



May 3, 2018

Kellyanne Conway  
Counselor to the President of the United States  
The White House  
1600 Pennsylvania Ave. N.W.  
Washington, D.C. 20500

Dear Ms. Conway:

On November 29, 2017, Attorney General Sessions announced that President Trump appointed you to coordinate and lead efforts at the White House in response to the opioid addiction epidemic.

We write you today to request that the Trump Administration support affordable access to treatment and delivery systems that respond to the epidemic. Specifically, we ask that the Administration procure naloxone treatments and supply them to local health and law enforcement programs or authorize such programs to procure generic versions of patented naloxone treatments. Pursuant to 28 U.S.C. § 1498(a)<sup>1</sup>, the Administration should authorize use of any and all patents necessary to allow for the production of generic naloxone treatments and delivery systems to respond to the opioid epidemic, on behalf of the United States Government. This will facilitate competition and make treatment more affordable and accessible.

This request will provide background on the current state of the epidemic; the role of naloxone in the opioid response; how prices of naloxone treatments are acting as barriers to care, inhibiting the ability of our public health system and communities to respond to the opioid crisis; the authority granted to the U.S. government under 28 U.S.C. § 1498(a); and how exercising this authority would help expand access to treatment.

### **Current State of the Opioid Epidemic**

The opioid epidemic is the largest public health crisis in the United States of our time. According to the Center for Disease Control (CDC), every day 115 Americans die from opioid overdose<sup>2</sup> and more than 1,000 people are treated in emergency departments for misusing prescription opioids.<sup>3</sup> In 2016, more

---

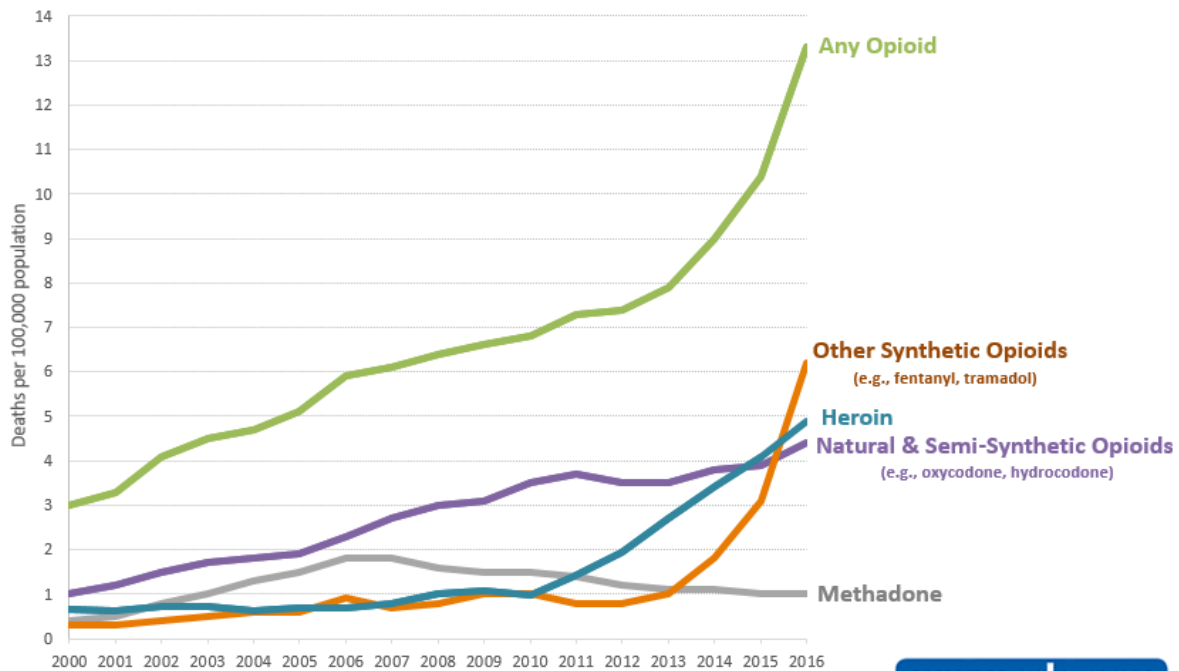
<sup>1</sup> "Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture."

<sup>2</sup> U.S. Centers for Disease Control and Prevention. (August 30, 2017). Understanding the Epidemic. Retrieved January 23, 2018, from <https://www.cdc.gov/drugoverdose/epidemic/index.html>

<sup>3</sup> U.S. Centers for Disease Control and Prevention. (August 1, 2017). Prescription Opioid Overdose Data. Retrieved January 23, 2018, from <https://www.cdc.gov/drugoverdose/data/overdose.html>

than 63,600 people died from overdose<sup>4</sup> – more than the number of people killed by gun homicide and in car accidents combined.<sup>5</sup> More than six-in-10 of the deaths from drug overdose in 2016 involved an opioid.<sup>6</sup> While the rate of increase in opioid death rates has slowed, policy responses thus far have been inadequate to begin reducing the number of deaths.<sup>7</sup>

### Overdose Deaths Involving Opioids, by Type of Opioid, United States, 2000-2016



SOURCE: CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER, Atlanta, GA; US Department of Health and Human Services, CDC; 2016. <https://wonder.cdc.gov/>.



Source: U.S. Centers for Disease Control and Prevention. (February 9, 2017). Opioid Data Analysis. Available at: <https://www.cdc.gov/drugoverdose/data/analysis.html>

Men in the 25-34, 35-44, and 45-54 age groups have the highest death rates, collectively representing nearly half of all opioid-related deaths in 2016.<sup>8</sup> Some areas of the country have been hit particularly hard by the epidemic. West Virginia, New Hampshire, Ohio, the District of Colombia and Maryland have been the most strongly affected, but the epidemic harms communities across the country.<sup>9</sup>

<sup>4</sup> U.S. Centers for Disease Control and Prevention. (December 2017). NCHS Data Brief No. 294: Drug Overdose Deaths in the United States, 1999–2016. Retrieved January 23, 2018, from <https://www.cdc.gov/nchs/products/databriefs/db294.htm>

<sup>5</sup> Centers for Disease Control and Prevention. CDC Wonder. Accessed January 15, 2018. <http://wonder.cdc.gov/>

<sup>6</sup> U.S. Centers for Disease Control and Prevention. (December 2017). NCHS Data Brief No. 294: Drug Overdose Deaths in the United States, 1999–2016. Retrieved January 23, 2018, from <https://www.cdc.gov/nchs/products/databriefs/db294.htm>

<sup>7</sup> Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. MMWR Morb Mortal Wkly Rep 2016; 65:1445–1452. DOI: <http://dx.doi.org/10.15585/mmwr.mm650501e1>

<sup>8</sup> Centers for Disease Control and Prevention. CDC Wonder. Accessed January 15, 2018. <http://wonder.cdc.gov/>

<sup>9</sup> Ibid.

While overdose death rates involving natural and synthetic opioids, with the exception of methadone, have been rising across the board, the most drastic increase has been in deaths involving non-methadone synthetic opioids like fentanyl, which spiked 72.2% from 2010 to 2015.<sup>10</sup> Fentanyl is especially dangerous, as it is 50 to 100 times more potent than morphine and is sometimes illicitly distributed in forms that mimic other, less powerful opioids, increasing risk of overdose.<sup>11</sup>

### **The Role of Naloxone in the Response**

There is broad consensus that responding to the opioid epidemic requires a comprehensive approach, and that part of that approach should include increasing utilization of easy-to-use naloxone treatments.

Naloxone was first approved by the FDA in 1971 for reversing opioid intoxication or overdose.<sup>12</sup> In more recent years, easy-to-use forms of naloxone have received FDA approval, including an auto-injector formulation (brand name Evzio) in 2014 and a nasal-spray formulation (brand name Narcan) in 2015.<sup>13</sup> While older forms of naloxone that are intended for use in healthcare settings are sometimes used off-label in community settings, Evzio and Narcan were the first naloxone products that were approved that are intended for community use.<sup>14</sup> Experts have increasingly called for expanded access to naloxone for people struggling with addiction and those around them – people who most benefit from having an easy-to-use form of the drug – under the premise that if someone nearby overdoses, “dispensing the drug should be as easy as pulling a fire alarm.”<sup>15</sup>

The CDC urgently calls for “[a] multifaceted, collaborative public health and law enforcement approach” to respond to the epidemic, including “expanding naloxone distribution.”<sup>16</sup>

In its 2015 issue brief on “Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Death,” HHS calls for expanded utilization of naloxone and to accelerate the development of new naloxone formulations and user friendly products, like auto-injectors.<sup>17</sup>

---

<sup>10</sup> Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. *MMWR Morb Mortal Wkly Rep* 2016; 65:1445–1452. DOI: <http://dx.doi.org/10.15585/mmwr.mm6505051e1>. Retrieved January 23, 2018, from <https://www.cdc.gov/mmwr/volumes/65/wr/mm6505051e1.htm>

<sup>11</sup> National Institute of Drug Abuse. (June 2016). Drug Facts: Fentanyl. Retrieved January 23, 2018, from <https://www.drugabuse.gov/publications/drugfacts/fentanyl>

<sup>12</sup> Gupta, R., Shah, N.D., & Ross J.S. (December 8, 2016). The Rising Price of Naloxone — Risks to Efforts to Stem Overdose Deaths. *The New England Journal of Medicine*, 375:2213-2215. Retrieved January 24, 2018, from <http://www.nejm.org/doi/full/10.1056/NEJMp1609578#t=article>

<sup>13</sup> Ibid.

<sup>14</sup> Nadel, J. (October 5, 2016). Clinical and Regulatory Perspectives on Naloxone Products Intended for Use in the Community [PowerPoint slides]. Retrieved January 24, 2018 from <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM524332.pdf>

<sup>15</sup> Luthra, S. (2017, January 30). Getting Patients Hooked On An Opioid Overdose Antidote, Then Raising The Price. *Kaiser Health News*. Retrieved March 8, 2018, from <https://khn.org/news/getting-patients-hooked-on-an-opioid-overdose-antidote-then-raising-the-price/>

<sup>16</sup> Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. *MMWR Morb Mortal Wkly Rep* 2016; 65:1445–1452. DOI: <http://dx.doi.org/10.15585/mmwr.mm6505051e1>

<sup>17</sup> U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation. (March 26, 2015). ASPE Issue Brief: Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths. Retrieved January 25, 2018, from [https://aspe.hhs.gov/system/files/pdf/107956/ib\\_OpioidInitiative.pdf](https://aspe.hhs.gov/system/files/pdf/107956/ib_OpioidInitiative.pdf)

In November, 2015, a diverse group of experts convened by the Johns Hopkins Bloomberg School of Public Health and the Clinton Foundation issued a comprehensive set of recommendations for responding to the epidemic.<sup>18</sup> Their recommendations include a call for naloxone formulations that are easier to use by nonmedical personnel and less costly to deliver, stating that “[p]rice is consistently raised as a concern impacting the sustainability of various naloxone distribution programs,” and that “the cost of the drug is increasing dramatically.”<sup>19</sup>

The final report of the President’s Commission on Combatting Drug Addiction and the Opioid Crisis calls for expanded access to naloxone treatment, to “ensur[e] naloxone is made as widely available as possible to save lives,” all law enforcement officials to be equipped with naloxone and revisions to National Highway Traffic Safety Administration guidance to allow for more first responders to be equipped with Naloxone.<sup>20</sup>

Most recently, on April 5, 2018, the Surgeon General issued an Advisory on Naloxone and Opioid Overdose emphasizing the importance of naloxone. Surgeon General Vice Admiral Jerome M. Adams states in the advisory states that “increasing the availability and targeted distribution of naloxone is a critical component of our efforts to reduce opioid-related overdose deaths and, when combined with the availability of effective treatment, to ending the opioid epidemic.”<sup>21</sup>

### **Naloxone Pricing Abuses and Access / Rationing**

Despite the consensus around the need to expand access to naloxone to save the lives of people overdosing on opioids as part of a comprehensive approach to help people recover from opioid addiction, prices of these treatments, anchored by patent monopolies, pose barriers to care.

Kaléo Pharmaceuticals severely spiked the price of one of these important treatments in recent years. Early in 2017, Kaléo Pharmaceuticals raised the price of a two-pack of its naloxone auto-injector, Evzio, from \$690 to \$4,500.<sup>22</sup> While the price for a two-pack of the Narcan naloxone nasal spray has remained steady at \$150 since its introduction in 2015, this represents a significant premium over prices for vials of generic naloxone.<sup>23</sup>

---

<sup>18</sup> Alexander GC, Frattaroli S, Gielen AC, eds. *The Prescription Opioid Epidemic: An Evidence-Based Approach*. Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland: 2015. Retrieved January 25, 2018 from [https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH\\_OPIOID\\_EPIDEMIC\\_REPORT.pdf](https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf)

<sup>19</sup> Ibid.

<sup>20</sup> The President's Commission on Combatting Drug Addiction and the Opioid Crisis. (November 1, 2017). Final Report. Retrieved January 25, 2018 from [https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final\\_Report\\_Draft\\_11-1-2017.pdf](https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf)

<sup>21</sup> U.S. Department of Health and Human Services Office of the Surgeon General. (April 5, 2018). Surgeon General's Advisory on Naloxone and Opioid Overdose. Retrieved April 5, 2018 from <https://www.surgeongeneral.gov/priorities/opioid-overdose-prevention/naloxone-advisory.html>

<sup>22</sup> Sen. Patrick Leahy, et. al. (February 8, 2017). Letter to Mr. Spencer Williamson, Kaleo Pharmaceuticals. Retrieved January 25, 2018 from [https://www.leahy.senate.gov/imo/media/doc/kaleo\\_final02082017.pdf](https://www.leahy.senate.gov/imo/media/doc/kaleo_final02082017.pdf)

<sup>23</sup> Gupta, R., Shah, N.D., & Ross J.S. (December 8, 2016). The Rising Price of Naloxone — Risks to Efforts to Stem Overdose Deaths. *The New England Journal of Medicine*, 375:2213-2215. Retrieved January 24, 2018, from <http://www.nejm.org/doi/full/10.1056/NEJMp1609578#t=article>

While ADAPT Pharma provides a 50% discount on Narcan to certain purchasers, like first responders, other payers do not have access to this price.<sup>24</sup> Kaléo advertises that Evzio is available to U.S. patients with commercial insurance without copay and offers it for free to certain patients.<sup>25,26</sup> The Clinton Foundation announced in January 2015 that it had reached an arrangement with Kaléo to make the Federal Supply Schedule (FSS) price that is paid by certain federal agencies available to local municipalities<sup>27</sup>, but FSS prices for Evzio range from \$573.41 to \$4,038.19 per two-pack.<sup>28</sup> The price of \$180 per auto-injector newly available to government programs for Evzio is a modest improvement, but still nearly five-times that of Narcan (\$37.50 per dose), which itself is too expensive for public health programs to meet demand and is resulting in treatment rationing.<sup>29</sup> By way of contrast, in India, a dose of naloxone is available for as little as 15 cents<sup>30</sup>; and in 2009, here in the United States, a vial of naloxone cost \$4.<sup>31</sup> The EpiPen auto-injector, which is similar to the in its functionality to Evzio, but administers epinephrine, has component costs between \$2 and \$4 according to a medical technology consultant.<sup>32</sup>

The President's Commission recognized price as a barrier to naloxone access in its report, stating, "price increases of the various forms of naloxone continue to create affordability issues, preventing state and local governments, as well as community organizations, from stocking naloxone at the levels necessary to rescue more people from overdose."<sup>33</sup>

Naloxone price spikes are being felt in communities across the nation.<sup>34</sup> Tom Miller, the West Virginia director of the National Volunteer Fire Council stated that many in the state have "trouble getting

---

<sup>24</sup> ADAPT Pharma. Narcan® Nasal Spray Affordability. Retrieved January 25, 2018, from <https://www.narcan.com/affordability>

<sup>25</sup> Kaléo Pharmaceuticals. EVZIO2YOU DIRECT-DELIVERY SERVICE. Retrieved March 8, 2018, from <https://www.evzio.com/patient/evzio2you/>

<sup>26</sup> Kaléo Pharmaceuticals. KALÉO CARES PATIENT ASSISTANCE PROGRAM. Retrieved March 8, 2018, from <https://www.evzio.com/patient/kaleo-cares/>

<sup>27</sup> Tavernise, S. (2015, January 26). Treatment of Overdose Will Cost Cities Less. New York Times. Retrieved April 30, 2018, from <https://www.nytimes.com/2015/01/27/science/treatment-of-overdose-will-cost-cities-less.html>

<sup>28</sup> U.S. Department of Veterans Affairs Office of Acquisition and Logistics. Federal Supply Schedule Pharmaceutical Pricing database. Accessed April 30, 2018. <https://www.va.gov/oal/business/fss/pharmPrices.asp>

<sup>29</sup> Kaléo Pharmaceuticals. (April 5, 2018) EVZIO® (naloxone HCl injection, USP) Auto-Injector Now Available to Patients in Select States Without a Prescription Through Kaléo's New Virtual Standing Order Pilot Program and to Government Agencies at a Direct Purchase Price. Retrieved April 24, 2018, from <https://www.prnewswire.com/news-releases/evzio-naloxone-hcl-injection-usp-auto-injector-now-available-to-patients-in-select-states-without-a-prescription-through-kaleos-new-virtual-standing-order-pilot-program-and-to-government-agencies-at-a-direct-purchase-price-300624974.html>

<sup>30</sup> indiamart. Naloxone Traders & wholesalers. Retrieved April 30, 2018 from <https://dir.indiamart.com/search.mp?ss=naloxone>

<sup>31</sup> Kodjak, A. (2017, August 8). First Responders Spending More On Overdose Reversal Drug. Retrieved April 30, 2018 from <https://www.npr.org/sections/health-shots/2017/08/08/541626627/first-responders-spending-more-on-overdose-reversal-drug>

<sup>32</sup> White, M. (2016, September 7). It's Jaw-Dropping How Little It Costs to Make an EpiPen. Time. Retrieved April 30, 2018, from <http://time.com/money/4481786/how-much-epipen-costs-to-make/>

<sup>33</sup> The President's Commission on Combatting Drug Addiction and the Opioid Crisis. (November 1, 2017). Final Report. Retrieved January 25, 2018 from [https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final\\_Report\\_Draft\\_11-1-2017.pdf](https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf)

<sup>34</sup> Zezima, K. (2017, November 21). As opioid crisis worsens, a drug used to reverse overdoses can be difficult to access. Washington Post. Retrieved January 25, 2018, from <https://www.washingtonpost.com/national/2017/11/21/as-opioid-crisis-worsens-a-drug-used-to-reverse-overdoses-can-be-difficult-to-access/>

[naloxone] and getting it replaced.”<sup>35</sup> Chris Bell, Director of Vermont’s Division of Emergency Preparedness, Response & Injury Prevention, stated that because of Evzio’s high price, it is not an option for the state’s distribution centers set up to get naloxone to people who use opioids.<sup>36</sup> Eliza Wheeler of the Harm Reduction Coalition in San Francisco says that naloxone price increases are causing nonprofit groups that distribute naloxone to limit their operations, and that “To reduce mortality you need to flood the community of drug users with naloxone. [...] That model is only effective if we have a low-cost product.”<sup>37</sup>

As Dr. Eric Ketcham testified before the U.S. House of Representatives Judiciary Subcommittee on Regulatory Reform, Commercial and Antitrust Law in September, 2016, “The pricing of [buprenorphine and naloxone] medications by several pharmaceutical companies obstructs access to treatment for opioid addiction and overdose in America, and thus prolongs the scourge of heroin and prescription opioid addiction, and puts American lives at risk.”<sup>38</sup>

In Baltimore, everyday residents have used naloxone to save more than 1,800 lives since 2015. This total does not include lives saved by first responders, who reversed more than 10,000 overdoses over the same time period. Baltimore City has approximately \$1,000,000 per year to spend on naloxone, which at the discounted rate of \$75 per Narcan kit purchases about 13,000 kits. To have enough kits for every Baltimore City resident with opioid use disorder—let alone kits for their loved ones or for other community members—that number would need to be doubled. Even with a newly reduced public interest price, Evzio remains prohibitively expensive for BCHD and other local health departments. Kaléo has donated Evzio kits to BCHD, but the city cannot rely on donations alone. High prices have forced the BCHD to ration treatment, constantly stretching supplies that could be distributed in a week across months.<sup>39</sup>

Baltimore City has not reached naloxone saturation; there is significant unmet demand. If, for example, the price of naloxone were cut in half, Baltimore would be able to purchase twice as many doses and plausibly save hundreds more lives every year. Lower naloxone prices would translate directly into more naloxone to distribute in the community, which would mean that fewer people die from opioid overdose.

---

<sup>35</sup> Ibid.

<sup>36</sup> Luthra, S. (2017, January 30). Getting Patients Hooked On An Opioid Overdose Antidote, Then Raising The Price. Kaiser Health News. Retrieved March 8, 2018, from <https://khn.org/news/getting-patients-hooked-on-an-opioid-overdose-antidote-then-raising-the-price/>

<sup>37</sup> Petersen, M. (2016, July 27). As need grows for painkiller overdose treatment, companies raise prices. Los Angeles Times. Retrieved January 25, 2018, from <http://www.latimes.com/business/la-fi-naloxone-sales-20160707-snap-story.html>

<sup>38</sup> Ketcham, Eric. (2016, September 22). Statement Before the Judiciary Subcommittee on Regulatory Reform, Commercial and Antitrust Law, U.S. House of Representatives, Hearing on "Treating the Opioid Epidemic: The State of Competition in the Markets for Addiction Medicine". Retrieved January 25, 2018 from <https://judiciary.house.gov/wp-content/uploads/2016/09/Ketcham-Testimony-.pdf>

<sup>39</sup> Facher, L., & Joseph, A. (2017, October 27). In White House opioid plan, advocates see a major puzzle piece missing: naloxone. STAT News. Retrieved January 25, 2018, from <https://www.statnews.com/2017/10/27/naloxone-story/>



## **Background on 28 U.S.C. § 1498**

Existing law, 28 U.S.C. § 1498, gives the U.S. government the authority to make or purchase a patented invention without the permission of the patent holder in exchange for reasonable compensation.<sup>40</sup> When the government exercises its authority under § 1498, the patent holder may not seek injunctive relief, nor can a government contractor or subcontractor be held liable for infringement by the patent holder.<sup>41</sup>

The government routinely relies on § 1498 to use or acquire a wide array of patented inventions without permission of the patent holder, ranging from fraud detection banking software and electronic passports to methods of removing hazardous waste and genetically mutated mice.<sup>42</sup>

In the pharmaceutical context, through § 1498, the government could either produce a patented medicine or contract with generic producers to manufacture the medicine or drug-device combination product. In exchange, the government would provide the patent holder with compensation. If the patent holder does not believe it has been adequately compensated, it can sue the government over the level of compensation, but it may not prevent the government or a government contractor from making use of the patent.<sup>43</sup>

§ 1498 requires that the government provides the patent holder with “reasonable and entire compensation” in exchange for making use of its patent. In modern cases on compensation under § 1498, the appropriate level of compensation has consistently been determined to be a reasonable royalty payment and not “lost profits.”<sup>44</sup> What is deemed an appropriate royalty payment is determined by previous licenses, where they exist, or rely on a range of factors, such as the “willing buyer, willing seller” rule, and a set of considerations known as the “*Georgia-Pacific* factors”.<sup>45</sup> Previously, some courts have also ruled that reasonable compensation should reflect development costs plus a reasonable return on investment.<sup>46</sup>

The most recent use of § 1498 in the pharmaceutical context was in 2001, when then-Secretary of Health and Human Services, Tommy Thompson, publicly considered using the authority to procure generic ciprofloxacin during the post-September 11th anthrax scare.<sup>47</sup> The ciprofloxacin patent holder, Bayer, quickly cut its prices in half.<sup>48</sup>

## **Invoking 28 U.S.C. § 1498 in the Opioid Addiction Epidemic Response**

As detailed above, access to naloxone is integral to the ability of our country to adequately respond to the opioid addiction crisis we face. Excessive prices rooted in government-granted patent monopolies are currently serving as barriers to that access.

---

<sup>40</sup> Brennan, Hannah; Kapczynski, Amy; Monahan, Christine H.; and Rizvi, Zain. "A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health," Yale Journal of Law and Technology: Vol. 18 : Iss. 1 , Article 7. Available at: <http://digitalcommons.law.yale.edu/yjolt/vol18/iss1/7>

<sup>41</sup> Ibid.

<sup>42</sup> Ibid.

<sup>43</sup> Ibid.

<sup>44</sup> Ibid.

<sup>45</sup> Ibid.

<sup>46</sup> Ibid.

<sup>47</sup> Ibid.

<sup>48</sup> Ibid.

Narcan is protected by seven patents that expire in March 2035, while Evzio is protected by 25 patents, the latest of which expires in July, 2034.<sup>49</sup> Neither is protected by FDA-granted regulatory exclusivity, and the active ingredient in these products, naloxone, is not patent protected.

The government establishing a program to purchase naloxone, allowing for competitive supply under § 1498, would be an important step towards ensuring that patients have access to medicines that are vital to the nation's opioid response, and that high prices do not result in treatment rationing.

One possible model for such a program is the Vaccines for Children (VFC) Program.<sup>50</sup> Under the VFC Program, the CDC purchases vaccines at a discount and distributes them to state health departments and certain local and territorial public health agencies, which then provide them at no charge to physicians' offices and clinics that are registered as VFC providers.<sup>51</sup> Putting in place a similar program for naloxone purchasing and distribution and exercising its authority under § 1498 would allow the government purchase naloxone indicated for community use at lower cost and distribute it to local health departments, police departments, fire departments, first responders and others at the front lines of combatting the opioid addiction epidemic.

Alternatively, the federal government could authorize states and territories that receive federal funding through State Targeted Opioid Response Grant program; as well as local jurisdictions within those states and territories, including local health departments, police departments, fire departments, first responders and others; to procure naloxone indicated for community use from generic manufacturers that put out competitive bids. In this instance, the states and local authorities would be acting as agents of the federal government, and using delegated authority pursuant to § 1498, similar to how federal contractors employ § 1498 government use authority.

Generic competition has consistently proven the most effective means of reducing prices and ensuring prices continue to fall over time. A recent study in the *New England Journal of Medicine* found that, on average, drugs with three generic manufacturers are priced at 60% of the brand name level.<sup>52</sup> Drugs with five manufacturers are priced at less than half the brand price, and that prices of drugs with 10 or more manufacturers are only about one-fifth of brand prices.<sup>53</sup>

While trained paramedics may use generic intramuscular and intranasal naloxone, in many situations Narcan and Evzio are favored by providers and health care systems because they are designed and FDA-approved for bystander administration.<sup>54</sup> But the amount of naloxone that public health programs currently are able to purchase under the prices set by Kaléo and ADAPT Pharma is insufficient to meet the demands for these treatments. At current prices, for every \$75 that public health programs and first responders do not have to spend on a Narcan kit, it is potentially two people dying. Public programs report the price of Evzio being prohibitive for purchase. Communities are being forced to ration

---

<sup>49</sup> U.S. Food and Drug Administration. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Accessed April 13, 2018. <https://www.accessdata.fda.gov/scripts/cder/ob/>

<sup>50</sup> U.S. Centers for Disease Control and Prevention. (February 18, 2016). Vaccines for Children Program (VFC). Retrieved April 5, 2018, from <https://www.cdc.gov/vaccines/programs/vfc/about/index.html>

<sup>51</sup> Ibid.

<sup>52</sup> Dave, C. V., Hartzema, A., & Kesselheim, A. S. (2017). Prices of Generic Drugs Associated with Numbers of Manufacturers. *New England Journal of Medicine*, 377(26), 2597-2598. doi:10.1056/nejmc1711899

<sup>53</sup> Ibid.

<sup>54</sup> Kerensky, T., & Walley, A. Y. (2017). Opioid overdose prevention and naloxone rescue kits: what we know and what we don't know. *Addiction Science & Clinical Practice*, 12(1). doi:10.1186/s13722-016-0068-3



naloxone treatment and make decisions about who will receive lifesaving medication. Establishing a program that purchases low-cost generic naloxone under § 1498 and distributes it to communities in need would be a boon to efforts to combat the crisis and reduce the number of opioid-related deaths.

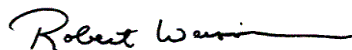
Therefore, to reiterate, we request that the Trump Administration establish a national program to procure naloxone treatments and supply them to state and local health and law enforcement programs responding to the epidemic or authorize state and local programs to procure generic versions of patented naloxone treatments. Pursuant to 28 U.S.C. § 1498(a), the Administration should authorize use of any and all patents necessary to allow for the production of generic naloxone treatments and delivery systems to respond to the opioid epidemic, on behalf of the United States Government.

We also ask the Trump Administration to explore the impacts of prices on access to naloxone/buprenorphine and naltrexone medication-assisted treatments, and to what extent permitting generic competition through § 1498 would improve access. While other, non-pricing barriers exist that prevent patients from receiving medication-assisted treatment, to the extent high prices inhibit access, the U.S. government should do everything in its power to remove that treatment barrier, including through exercising its § 1498 authority.

The U.S. government must place the people and families across the country impacted by this epidemic above the ability of pharmaceutical companies to set unaffordable prices with impunity.

Please contact Steven Knievel ([sknievel@citizen.org](mailto:sknievel@citizen.org)), Access to Medicines Advocate at Public Citizen and Evan Behrle ([Evan.Behrle@baltimorecity.gov](mailto:Evan.Behrle@baltimorecity.gov)), Special Advisor, Opioid Policy at the Baltimore City Health Department, about this request.

Sincerely,



Robert Weissman, President  
Public Citizen  
1600 20th St. NW  
Washington, DC 20009



Dr. Leana Wen, Commissioner  
Baltimore City Health Department  
1001 E. Fayette Street  
Baltimore, MD 21202

### **About the Petitioners**

The Baltimore City Health Department is the oldest, continuously-operating health department in the United States, formed in 1793, when the governor appointed the city's first health officers in response to a yellow fever outbreak in the Fells Point neighborhood. During the more than 220 years since then, the Baltimore City Health Department has been working to improve the health and well-being of Baltimore residents, striving to make Baltimore a city where all residents realize their full health potential.

Public Citizen is a national consumer advocacy organization with more than 400,000 members and supporters. Public Citizen advocates in an array of issue areas to advance the public interest, including ensuring prescription drugs meet high safety and efficacy standards and are made more affordable both in the U.S. and abroad.