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## AFFIDAVIT OF CHRISTOPHER BUTLER

1. I am the Office Manager at the Internet Archive, located in San Francisco, California. I make this declaration of my own personal knowledge.

2. The Internet Archive is a website that provides access to a digital library of Internet sites and other cultural artifacts in digital form. Like a paper library, we provide free access to researchers, historians, scholars, and the general public. The Internet Archive has partnered with and receives support from various institutions, including the Library of Congress.

3. The Internet Archive has created a service known as the Wayback Machine. The Wayback Machine makes it possible to surf more than 450 billion pages stored in the Internet Archive's web archive. Visitors to the Wayback Machine can search archives by URL (i.e., a website address). If archived records for a URL are available, the visitor will be presented with a list of available dates. The visitor may select one of those dates, and then begin surfing on an archived version of the Web. The links on the archived files, when served by the Wayback Machine, point to other archived files (whether HTML pages or images). If a visitor clicks on a link on an archived page, the Wayback Machine will serve the archived file with the closest available date to the page upon which the link appeared and was clicked.

4. The archived data made viewable and browseable by the Wayback Machine is compiled using software programs known as crawlers, which surf the Web and automatically store copies of web files, preserving these files as they exist at the point of time of capture.

5. The Internet Archive assigns a URL on its site to the archived files in the format `http://web.archive.org/web/[Year in yyyy][Month in mm][Day in dd][Time code in hh:mm:ss]/[Archived URL]`. Thus, the Internet Archive URL `http://web.archive.org/web/19970126045828/http://www.archive.org/` would be the URL for the record of the Internet Archive home page HTML file (`http://www.archive.org/`) archived on January 26, 1997 at 4:58 a.m. and 28 seconds (1997/01/26 at 04:58:28). A web browser may be set such that a printout from it will display the URL of a web page in the printout's footer. The date assigned by the Internet Archive applies to the HTML file but not to image files linked therein. Thus images that appear on a page may not have been archived on the same date as the HTML file. Likewise, if a website is designed with "frames," the date assigned by the Internet Archive applies to the frameset as a whole, and not the individual pages within each frame.

6. Attached hereto as Exhibit A are true and accurate copies of printouts of the Internet Archive's records of the HTML files or PDF files for the URLs and the dates specified in the footer of the printout (HTML) or attached coversheet (PDF).

7. I declare under penalty of perjury that the foregoing is true and correct.

DATE: 12/17/18

  
\_\_\_\_\_  
Christopher Butler

CALIFORNIA JURAT

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See Attached Document.

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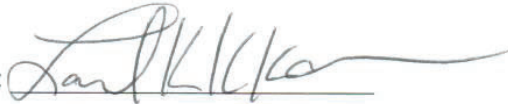
Subscribed and sworn to (or affirmed) before me on this

17 day of December, 2018, by

Christopher Butler,

proved to me on the basis of satisfactory evidence to be the person who appeared before me.

Signature:



# Exhibit A

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## Drugs

### Role of Naloxone in Opioid Overdose Fatality Prevention; Request for Comments; Public Workshop

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), in collaboration with the Office of the Assistant Secretary for Health, National Institutes of Drug Abuse and the Centers for Disease Control and Prevention, is announcing a scientific workshop to initiate a public discussion about the potential value of making naloxone more widely available outside of conventional medical settings to reduce the incidence of opioid overdose fatalities. Academia, government, industry experts and patient advocates will be assembled to discuss which populations are at-risk for opioid overdose and how public health groups are working together to curb the abuse of opioids. We will also seek to identify potential health concerns, social concerns, legal concerns, regulatory issues and future research needs related to making naloxone more widely available.

**Date:** April 12, 2012

**Time:** 8:30 a.m. to 5:30 p.m.

**Location:** FDA White Oak Campus  
10903 New Hampshire Avenue  
Bldg. 31 Conference Center  
Silver Spring, MD 20993

- [Federal Register Notice](#)<sup>1</sup>
- [Speakers List](#)<sup>2</sup>
- [Purpose Statement, Meeting goals, and Agenda](#)<sup>3</sup>
- [Attendee List \(PDF - 34KB\)](#)<sup>4</sup>
- [Transcript: Thursday, April 12, 2012 \(PDF - 655KB\)](#)<sup>5</sup>
- [Post Meeting Summary \(PDF - 27KB\)](#)<sup>6</sup>

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#### Presentations

- [Populations at Risk for Opioid Overdose \(PDF - 569KB\)](#)<sup>7</sup>  
Len Paulozzi, MD, MPH
- [Public Health Interventions to Address Opioid Overdose \(PDF - 1.4MB\)](#)<sup>8</sup>  
Nicholas Reuter
- [Naloxone: Effects and Side Effects \(PDF - 5.8MB\)](#)<sup>9</sup>  
Gregory W. Terman MD, PhD
- [Naloxone: Overview, Criminal Justice and other Special Settings \(PDF - 204KB\)](#)<sup>10</sup>  
Ingrid Binswanger, MD, MPH, MS
- [Bystander Overdose Education and Naloxone Distribution in Massachusetts \(PDF - 1.8MB\)](#)<sup>11</sup>  
Alexander Y. Walley, MD, MSc
- [Role of Naloxone in Opioid Overdose Fatality Prevention, April 12, 2012 \(PDF - 2MB\)](#)<sup>12</sup>  
Nabila El-Bassel
- [Naloxone for Outpatient Use: Data Required to Support an NDA \(PDF - 191KB\)](#)<sup>13</sup>  
Sharon Hertz, MD
- [Naloxone Expanded Access: OTC status Considerations for a Nonprescription Drug Development Program \(PDF - 151KB\)](#)<sup>14</sup>  
Andrea Leonard-Segal, MD, MS
- [Considerations for Development and Marketing of Needleless Naloxone HCl Delivery Systems \(PDF - 896KB\)](#)<sup>15</sup>  
Daniel Wermeling, Pharm.D.
- [Ethical and Regulatory Considerations in Drug Development for IN Naloxone \(PDF - 108KB\)](#)<sup>16</sup>  
Robert 'Skip' Nelson, MD, PhD
- [Lessons Learned from Implementation of HPV Vaccine \(PDF - 170KB\)](#)<sup>17</sup>  
Gregory Zimet, PhD

Page Last Updated: 09/11/2012

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U.S. Department of Health & Human Services

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