

SEPARATE AGREEMENT PURSUANT TO RELEASE AGREEMENT

This agreement (“Agreement”) is entered into by Pfizer Inc (“Pfizer”) and the People of the State of California, acting by and through Santa Clara County Counsel James R. Williams (“People”) (collectively, the “Parties”) as of July 19, 2017 (the “Effective Date”).

PREAMBLE

I. The Parties are entering into this Agreement voluntarily and agree that Pfizer has cooperated with and is continuing to cooperate with the People.

II. The People have made no findings that Pfizer has violated any law or ordinance; and Pfizer’s cooperation should not be seen in any way as an admission of any liability or wrongdoing. Pfizer, in fact, denies any liability and denies that it has engaged in any wrongdoing. Pfizer specifically does not admit any violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.* or 17500, *et seq.*, Cal. Civ. Code § 3479, *et seq.*, or violation of any common law including insurance fraud, civil conspiracy, or fraud and does not admit any wrongdoing that could have been alleged by the People. No part of this Agreement, including its statements and commitments, shall constitute an admission or evidence of any liability, fault, or wrongdoing by Pfizer.

III. For the avoidance of doubt, in the event of a conflict between this Agreement and federal regulatory standards and policies, nothing in this Agreement shall require Pfizer to: (i) take any action that is prohibited by the Federal Food, Drug, and Cosmetic Act (“FDCA”) or any regulation promulgated thereunder, or by the Food and Drug Administration (“FDA”) or any other government entity; (ii) fail to take any action that is required by the FDCA or any regulation promulgated thereunder, or by the FDA or any other government entity; (iii) take or refrain from taking any action inconsistent with published FDA guidance documents or specific written guidance offered by FDA officials to Pfizer; or (iv) take or refrain from taking any action contrary to the FDA-mandated Risk Evaluation and Mitigation Strategy (“REMS”) for Extended Release/Long Acting Opioid Analgesics.

IV. The Parties acknowledge and agree that nothing in this Agreement shall restrict, limit, or infringe Pfizer’s right to engage in any speech, conduct, or activity that is truthful and non-misleading, or otherwise protected under the First Amendment to the Constitution of the United States.

V. The Parties acknowledge and agree that nothing in this Agreement shall waive or limit Pfizer’s ability to raise any defense otherwise available to Pfizer in any action, nor does it limit Pfizer’s right to defend itself from, or make any arguments in connection with, any lawsuit or claim brought by private parties, regulatory authorities, or government entities relating to the subject matter or terms of this Agreement. This Agreement is made without any litigation having been pursued against Pfizer and without trial or adjudication of any issue of fact or law or any finding of liability of any kind. Nothing in this Agreement is meant to state, suggest, or imply that Pfizer has taken any inappropriate action (or failed to take any appropriate action) with regard to the sale or promotion of opioids in the County of Santa Clara (“County”) or any other jurisdiction.

VI. It is the intent of the Parties that this Agreement not be admissible in any case against Pfizer except an action to enforce this Agreement or binding on Pfizer in any respect other than in connection with the enforcement of this Agreement. No part of this Agreement shall create a private cause of action or confer any right to any third party for violation of any federal, state, county, or municipal statute or code. This Agreement and its contents are not intended for use by any third party for any purpose, including submission to any court for any purpose.

DEFINITIONS

These definitions apply for purposes of this Agreement only.

1. Disseminate means to distribute, offer on-line, or make available through any other means.
2. For purposes of this Agreement, Opioids means prescription opioid analgesics that are classified as Schedule II or Schedule III on the list of controlled substances maintained by the Drug Enforcement Administration, except that Opioids shall not include prescription opioid analgesics that are (i) approved by the FDA for intravenous administration and (ii) predominantly administered in a hospital setting.
3. Pfizer means Pfizer Inc and all of its United States affiliates, subsidiaries, predecessors, successors, parents and assigns, that manufacture, sell, and/or distribute Opioids.
4. Pfizer's Opioid drugs means Opioids manufactured, marketed, or sold by Pfizer.
5. Opioid-related refers to programs or publications that include more than an incidental discussion of Opioids, and is not limited to programs or publications that exclusively or primarily discuss Opioids.
6. Advertising means "advertising" as it appears in Cal. Bus. & Prof. Code §§ 17200, *et seq.* and 17500, *et seq.* Advertising also means "advertising" as it appears in 21 C.F.R. § 202.1.

TERMS AND CONDITIONS

1. Promotion of Pfizer's Opioid Drugs.
 - (a) Pfizer shall not disseminate (or cause to be disseminated) advertising or promotional labeling (whether written or electronic) that is likely to deceive a member of the public, including advertising or promotional labeling that is false or misleading, lacks fair balance, or fails to reveal material facts, as defined by 21 U.S.C. §§ 321(n) and 352(a)(n), and 21 C.F.R. §§ 1.21 and 202.1(e), as applicable.
 - (b) Subject to Preamble Section III, advertising and promotional labeling that includes information about the effectiveness of Pfizer's Opioids shall also include information concerning the potential risks of addiction, abuse, and misuse of the products when used in accordance with their FDA-approved prescribing information.

(c) Pfizer shall not make or disseminate claims that are contrary to the “Recommendations” of the Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain, issued in March 2016 (“CDC Recommendations”). Nothing in this sub-paragraph shall restrict or limit Pfizer’s ability to fairly and accurately promote Opioids in a manner consistent with their FDA-approved prescribing information.

(d) Pfizer shall not promote Opioids for off-label uses.

(e) Pfizer shall fairly and accurately disclose the design of the clinical studies underlying the FDA-approved indications for its Opioid products. When doing so, and for so long as it is true, Pfizer shall make clear that there are no adequate and well-controlled studies of the use of these products longer than 12 weeks. Nothing in this sub-paragraph shall restrict or limit Pfizer’s ability to fairly and accurately promote Opioids in a manner consistent with their FDA-approved indications and the CDC Recommendations.

(f) For as long as Pfizer promotes Opioids, Pfizer shall (i) maintain an unbranded website that prominently discloses Pfizer’s sponsorship and provides healthcare professionals with information on identifying and responding to signs of Opioid addiction, abuse, or misuse; (ii) continue to make healthcare professionals aware of this unbranded website in a manner and to the extent consistent with all applicable laws; and (iii) provide information on identifying and responding to signs of Opioid addiction, abuse, and misuse.

2. Promotion by Pfizer’s Sales Representatives.

In connection with their promotion of Opioids or their dissemination of any unbranded information concerning Opioids, Pfizer sales representatives:

(a) shall comply with the relevant provisions of Paragraph 1 of this Agreement’s Terms and Conditions.

(b) shall not provide free or discounted samples of Opioids to healthcare professionals with authority to prescribe Opioids (“prescribers”).

(c) shall comply with paragraphs 2, 7, 10, and 13 of the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals (revised, effective January 2009) (“Code”) for as long as the Code is in effect, except that if the Code conflicts with this Agreement, the Agreement shall control.

3. Dissemination of Unbranded Information.

(a) When presenting unbranded information relating to the use of Opioids for chronic pain, Pfizer shall also present information relating to the potential risks of addiction, abuse, and misuse.

(b) In the event that the People seek and obtain written authorization from the FDA stating that all makers of extended-release Opioids may proactively disseminate the U.S.

Surgeon General’s “Checklist for prescribing opioids for chronic pain”¹ to healthcare professionals without violating the FDCA, any regulation promulgated thereunder, the REMS for Extended Release/Long Acting Opioids, or any other agency guidance, Pfizer shall make good faith efforts to distribute the Checklist to primary care physicians to whom the Company promotes Opioids.

4. Continuing Medical Education (“CME”) Programs.

(a) To the extent Pfizer sponsors or supports CME programs related to Pfizer’s Opioid drugs, or to Opioid use or pain treatment generally:

- i. the CME provider shall disclose Pfizer’s financial support to participants prior to the beginning of the educational activity; and
- ii. in order to qualify for financial support from Pfizer, a representative from the independent medical education organization must certify to the organization’s commitment to act in accordance with the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support in the event that Pfizer decides to fund its activity.

(b) In connection with support of CME programs related to Opioids, Pfizer shall take no action inconsistent with the ACCME Standards for Commercial Support.

(c) If Pfizer supports CME programs related to Opioids, Pfizer shall, upon request and consistent with existing Pfizer policies relating to support of CME programs, provide reasonable support for CME programs that are aimed at increasing awareness of the risks of Opioid addiction, abuse, and misuse and detecting and preventing abuse, misuse, and diversion of Opioids.

5. Organizations and Individuals That Pfizer Supports.

(a) For Opioid-related presentations, events, and materials that are produced for, directed, edited, approved, or disseminated by Pfizer, Pfizer shall ensure that the presentations, events, and materials do not violate the relevant provisions of Paragraphs 1 and 3 of the Terms and Conditions of this Agreement.

(b) Pfizer shall not support outside organizations and individuals for Opioid-related work to the extent Pfizer is on notice that these organizations or individuals make claims about Opioids that violate the relevant provisions of Paragraphs 1 and 3 of the Terms and Conditions of this Agreement. In such circumstances, Pfizer shall as soon as practicable: (i) terminate support to the organization or individual for Opioid-related work; (ii) cease to disseminate the materials that violate Paragraphs 1 or 3; and (iii) to the extent possible, correct misleading statements to the audience to which the statements were aimed.

¹ Available at https://www.cdc.gov/drugoverdose/pdf/pdo_checklist-a.pdf.

(c) Consistent with Pfizer's existing policy governing "Funding Requests for Not-For-Profit Organizations" (USFR-SOP-01-03), Pfizer shall not provide financial support to any external, independent not-for-profit organizations (including patient advocacy groups, charitable organizations, and healthcare professional groups and associations) for work related to Opioids unless Pfizer receives confirmation from the organization that Pfizer's support shall not constitute a majority of the organization's funding during the year starting as of the effective date of Pfizer's agreement. Should Pfizer amend USFR-SOP-01-03 subsequent to the Effective Date of this Agreement, such amendment will have no impact on Pfizer's substantive obligations under this Agreement.

6. Treatment Guidelines. Pfizer shall not disseminate or promote any treatment guidelines concerning Opioids that violate the relevant provisions of Paragraphs 1 or 3 of the Terms and Conditions of this Agreement.

7. Other Abuse Prevention Strategies. If requested, Pfizer shall provide reasonable support for government or private sector efforts to (a) appropriately dispose of unused or unwanted Opioids; or (b) educate the public and prescribers about the risks of Opioids, including the risks of abuse, addiction, and diversion.

8. Miscellaneous.

(a) Pfizer's obligations under this Agreement shall apply prospectively. This Agreement shall remain in effect for four (4) years from its Effective Date. In the event of a dismissal or judgment in favor a majority of the defendants in *People of the State of California v. Purdue Pharma L.P., et al.*, No. 30-2014-00725287 (Orange County Superior Court, original complaint filed May 21, 2014), Paragraphs 1(c), 1(f), 3(b), 4(c), 5(b)(iii), 7, and 8(d)-(h) of this Agreement shall immediately become null and void.

(b) The terms of this Agreement are limited to the jurisdiction of the State of California.

(c) The Parties incorporate by reference here, as though set forth in full, paragraphs I through VI of the Preamble to this Agreement.

(d) Pfizer shall provide to the People any warning or untitled letters issued by the FDA regarding its promotion of Opioids within thirty (30) days of receiving such letter.

(e) Pfizer shall promptly notify the People if it believes or is notified that it has violated any provision of this Agreement. If Pfizer provides such notice and cures and remediates any and all violations within ninety (90) days, the People shall not take action against Pfizer for the violations.

(f) Upon request, Pfizer shall provide the People, within thirty (30) days of the request, any documents relating to or reflecting Pfizer's external communications concerning Opioids, branded or unbranded, including, but not limited to: marketing or launch plans; promotional materials, talking points, scripts or FAQs provided to sales representatives; and any materials disseminated by its sales representatives.

- i. To the extent these documents are not otherwise public, the People acknowledge that Pfizer claims that documents provided by Pfizer pursuant to this Agreement are confidential and exempt from disclosure under the California Public Records Act (“CPRA”), CAL. GOV’T CODE § 6250 *et seq.* These records are intended to be confidential records that are exempt from disclosure. If the People receive a public record request and the People intend to comply with that request because they are not aware of an applicable CPRA exception or do not have sufficient information to determine whether a CPRA exception applies, the People will promptly notify Pfizer of the request so that Pfizer may, at Pfizer’s own expense, seek to prevent disclosure of the documents. If Pfizer is unable to obtain or does not seek a protective order in a timely manner, the People may make such disclosure without liability.
- ii. Notwithstanding the foregoing, the People may disclose these documents pursuant to any governmental, judicial, or administrative order, subpoena, or regulatory request, provided that the People promptly notify Pfizer to the extent practicable of such demand for disclosure so that Pfizer may, at Pfizer’s own expense, seek to make the disclosure subject to a protective order or other appropriate remedy to preserve the confidentiality of the documents. If Pfizer is unable to obtain or does not seek a protective order in a timely manner, and the People are legally required to disclose the documents, the People may make such disclosure without liability.
- iii. If the People receive a civil discovery request for documents that Pfizer has produced to the People under this Agreement, the People shall promptly notify Pfizer and object to the request citing the confidentiality provisions of this Agreement. If the party seeking discovery indicates that it intends to file a motion to compel disclosure of those documents and the People reasonably take the position that disclosure is legally required, the People shall promptly notify Pfizer so that Pfizer may, at Pfizer’s own expense, promptly seek to prevent disclosure of the documents. If Pfizer is unable to obtain or does not seek a protective order in a timely manner, the People may make such disclosure without liability.
- iv. During the term of this Agreement, Pfizer shall preserve, and provide upon request, (1) all versions of websites (branded or unbranded) on which it disseminates information regarding Opioids; (2) disciplinary records relating to Opioids sales representatives whose territory includes any portion of the State of California; (3) reports or complaints regarding the promotion or prescribing of Opioids in the State of California; and (4) call notes

relating to Opioids relating to interactions with healthcare professionals in the State of California.

(g) Pfizer shall, each year on the anniversary of the Effective Date of this Agreement, for four (4) years, provide the People [County Counsel, Santa Clara County Counsel's Office, 70 W. Hedding St., East Wing, 9th Floor, San Jose, CA 95110] with an affidavit of compliance with this Agreement, signed by an authorized Pfizer employee.

(h) Violation of Paragraphs 1 (a)-(e), 2, 3(a), 5(a)-(c), and 6 of this Agreement shall be considered *prima facie* evidence that Pfizer engaged in false advertising in violation of California's False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, *et seq.* Pfizer shall have a reasonable opportunity to rebut any such *prima facie* evidence.

(i) This Agreement is made under, and shall be interpreted in accordance with the laws of the State of California. In the event of any dispute concerning the meaning of or compliance with this Agreement, suit may be brought in Santa Clara County Superior Court.

(j) Nothing in this Agreement excuses Pfizer from its obligation to comply with federal, state, or other law.

(k) If Pfizer enters into any other agreement regarding, in whole or in part, the conduct that is the subject of this Agreement, Pfizer shall provide the agreed-upon terms to the People within thirty (30) days of entering into that agreement.

(l) The failure of any party to exercise any rights under this Agreement shall not be deemed a waiver of such rights.

(m) This Agreement may be signed in one or more counterparts, each of which will be deemed an original. Facsimile or electronic copies of this Agreement may be used with the same force and effect as an original.


(n) This Agreement is binding and inures only to the benefit of the Parties hereto and their respective predecessors, successors, and assigns.

(o) Captions are for organizational purposes only and shall not be used in construing or interpreting this Agreement.

(p) This Agreement constitutes the entire agreement of the Parties with respect to the subject matter hereof and supersedes all prior drafts and understandings related to the subject matter.

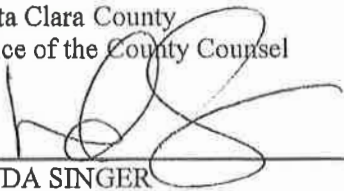
(q) This Agreement may be amended only in writing and by agreement of all of the Parties.

(r) The Parties represent and warrant that each has the full legal power, authority, and capacity to bind the parties for whom it is acting.

By: 

DANNY CHOU
Santa Clara County
Office of the County Counsel

Date: 7/19/17

By: 

LINDA SINGER
Motley Rice LLC
Attorney for Santa Clara County

Date: 7/17/17

By: _____
CARLTON WESSEL
Senior Vice President
Associate General Counsel and Chief Litigation Counsel
Pfizer Inc

Date: _____

By: _____
LOREN BROWN
DLA Piper LLP (US)
Attorney for Pfizer Inc

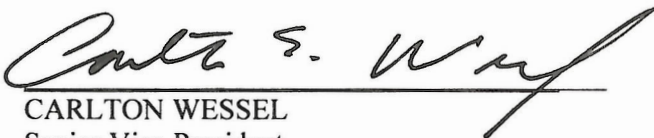
Date: _____

By: _____
DANNY CHOU
Santa Clara County
Office of the County Counsel

Date: _____

By: _____
LINDA SINGER
Motley Rice LLC
Attorney for Santa Clara County

Date: _____

By: 
CARLTON WESSEL
Senior Vice President
Associate General Counsel and Chief Litigation Counsel
Pfizer Inc

Date: 7/18/17

By: _____
LOREN BROWN
DLA Piper LLP (US)
Attorney for Pfizer Inc

Date: _____

By: _____
DANNY CHOU
Santa Clara County
Office of the County Counsel


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LINDA SINGER
Motley Rice LLC
Attorney for Santa Clara County

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CARLTON WESSEL
Senior Vice President
Associate General Counsel and Chief Litigation Counsel
Pfizer Inc

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LOREN BROWN
DLA Piper LLP (US)
Attorney for Pfizer Inc

Date: 7/18/17