public-private partnership, an independent organization to implement and enforce a fair and robust national anti-doping program. This bipartisan effort sparked the courage of the entire U.S. Olympic and Paralympic movement to agree to give up control to an independent organization. This independence, the life blood of any successful anti-doping program, is possible only through the government support USADA receives each year. The congressional funding is through ONDCP and is combined with private funding from the USOPC and other sources. An essential component of any effective anti-doping program is the ability to demonstrate to the athlete, coach and sport community that you can be trusted and relied on to do the job in fairly enforcing the rules even when not easy or popular to do so. The final component of the USADA program is our scientific and research efforts. We know the testing is only as good as its value as a deterrent or to detect as the ability of the laboratory to accurately and robustly analyze for the prohibited substances and methods being used to cheat by athletes. USADA's reauthorization, takes on even more importance since the Summer Olympic and Paralympic Games are coming to the United States to Los Angeles, California in 2028. By passing this reauthorization, we can make it clear that the rules matter and that clean sport matters. The independent model works and has becomes a beacon to others around the world and as a result, USADA is humbled to be in the unique position to demonstrate leadership within the global community and to also fight for fairness for our athletes on the international playing field as well.

Questions and Answers

(1:00:10) Chairman Eshoo asked how to explain the difference in findings regarding the success of the voucher program. **Dr. Kesselheim** said the difference is that the GAO report is based on anecdotal interviews with companies. Dr. Kessleheims study was a true comprehensive study. **Chairman Eshoo** asked what made the GAOs report anecdotal. **Dr. Kesselheim** said that is how GAO defines their own

study. **Chairman Eshoo** asked if the voucher program is important in the development of pediatric cancer drugs. **Ms. Goodman** said yes. This is evident in the drug development pipeline.

(1:06:30) Ranking Member Burgess asked how the United States compares to other nations when it comes to rare pediatric drug development. **Dr. Kesselheim** said thanks to the NIH, the US is a very important player in the development of pediatric drugs. **Ms. Goodman** said that a vast majority of drug development occurs in the United States. **Ranking Member Burgess** asked what people should know about being a bone marrow donor. **Mr. Lindberg** said that people should know that they age out of the program at age 61. It is known that as a donor ages there are poorer outcomes for the recipient. Thus young healthy donors are prioritized.

(1:12:10) Rep. Pallone asked what Dr. Kesselheim's study found regarding the voucher program. **Dr. Kesselheim** said that his study found that there is no difference in the development of rare disease drugs based on their participation in the voucher program. They learned that rare disease drug development is increasing in general. **Rep. Pallone** asked how the voucher program uses government resources. **Dr. Kesselheim** said that it results in Medicare and Medicaid paying higher costs for drugs. It also takes up significant bandwidth within the FDA. **Rep. Pallone** asked what should be improved about the voucher program. **Dr. Kesselheim** said that it should only apply to drugs that are the first in their class, the program should not apply to drugs in the accelerated approval pathway, finally any drug developed using the program should be made available at a value based price. **Ms. Goodman** said she disagrees with every point Dr. Kesselheim made.

(1:18:40) Rep. Upton asked how Congress can make sure that children can benefit from school-based health centers. **Mr. Boyd** said that school-based health centers have not closed. Instead they have transitioned to telehealth. There is a health crisis that is heading towards schools. School-based health centers serve at the front line protecting students. There will be a mental health crisis and a vaccination crisis. These centers need more funding. **Rep. Upton** asked how many children have missed vaccinations. **Mr. Boyd** said that the evidence is only anecdotal at this point. It is assumed that a significant amount of children have missed vaccinations.

(1:25:01) Rep. Butterfield asked how a long-term expansion of the voucher program would help children. **Ms. Goodman** said that the need for continual reauthorization undercuts the long-term financial predictability of the program. Thus if it were expanded long term, it would attract more manufacturers. **Rep. Butterfield** asked if this program costs tax payers any money. **Ms. Goodman** said the CBO has scored it at zero cost. **Rep. Butterfield** asked if funding is a factor when schools consider reopening. **Mr. Boyd** said yes.

(1:30:40) Rep. Guthrie asked if the National Bone Marrow Program works with HHS. **Mr. Lindberg** said yes. The two have a very good relationship. **Rep. Guthrie** asked what needs to be done to ensure that transplants can continue during COVID-19. **Mr. Lindberg** said going forward, the program needs to be reauthorized. If the program lapses the impact would be devastating.

(1:36:10) Rep. Matsui asked what role Be The Match plays in bone marrow transplants. **Mr. Lindberg** said that Be The Match is the largest, most comprehensive list of bone marrow donors in the world. **Rep. Matsui** asked what Be The Match is doing to ensure that minority groups have access to bone marrow transplants. **Mr. Lindberg** said that Be The Match has doubled their efforts to serve

underserved communities. They have set a goal to double the number of transplants among ethnic minorities.

(1:41:30) Rep. Griffith asked why the US is not on the executive committee of the world Anti-Doping Agency. **Mr. Tygart** said that the process for selecting members resulted in the US not receiving the seat. **Rep. Griffith** asked if this was done because the US is vehemently anti-doping. **Mr. Tygart** said he is not sure, but it is certainly strange.

(1:47:00) Rep. Castor asked why Black women are at a higher risk for developing breast cancer. **Ms. Blount** said that researchers often point to increased rates of obesity, child bearing patterns and other underlying conditions. However this does not explain everything. It is clear that there is much that is still unknown. We need to know more about the lived experience of Black women. **Rep. Castor** asked what interventions are most successful. **Ms. Blount** said that community based interventions are crucially important. Education needs to be started early.

(1:52:20) Rep. Brooks asked what the state of breast cancer education is in the United States. **Ms. Blount** said that it is clearly not enough. The infrastructure exists to deliver effective outreach to many communities. **Rep. Brooks** asked what strategies should be used to educate women. **Ms. Blount** said that social media needs to be leveraged. It is important to meet individuals where they are.

(1:57:50) Rep. Cardenas asked how school-based health centers can improve mental health care. **Mr. Boyd** said primarily it can help to increase access to mental health care. Over the next ten years it will be important to invest in human capital and cultural competency. Furthermore, telehealth presents an opportunity to deliver more care and leverage more medical professionals. **Rep. Cardenas** asked what impact COVID-19 will have on the health of students. **Mr. Boyd** said that it is a disaster. Students are missing immunizations, feeling food insecurity, and getting sick.

(2:04:30) Rep. Mullin asked how the Pediatric Voucher Program works. **Ms. Goodman** said the program works by providing manufacturers with a chance to attract additional investors and receive a designation earlier. **Rep. Mullin** asked if the program has a CBO score. **Ms. Goodman** said yes, the score is zero. **Rep. Mullin** asked what measures the FDA has in place to ensure the drugs are safe. **Ms. Goodman** said that the FDA will only approve a drug if it is safe.

(2:10:00)Rep. Sarbanes asked how health centers in schools can be a gateway to accessing broader health supports. **Mr. Boyd** said that these health centers can help connect students to care outside of their capacity. This will especially help students in low income communities.

(2:15:30) Rep. Gianforte asked if there is anything else that Ms. Goodman would like to say about the Voucher Program. **Ms. Goodman** said that the program currently has 22 drugs in the pipeline. The program will deliver change to the American people.

(2:18:15) Rep. Kennedy asked if school-based health centers should be a part of the decision to reopen schools. **Mr. Boyd** said yes. **Rep. Kennedy** asked what challenges exist in delivering mental health services to children in school based settings. **Mr. Boyd** said the true challenge now is to protect the privacy of students. Students should feel like they are in an environment that allows them to be vulnerable. Telehealth will help with this.

(2:25:00) Rep. Ruiz asked how school based health centers address health equity. **Mr. Boyd** said that it would improve access for students who are at the highest risk for poor health outcomes. **Rep. Ruiz** asked what connections exist between health outcomes and education outcomes. **Mr. Boyd** said that the data is clear, good health outcomes are associated with good education outcomes. **Rep. Ruiz** asked if there is any data that shows the cost effectiveness of school-based health center. **Mr. Boyd** said that it is important to remember that these health centers do not cost the school anything. They are fully reimbursed by Medicaid.

(2:30:00) Rep. Bilirakis asked what challenges COVID-19 has presented for bone marrow transplants. **Mr. Lindberg** said that like other industries it has made business very difficult. Luckily, his staff has been able to work around the clock to tackle these challenges. **Rep. Bilirakis** asked if the Voucher Program has been effective. **Ms. Goodman** said yes.

(2:37:00) Rep. Kuster asked how school based health centers can address adverse childhood events. **Mr. Boyd** said that there is a youth advisory committee to work closer with young people. The challenge is that the pandemic has likely increased the frequency of adverse childhood events. Substance abuse services will be critical in school based environments. **Rep. Kuster** why it is so important for youth athletes to know that professional athletes are drug free. **Mr. Tygart** said that it is important to have real life role models. This will help to promote drug free sports.

(2:43:0) Rep. Carter asked how to respond to critics that say the Voucher program is not effective. **Ms. Goodman** said that 22 drugs have been approved since the program's inception. This is success. **Rep. Carter** asked how this compares to before the program existed. **Ms. Goodman** said only 2 drugs were approved in this time. **Rep. Carter** asked if there have been any instances of drugs that have been pulled back due to the accelerated approval pathway. **Dr. Kesselheim** said yes.

(2:48:30) Rep. Blunt Rochester asked what challenges young Black women face in identifying breast cancer. **Ms. Blount** said the number one challenge is getting an individual to understand their own risk. It is also still not understood why black women have such a high rate of breast cancer. **Rep. Blunt Rochester** asked how the EARLY Act improves access to diagnostic care. **Ms. Blount** said that the EARLY Act helps to encourage frequent breast cancer screening.

(2:45:00) Rep. Rush asked what best practices surrounding breast cancer could be applied to heart disease awareness. **Ms. Blount** said that it is important to get individuals to understand their own personal risk.

(2:49:15) Rep. Barragan asked if a community clinic would have 3d mapping available for breast cancer screening. **Ms. Blount** said that this type of technology is only available in high income areas. **Rep. Barragan** asked how the EARLY Act may reduce health disparities. **Ms. Blount** said the Act will make sure that women understand the importance of screening. **Rep. Barragan** asked how investing in social determinants of health will improve health outcomes. **Ms. Blount** said that this will help improve access to care.

(3:05:00) Rep. Johnson asked why it is important to promote anti-doping. **Mr. Tygart** said that it is important to promote integrity around the world. Athletes should abide by the rules.

(3:11:40) Rep. O'Halloran asked what changes have been seen surrounding mental health among school aged children. **Mr. Boyd** said they are in the middle of gathering this data.