

**Attachment—Response of Ms. Ellyn Miller, President and Founder, Smashing Walnuts  
Foundation, to Additional Questions for the Record**

**Subcommittee on Health  
Hearing on  
“Enhancing Public Health: Legislation to Protect Children and Families”  
October 20, 2021**

Responses are provided to the questions posed in **bold** below.

**The Honorable Frank Pallone, Jr. (D-NJ)**

**Pediatric research often goes underfunded due to the difficulty in conducting this research, or because the number of patients or need is lower than for the general adult population.**

- 1. You noted in your testimony that the lack of involvement from pharmaceutical companies led to the reliance on government and private charities as the key supporters for childhood cancer research. How have these funding sources worked in supporting cutting-edge childhood cancer research?**

The principal government funder of biomedical research, including cancer research, is the National Institutes of Health (NIH).<sup>1</sup> Childhood cancer research funding within NIH primarily stems from the National Cancer Institute (NCI).<sup>2</sup> In recent years, the Gabriella Miller Kids First Pediatric Research Program has also made the NIH Common Fund an important source of funding.<sup>3</sup> Important childhood cancer research takes place within NCI, particularly through NCI’s Center for Cancer Research Pediatric Oncology Branch and Childhood Cancer Data Initiative.<sup>4</sup> NCI also funds clinical trials and consortia on childhood cancer.<sup>5</sup>

The majority of NCI’s budget supports extramural grants and cooperative agreements to facilitate cancer research done externally at places like universities, medical schools, hospitals, and cancer centers.<sup>6</sup> The Gabriella Miller Kids First Pediatric Research Program has also allocated money to research grants looking into pediatric cancer through the NIH Common Fund, supporting dozens of research projects. Finally, private charities have also stepped up to raise funds for research grants in the absence of pharmaceutical company involvement.<sup>7</sup>

There have been a number of important developments over the last several years in childhood cancer research, many of which we owe to government and charitable research funding. Results from an NCI-sponsored clinical trial led to the approval of a novel molecularly targeted therapy to treat high-risk neuroblastoma.<sup>8</sup> NIH grants have also helped pay the way for the use of promising immunotherapy treatments for children with acute lymphoblastic leukemia (ALL).<sup>9</sup>

However, as previously noted in my written testimony, the amount of resources devoted to childhood cancer research remains low. From 2008 through 2018, the NCI spent an average of just 4.08% of its obligations on childhood cancer research.<sup>10</sup> Moreover, while individual charities have worked to fill the gap, we simply cannot provide the same level or centralized source of funding that the government can provide.

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Recognizing the need for more resources to meet this challenge, Congress worked on a bipartisan basis to pass the Gabriella Miller Kids First Research Act (Kids First Act 1.0), enacted in 2014.<sup>11</sup> The Act also established a ten-year Pediatric Research Initiative Fund and authorized \$12.6 million in annual funds for childhood disease research through Fiscal Year 2023. It led to the creation of the Gabriella Miller Kids First Pediatric Research Program and Data Resource Center – housed within the NIH Common Fund – and has allocated millions of dollars to research grants looking into pediatric cancer, supporting over 60 research projects.<sup>12</sup> The Kids First Data Resource Center has focused on building a large-scale database for both clinical and genetic data from kids with cancer, with the goal of finding patterns that will accelerate research into cures and less harsh treatments. Currently, over 25,000 samples have been genetically sequenced to promote new scientific discoveries.<sup>13</sup>

There is still so much work to be done, however. One area that illustrates the need for additional funding is the lack of treatment options for children with cancer. As of 2020, only a few drugs in use have received FDA approval in the first instance for cancer treatment for children.<sup>14</sup> Survivors of childhood cancer often suffer long-term health consequences due to the side effects of the treatment regimens available today, the vast majority of which were initially approved for use in adult populations. As many as 95 percent of childhood cancer survivors will experience a significant health-related issue by the time they are 45 years of age – not only due to their illness, but also due to types of treatment they are receiving.<sup>15</sup>

The progress we have made in fighting childhood cancer over the last few years is worth celebrating. But it is also a testament to the magnitude of the problem and of how much more could be done with additional funding. Pediatric oncologists are continuing to sound the alarm about the desperate need for more investment in research.<sup>16</sup> I am asking Congress to answer their call.

- 2. You note in your testimony that the Kids First Program needs a new, stable, and robust source of funding. We have heard from the National Institutes of Health (NIH) and U.S. Securities and Exchange Commission (SEC) that the proposed funding source in this legislation may not provide predictable funding streams for the program. How will civil Foreign Corrupt Practices Act penalties provide stable funding for this program, and what empirical data was used in making this decision?**

The Foreign Corrupt Practices Act (FCPA), first enacted in 1977, makes it unlawful to pay bribes to foreign officials to assist in obtaining or retaining business.<sup>17</sup> Sanctions for FCPA violations can be significant, and civil enforcement of the FCPA continues to be a “high priority area” for the SEC.<sup>18</sup>

The Gabriella Miller Kids First Act 2.0 (Kids First Act 2.0) would redirect money from penalties and disgorgement paid by pharmaceutical, cosmetic, supplement, and medical device companies found in violation of the FCPA. The Kids First Act 2.0 would require the Secretary of the

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Treasury to transfer these funds directly into the Pediatric Research Initiative Fund established by the Kids First Act 1.0.

Below is a table of showing the civil penalties and disgorgement assessed by the SEC across these categories from 2016 to 2020<sup>19</sup>:

Year	Total FCPA Penalties Against Pharmaceutical, Cosmetic, Supplement and Medical Device Companies
2020	\$208.8 million
2019	\$147.0 million
2018	\$7.8 million
2017	\$40.3 million
2016	\$300.3 million

As you can see, while the precise amount of penalties varies from year to year, recoveries against companies in these industries are typically substantial.<sup>20</sup> The Kids First Act 2.0 was written to account for the fact that penalties may be larger some years than others. The penalties, which are collected in the General Treasury, are transferred to the Pediatric Research Initiative Fund. The balance of the Fund can then roll over from one year to the next. This allows for a stable source of funding over time, even in the event that penalties are lower than normal one year or the next.

There are a number of reasons to believe that FCPA enforcement will be a priority in 2022 and beyond. On June 3, 2021, the White House released the “National Security Study Memorandum,” which named “combating corruption” as a “core national security interest.”<sup>21</sup> It calls for an “interagency review process” in order to formulate a “Presidential strategy” to “significantly bolster” the capacity of the U.S. government to respond to corruption abroad.<sup>22</sup> The White House then issued the “U.S. Strategy on Countering Corruption” on December 6, 2021.<sup>23</sup> The strategy calls for agencies to “vigorously pursue enforcement of foreign bribery cases through the FCPA” and to enhance enforcement efforts.<sup>24</sup>

Furthermore, the SEC and Department of Justice (DOJ) – who frequently levy joint civil and criminal penalties in FCPA cases – have accordingly taken steps to bolster their enforcement capacities and have signaled a focus on FCPA enforcement. In March 2021, the DOJ increased the number of prosecutors in its FCPA Unit to a record number.<sup>25</sup> In June 2021, then-Acting Assistant Attorney General Nicholas McQuaid announced that the DOJ would employ novel enforcement mechanisms, anticipating this would lead to enforcement levels on par with the “size, scope, and significance” of prior years.<sup>26</sup> Finally, in August 2021, Chairman Gensler ordered that amendments to SEC regulations criticized for weakening protections for whistleblowers be revised.<sup>27</sup>

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Overall, given the structure of the Kids First Act 2.0, past penalties assessed, and enforcement priorities, my colleagues and I are confident that the FCPA will serve as a robust and stable funding mechanism.

**3. You also shared in your testimony that Congress has channeled fines or penalties into other programs. How have similar funding mechanisms worked in other agencies? Has this mechanism provided reliable, year after year funding?**

The Kids First Act 2.0 proposes a new, stable and robust source of funding for the Gabriella Miller Kids First Pediatric Research Program. While this is a novel funding mechanism, there are other long-existing statutory provisions whereby collected pharmaceutical fines and penalties are transferred to other trust funds in the General Treasury.

The first of these funds is the Federal Hospital Insurance Trust Fund (HI Trust Fund), which funds Medicare Part A. The HI Trust Fund receives penalties and damages from violations of the False Claims Act (FCA), as well as criminal fines and forfeitures from violations of the Federal Food, Drug and Cosmetic Act (FDCA).<sup>28</sup> \$1.6 billion was transferred to the HI Trust Fund in 2020 from fines and penalties.<sup>29</sup>

The HI Trust Fund began to receive penalties from fraud and abuse cases after the passage of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This created the Fraud and Abuse Control Program, which was designed to coordinate federal, state, and local health care fraud enforcement efforts. Funds in the HI Trust Fund from FCA and FDCA cases are used either for Medicare Part A funding, or are transferred to the Health Care Fraud and Abuse Control Account to fund further enforcement efforts.<sup>30</sup>

The second such fund is the Crime Victims Fund (CVF), which is administered by the Department of Justice (DOJ). The CVF generally receives criminal fines that the DOJ secures through its successful prosecutions.<sup>31</sup> In the pharmaceutical space, this has included large fines from FDCA violations.

The CVF was established by the Victims of Crime Act of 1984. Funds in the CVF are authorized to be used only for specific purposes (outlined below), including crime victims' assistance and compensation. When the fund was first authorized, an eight-year cap was placed on deposits. The cap was lifted in 1993, but caps were reinstated starting in FY 2000. The cap in FY 2020 was set at \$2.6 billion.<sup>32</sup> While caps are placed on the CVF during the annual appropriations process, the HI Trust Fund and CVF receive these funds through permanent appropriations.

The table below has more detail on how these two funds operate:

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Fund	Enforcement Agencies Involved	Purpose	Required Deposits
HI Trust Fund	DOJ, HHS OIG	Finances health care services related to stays in hospitals, skilled nursing facilities, and hospices for eligible beneficiaries.	<p>(1) Criminal fines recovered in cases involving a federal health care offense, including collections those relating to health care fraud;</p> <p>(2) Civil monetary penalties in cases involving a federal health care offense;</p> <p>(3) Amounts resulting from the forfeiture of property by reason of a federal health care offense; and</p> <p>(4) Penalties and damages obtained under the FCA, in cases involving claims related to the provision of health care items and services (other than funds awarded to a relator, for restitution or otherwise authorized by law).<sup>33</sup></p>
CVF	DOJ, FBI	Funds the investigation and prosecution of child abuse and neglect cases, administrative support for victim services, victim specialists assigned to FBI field offices, the Federal Victim Notification System, and state grants for victim assistance and support.	Criminal fines assessed against individuals and companies. Since 1996, deposits have included several large fines from violations of the FDCA. <sup>34,35</sup>

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The table below shows the levels of funding from fines and penalties for the HI Trust Fund and CVF from 2016 to 2020:

Year	Total Amount Transferred from General Treasury	
	HI Trust Fund <sup>36</sup>	CVF <sup>37</sup>
2020	\$1.6 billion	\$503 million
2019	\$931.8 million	\$495 million
2018	\$664.2 million	\$445 million
2017	\$540.3 million	\$6.6 billion
2016	\$925.4 million	\$1.5 billion

As you can see, while there has been some variation in the amount of money deposited into each of these funds over the last several years, funding levels derived from penalties have been increasing since 2018. While concerns have been raised about the solvency of the HI Trust Fund, this has largely been attributed to decline in payroll tax revenue and increased spending.<sup>38</sup> Decreases in the balance of the CVF following 2017, on the other hand, were attributed to the increased use of deferred prosecution agreements (DPAs) and non-prosecution agreements (NPAs) in criminal cases; money from DPA and NPA settlements was being deposited in the General Treasury, rather than the CVF. Congress stepped into solve this problem with the bipartisan passage of the VOCA Fix to Sustain the Crime Victims Fund Act of 2021, which requires these funds to be deposited in the CVF.<sup>39</sup>

In sum, despite some degree of variation from year-to-year, and despite recent legislative changes to update the 30-year-old CVF, fines and penalties assessed by federal agencies have served as crucial and robust funding mechanisms for both the HI Trust Fund and the CVF. My colleagues and I believe that the same will prove true for the use of FCPA penalties to fund the Pediatric Research Initiative Fund.

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**The Honorable Michael C. Burgess, M.D. (R-TX)**

**Ms. Miller, thank you for all your work and the legacy your daughter left in the fight against childhood cancer. The National Institute of Health’s Kids First Pediatric Research Program and Data Resource Center are truly stories of success. In your testimony, you specifically mention that the Data Resource Center, originally authorized by the Gabriella Miller Kids First Research Act, has logged over 25,000 genetically sequenced samples.**

**1. Why is access to this research so important for those investing in the development of new treatments and even cures for childhood cancers?**

To best answer this question, I consulted with Dr. Adam Resnick, Co-Director of the Center for Data Driven Discovery in Biomedicine at the Children’s Hospital of Philadelphia – which leads the Gabriella Miller Kids First Data Resource Center (DRC) – and Scientific Co-Chair of the multi-institutional Children’s Brain Tumor Network (CBTN).

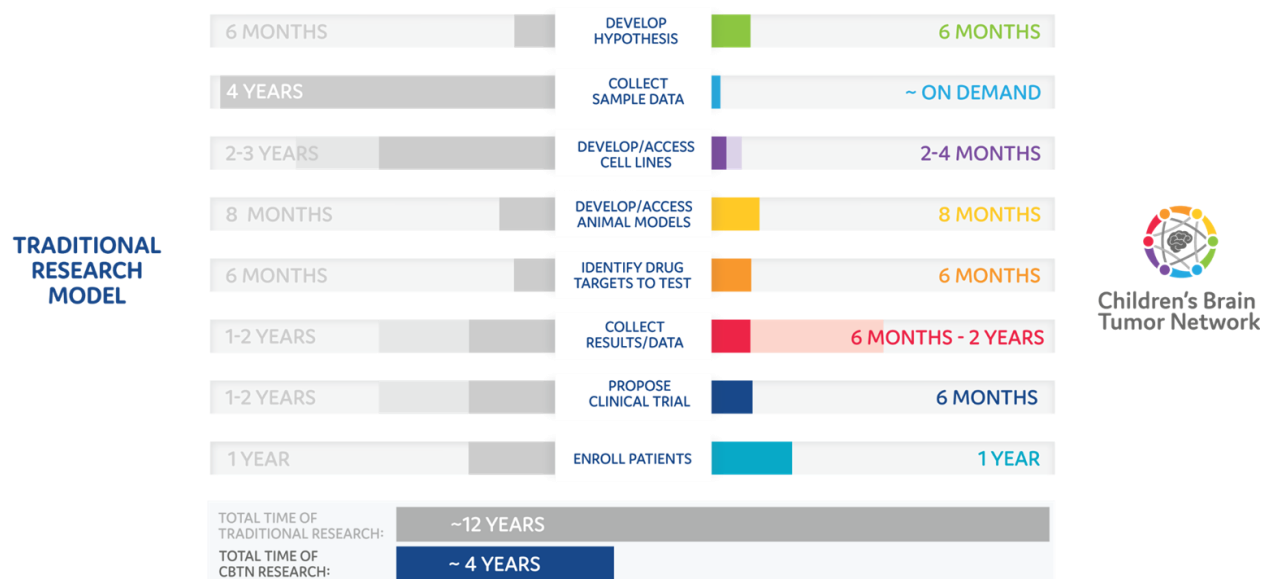
Cancer remains the leading cause of disease related death in children,<sup>40</sup> but only a handful of drugs have been developed specifically for use in children with cancer. Unlike in adults, cancer in kids is not linked to factors like drinking and smoking. We simply don’t know why some kids get cancer and others don’t. Progress requires an understanding of the molecular make-up of different tumors – thus, without understanding what’s going on inside each tumor (at the molecular level), it is impossible to identify trends and develop targeted solutions and treatment. One investigator commented that trying to identify cures for pediatric solid tumors without molecular data “is like trying to put together a car without an instruction manual or an understanding of the different parts you have to work with.”

Because of the complexity of childhood cancers and the many different disease types, it would take years for any one researcher to amass enough samples on their own to create an effective study. The Kids First Program has enabled the molecular classification of more than 25,000 samples from patients all over the country, across disease types.<sup>41</sup> This provides the opportunity to identify similar cancer mechanisms across different diseases and therapeutic options. This data is made available through the DRC to researchers across the country at no charge, enabling them to investigate the molecular underpinnings of pediatric cancers in new and collaborative ways.<sup>42</sup>

Access to molecular data is required to conduct research and having a tool that aggregates this information across disease types saves investigators time and resources. Beyond access to data, the DRC supports analysis, allowing researchers to compare data sets, examine variants across different sample types, and enable collaboration among investigators. One researcher recently expressed, “This resource saved me 20 years!”

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For example, researchers using data from the CBTN, one of the initial data sets included in the Kids First Data Portal, have commented that access to the DRC shaved *between 8 and 20 years* off of the time it would have otherwise taken them to go from hypothesis to clinical trial, as illustrated below.



Large scale data resources created by the Kids First program are also paired with cloud-based computation and discovery planforms, further democratizing discoverability to researchers across both large and small institutions, regardless of their on-site informatics infrastructure. These platforms also empower collaboration across institutions and teams through shared, cloud-based workspaces, which reduces duplication of efforts and harnesses the full potential of a diversified stakeholder community that spans researchers, clinicians, and patient communities.

<sup>1</sup> NIH, *Impact of NIH Research: Our Society*, <https://www.nih.gov/about-nih/what-we-do/impact-nih-research/our-society> (last reviewed May 1, 2018). Note that the Department of Defense (DOD) is also a funder of cancer research. DoD funds cancer research through the Peer Reviewed Cancer Research Program (PRCRP), a part of the Congressionally Directed Medical Research Programs (CDMRP). See CDMRP, *Peer Reviewed Cancer*, <https://cdmrp.army.mil/pubs/press/2021/21prcrpreann> (last updated Feb. 23, 2021).

<sup>2</sup> See NIH, *The NIH Almanac: National Cancer Institute (NCI)*, <https://www.nih.gov/about-nih/what-we-do/nih-almanac/national-cancer-institute-nci> (last reviewed Nov. 27, 2019).

<sup>3</sup> The Gabriella Miller Kids First Pediatric Research Program has awarded millions of dollars in grants for childhood cancer research, as well as administering the Gabriella Miller Kids First Data Resource, a large-scale database of clinical and genetic data from patients with childhood cancers and structural birth defects and their families. See Common Fund, *Gabriella Miller Kids First*, NIH, <https://commonfund.nih.gov/kidsfirst> (last reviewed Nov. 18, 2021). The Gabriella Miller Kids First Pediatric Research Program was established through the 2014 Gabriella Miller Kids First Research Act. Pub.L. 113–94 (2014) (codified at 42 U.S.C. 282(b)).

<sup>4</sup> See NCI, *Research on Childhood Cancers*, NIH, <https://cancer.gov/research/areas/childhood> (last updated Sept. 2, 2021).



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<sup>5</sup> *Id.* The Childhood Cancer STAR (Survivorship, Treatment, Access, and Research) Act of 2018 has expanded efforts to collect biospecimens for childhood cancer patients enrolled in NCI-sponsored clinical trials. Pub.L. 115–180 (2018) (codified at 42 U.S.C. 285a-11).

<sup>6</sup> See *The NIH Almanac: National Cancer Institute (NCI)*, *supra* note 2.

<sup>7</sup> There are numerous charitable organizations raising money for childhood cancer research. St. Baldrick's Foundation purports to be the largest non-government funder of childhood cancer research grants. See St. Baldrick's Foundation, *Filling the Funding Gap*, <https://www.stbaldricks.org/filling-the-funding-gap> (last accessed Dec. 24, 2021); St. Baldrick's Foundation, *Announcing St. Baldrick's July 2021 Grants* (Jul. 20, 2021), <https://www.stbaldricks.org/blog/post/announcing-st-baldricks-july-2021-grants>. My own foundation, Smashing Walnuts, has issued several grants and awards to support childhood cancer research. See Trevor Baratto, *Gabriella's Smashing Walnuts makes first grant; \$100K to brain doctor*, LOUDON TIMES-MIRROR (Aug. 26, 2014), [https://www.loudontimes.com/news/gabriellas-smashing-walnuts-makes-first-grant-100k-to-brain-doctor/article\\_f13092f8-5d42-583a-9bf2-b0a14da26c90.html](https://www.loudontimes.com/news/gabriellas-smashing-walnuts-makes-first-grant-100k-to-brain-doctor/article_f13092f8-5d42-583a-9bf2-b0a14da26c90.html); Times-Mirror Staff, *Smashing Walnuts cancer research foundation gives \$55K grant*, LOUDON TIMES-MIRROR (Oct. 21, 2016), [https://www.loudontimes.com/news/smashing-walnuts-cancer-research-foundation-gives-55k-grant/article\\_823b3621-897e-5d77-bf6f-bf5fe33be6c6.html](https://www.loudontimes.com/news/smashing-walnuts-cancer-research-foundation-gives-55k-grant/article_823b3621-897e-5d77-bf6f-bf5fe33be6c6.html); John Battison, *Local nonprofit Smashing Walnuts announces brain cancer research scholarship*, LOUDON TIMES-MIRROR (Aug. 13, 2019), [https://www.loudontimes.com/news/local-nonprofit-smashing-walnuts-announces-brain-cancer-research-scholarship/article\\_047e3f94-bd2e-11e9-b225-f764ba3b10a3.html](https://www.loudontimes.com/news/local-nonprofit-smashing-walnuts-announces-brain-cancer-research-scholarship/article_047e3f94-bd2e-11e9-b225-f764ba3b10a3.html).

<sup>8</sup> See *Research on Childhood Cancers*, *supra* note 4. An NCI-sponsored clinical trial, conducted by COG and led by Alice Yu, M.D., Ph.D., of the University of California, San Diego, led to the approval of the monoclonal antibody dinutuximab (Unituxin). *Id.*

<sup>9</sup> See *Research on Childhood Cancers*, *supra* note 4; see also Diane Singhroy, *The public sector role in funding CAR T technologies*, KNOWLEDGE ECOLOGY INTERNATIONAL (Sept. 2017), [https://www.keionline.org/sites/default/files/CAR-T\\_Singhroy.pdf](https://www.keionline.org/sites/default/files/CAR-T_Singhroy.pdf).

<sup>10</sup> See NCI, *NCI Funded Research Portfolio*, <https://fundedresearch.cancer.gov/ncipportfolio/> (last accessed Dec. 24, 2021). This figure is derived by calculating the amount of childhood cancer funding as a percentage of total NCI funding. Note that this figure does not account for basic science awards, which may have applications to multiple types of cancer.

<sup>11</sup> The Gabriella Miller Kids First Research Act, *supra* note 3.

<sup>12</sup> NIH: Office of Strategic Coordination – The Common Fund, Gabriella Miller Kids First: Funded Research, <https://commonfund.nih.gov/kidsfirst/fundedresearch> (last reviewed Sept. 9, 2021).

<sup>13</sup> Gabriella Miller Kids First Research Program: Data Resource Center, <https://kidsfirstdrc.org/> (last accessed Dec. 24, 2021).

<sup>14</sup> These include clofarabine (2004 for ALL), dinutuximab (2015 for neuroblastoma (NB)), tisagenlecleucel (2017 for ALL), calaspargase pegol-mk (2018 for ALL), selumetinib (2020 for neurofibromatosis type 1 (NF1)) and naxitamab (2020 for NB). See NCI, *Drugs Approved for Childhood Cancers*, [https://www.cancer.gov/about-cancer/treatment/drugs/childhood-cancer-fda-approved-drugs?cid=eb\\_govdel](https://www.cancer.gov/about-cancer/treatment/drugs/childhood-cancer-fda-approved-drugs?cid=eb_govdel) (last updated Aug. 18, 2021). There are a number of additional drugs approved for use in children that were originally approved for cancer treatment in adults, as discussed herein.

<sup>15</sup> Melissa Hudson, et al., *Clinical Ascertainment of Health Outcomes Among Adults Treated for Childhood Cancer*, 309 JAMA 2371 (2013).

<sup>16</sup> See Kristen Benjamin, *Children deserve better: Increase funding of pediatric-cancer research*, SEATTLE TIMES (Oct. 29, 2021), <https://www.seattletimes.com/opinion/children-deserve-better-increase-funding-of-pediatric-cancer-research/>; Meghan Holohan, *'Miracle stories of modern medicine': Despite limited funds, pediatric cancer research succeeds*, TODAY (Feb. 4, 2021), <https://www.today.com/health/world-cancer-day-2021-why-childhood-cancer-gets-limited-funding-t207903>.

<sup>17</sup> Foreign Corrupt Practices Act of 1977 (FCPA), 15 U.S.C. § 78dd-1, et seq.

<sup>18</sup> SEC, *Spotlight on Foreign Corrupt Practices Act*, <https://www.sec.gov/spotlight/foreign-corrupt-practices-act.shtml> (last modified Feb. 2, 2017); SEC, *SEC Enforcement Actions: FCPA Cases*, <https://www.sec.gov/enforce/sec-enforcement-actions-fcpa-cases> (last modified Sept. 29, 2021).

<sup>19</sup> SEC, *SEC Enforcement Actions: FCPA Cases*, *supra* note 18.

<sup>20</sup> Part of SEC's concern may stem from the fact that enforcement activity was unusually low in 2021. To date, there have been just four civil FCPA penalties levied in 2021, none of which were brought against pharmaceutical, cosmetic, supplement, or medical device companies. Low numbers for 2021 may be attributable not only to the ongoing pandemic, but to major upheaval in senior agency staff following the change in administration. See Alan Friedman et al., *FCPA Enforcement Appears Primed to Reemerge*, JD SUPRA (Dec. 21, 2021),

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<https://www.jdsupra.com/legalnews/fcpa-enforcement-appears-primed-to-7605457/>. *Id.* As discussed herein, there are a number of reasons to think that FCPA enforcement will be a priority in 2022 and beyond – leading legal scholars to anticipate that penalties will return to more standard levels in 2022. *Id.*

<sup>21</sup> The White House, Memorandum on Establishing the Fight Against Corruption as a Core United States National Security Interest (2021), <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/06/03/memorandum-on-establishing-the-fight-against-corruption-as-a-core-united-states-national-security-interest/>.

<sup>22</sup> *Id.*

<sup>23</sup> The White House, United States Strategy on Countering Corruption (2021), <https://www.whitehouse.gov/wp-content/uploads/2021/12/United-States-Strategy-on-Countering-Corruption-1.pdf>.

<sup>24</sup> *Id.*

<sup>25</sup> Dylan Tokar, *Justice Department’s Foreign Bribery Unit Adds Prosecutors, Compliance Expertise*, WALL ST. J. (Mar. 8, 2021), <https://www.wsj.com/articles/justice-departments-foreign-bribery-unit-adds-prosecutors-compliance-expertise-11615199402>.

<sup>26</sup> See Nicholas McQuaid, Acting Assistant Attorney General, Dep’t of Justice, Keynote Address at the Foreign Corrupt Practices Act New York (June 2, 2021); see also Clara Hudson, FCPA Enforcement is “In An Entirely New” Place, Says Acting Criminal Division Chief, GLOBAL INVESTIGATIONS REV. (June 2, 2021), <https://globalinvestigationsreview.com/just-anti-corruption/fcpa/fcpa-enforcement-in-entirely-new-place-says-acting-criminal-division-chief>.

<sup>27</sup> See Foreign Corrupt Practices Act Clearinghouse, *2021 3rd Quarter FCPA Report*, <https://fcpa.stanford.edu/fcpac-reports/2021-fcpa-q3-report.pdf> (last accessed Dec. 24, 2021).

<sup>28</sup> 42 U.S.C. § 1395i(k).

<sup>29</sup> Dep’t of Health and Human Services (HHS) & DOJ, *Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2020* (July 2021), <https://oig.hhs.gov/publications/docs/hcfac/FY2020-hcfac.pdf>.

<sup>30</sup> Joan H. Krause, A Patient-Centered Approach to Health Care Fraud Recovery, 96 J. CRIM. L. & CRIMINOLOGY 579, 586 (2006).

<sup>31</sup> 34 U.S.C. § 20101(b).

<sup>32</sup> Dep’t of Justice, *Office for Victims of Crime: Crime Victims Fund*, <https://ovc.ojp.gov/about/crime-victims-fund> (last accessed Dec. 24, 2021).

<sup>33</sup> § 1395i(k), *supra* note 21.

<sup>34</sup> Steve Derene, *Crime Victims Fund Report: Past, Present, and Future*, NATIONAL ASS’N OF VOCA ASSISTANCE ADMINISTRATORS (2005).

<sup>35</sup> Steve Derene, Executive Director, National Ass’n of VOCA Assistance Administrators, Presentation at NAVAA Conference: Crime Victims Fundamentals (Aug. 6, 2018).

<sup>36</sup> HHS and DOJ co-publish an annual report with a detailed breakdown of deposits made into the HI Trust Fund. See DOJ, *Health Care Fraud and Abuse Control Program Annual Reports*, <https://www.justice.gov/criminal-fraud/health-care-fraud-and-abuse-control-program> (updated July 14, 2021).

<sup>37</sup> See Letter from Patrick Leahy, Chair of Senate Comm. on Appropriations, and Jeanne Shaheen, Chair of Subcomm. on Commerce, Justice, Sci. and Related Agencies, Senate Comm. on Appropriations, to Merrick Garland, Attorney General (Mar. 12, 2021), <https://www.shaheen.senate.gov/imo/media/doc/3.12.2021%20Garland%20Letter%20CVF.pdf>; see also Office for Victims of Crime, *2017 OVC Report to the Nation: Fiscal Years 2015-2016*, DOJ, <https://ovc.ojp.gov/sites/g/files/xyckuh226/files/pubs/reporttonation2017/crime-victims-fund.html> (last accessed Dec. 24, 2021).

<sup>38</sup> See Lauren Jett, *News: Addressing Medicare HI Trust Fund Insolvency*, HARVARD MEDICAL SCHOOL (Feb. 2, 2021), <https://hcp.hms.harvard.edu/news/addressing-medicare-hi-trust-fund-insolvency>; Juliette Cubanski and Tricia Neuman, *FAQs on Medicare Financing and Trust Fund Solvency*, Kaiser Family Foundation (Mar. 16, 2021), <https://www.kff.org/medicare/issue-brief/faqs-on-medicare-financing-and-trust-fund-solvency/>.

<sup>39</sup> VOCA Fix to Sustain the Crime Victims Fund Act of 2021, Pub.L. 117–27 (2021) (codified at 34 U.S.C. § 20101 et. Seq.).

<sup>40</sup> See NCI, *Cancer in Children and Adolescents*, <https://www.cancer.gov/types/childhood-cancers/child-adolescent-cancers-fact-sheet> (last reviewed Nov. 4, 2021).

<sup>41</sup> See Gabriella Miller Kids First Research Program: Data Resource Center, *supra* note 13.

<sup>42</sup> *Id.*