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March 29, 2018

Ms. Kellyanne Conway
Counselor to the President

Mr. James Carroll
Acting Director, Office of National Drug Control Policy
oipl@ondcp.eop.gov

Dear Ms. Conway and Mr. Carroll;

We are writing to ask that the Trump Administration use its authority under 28 USC § 1498(a) to authorize third parties to manufacture and sell affordable versions of two devices which deliver naloxone to treat persons suffering from an opioid overdose. This statute allows the federal government to authorize third parties to use patented inventions without the permission of the patent holder, if the use is by or for the federal government.

As you know, opioid overdose deaths in the United States have been rising throughout the past decades, and represent a significant public health concern across the country. Data from 2016, the most recent year for which it is available, showed that opioids were involved in 42,249 deaths. It is critical that first responders have the necessary tools at their disposal to save the lives of overdose victims before it is too late, and that friends, family, and colleagues are also able to access the devices that can save the life of a loved one.

Naloxone was first approved by the FDA as a priority drug on April 13, 1971, nearly 47 years ago, and the drug itself is not expensive. However, first responders prefer to use the drug in connection with delivery mechanisms that make its use safer and more effective, and these particular mechanisms are more useful for non-medical personnel. These safer and more effective devices are very expensive.

The two leading technologies are the Evzio and Narcan devices.

Narcan, which provides 4mg of naloxone through a nasal spray and is marketed by Adapt Pharma, has a price of \$150 for a set of two single use nasal spray devices. Some patients need several doses. Narcan is currently protected by seven patents, which are assigned to Adapt Pharma Limited, Opiant Pharmaceuticals, and Lightlake Therapeutics.

Evzio is an auto-injector of naloxone marketed by kaléo Inc. (Until 2014, kaléo was named Intelliject). This is the only naloxone auto-injector currently approved by the FDA, and provides a rapid dose of 2 mg of naloxone, and features both written and audio instructions for users, making it a useful tool not only for police or paramedics who may respond first to a call, but also for the family and friends of those who may suffer an overdose. Kaléo has filed 25 patents in the FDA Orange Book for Evzio, including several patents with similar names and the same priority dates, all listing two brothers, Evan and Eric Edwards, among the inventors.

Kaléo first put Evzio on the market in 2014 at a price of \$690 for a set of two auto-injectors. The product, also known as intramuscular naloxone, is intended for single use, and it is not uncommon for some overdose patients to require multiple doses for revival. Kaléo has capitalized on the worsening epidemic, raising the price of Evzio over 500 percent, to a current list price of \$4,500.

A consequence of the high price for the Evzio device is a combination of fiscal strain on the local budgets for first responders, or worse, a lack of access to the technology when it is needed.¹

The federal government can take action to moderate the price and to expand access to these life saving technologies.

The United States Government can authorize third parties to use any patents without the permission of the patent holder, when the use is by or for the federal government. In this case, the federal government is leading an effort to address the opioid epidemic and searching for ways to save lives. One concrete step would be to notify kaléo that unless the company rolls back its 500 percent increased price for Evzio, the U.S. will grant compulsory licenses on all of its patents, and authorize local responders of all types of to acquire less expensive versions

¹ There have been numerous instances in which the high cost of opioid-reversal medication has led to calls for rationing from local governments faced with constraints on first responder budgets. In June of 2017, the city council in Middletown, Ohio, discussed a three strikes policy for patients who overdose repeatedly, at which point first responders would no longer revive them. A few weeks later, a county commissioner in Martin County, Florida, discussed a similar proposal. The prohibitive cost of naloxone, a generic drug, completely due to patents on delivery devices, has raised concerns in Philadelphia, Baltimore, Allegany County Maryland, Cincinnati, and in countless other towns and counties across the country. For further reading, see:

Cleve R. Wootson Jr, "[One politician's solution to the overdose problem: Let addicts die](#)" *The Washington Post*, June 30, 2017.

Julius Whigham II, "[Should OD rescues be limited? Questions rise as Narcan's cost soars](#)" *Palm Beach Post*, July 20, 2017.

Christopher Moraff, "[Narcan Prices are Skyrocketing and Cities are Begging for Help to Buy It](#)" *The Daily Beast*, September 8, 2016.

Meredith Cohn, "[Cost of overdose drug could hamper access in Maryland and elsewhere](#)" *The Baltimore Sun*, February 13, 2017.

Heather Wolford, "[Decreased revenue, increased Narcan fee, shoot up cost of Allegany County EMS overdose calls](#)" *Cumberland Times-News*, September 14, 2017.

T.J. Parker, "[Cost of Narcan taking a bite out of emergency responders' budgets](#)" WCPO Cincinnati, April 13, 2017.

from new manufacturers. Even though it will take awhile for the competitors to enter the market, the compulsory license on the patents will shorten the effective monopoly, and that will give the federal government leverage to negotiate lower prices.

The legal basis for the compulsory license is 28 U.S.C. § 1498, which states:

(a) 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.

And, for clarity, the statute also says:

For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.

Government invocation of 28 U.S.C. § 1498 in order to improve access to overdose reversal treatment would be a strong, impactful action to correct the price gouging that these companies are engaging in.

The principal objection to the use of 28 U.S.C. § 1498 for the compulsory licensing of patents that is most often raised concerns the uncertainty regarding the compensation to the patent holder, a view expressed in 2002 by Alex Azar in connection with efforts to obtain sufficient quantities of ciprofloxacin for a stockpile.² We believe § 1498 is particularly appropriate for cases where the federal government has rights in some but not all relevant patents (as may be the case for Gilead's sofosbuvir, per KEI's recent letter to Secretary Azar on the issue of undisclosed federal funding³), where the use is for something that would not normally constitute a market for a product (e.g., the creation of a stockpile of ciprofloxacin to protect against an antibiotic resistant strain of anthrax poisoning in the wake of possible terror attack), or to remedy an excessive and unjustified price hike, which is the case for Evzio.

In any case, by authorizing third parties to make Evzio-like devices today, the issue of the compensation to the patent holders can be resolved before decisions have to be made on purchases. The court-ordered compensation is expected to be considerably less than the price kaléo is charging for the product, particularly if the court applies a conventional single-digit royalty against the older price or the competing device price. By framing the decision as one to

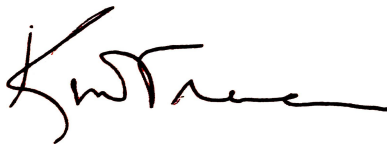
² Alex Azar II. CIPRO: Good Deal, Good Policy; Letters, The American Lawyer, April, 2002.

³ <https://www.keionline.org/27205>

remedy an excessive and unjustified price hike and to expand access for first responders, the government is also providing a context that will make it less likely that the court will set a royalty that frustrates the government's policy objective.

By beginning the process of overriding the exclusive rights in the Evzio patents, kaléo will have a strong incentive to avoid the compulsory license, and the Trump Administration will have an opportunity to lower the prices, and consequently save lives. To do nothing is the worst option, since the current outcome is unacceptably bad for first responders and patients.

We request a meeting to discuss this proposal in further detail.

A handwritten signature in black ink, appearing to read "Kim Treanor". The signature is fluid and cursive, with the first name "Kim" and last name "Treanor" clearly distinguishable.

Kim Treanor
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