BUZZFEED NEWS
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January 15, 2019

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Dear FOIA Officer,

This is a request under the Freedom of Information Act. BuzzFeed News hereby requests that you provide us copies of the records identified and described below – or of records containing the information identified and described below:

This request is for records related to the following three drug clinical trials:

- **CHAMPION PLATFORM, registered to ClinicalTrials.gov as NCT00385138, included in NDA 204958, in which The Medicines Company sought approval of cangrelor (brand name Kengreal)**
- **CHAMPION PCI, registered to ClinicalTrials.gov as NCT00305162, included in NDA 204958, in which The Medicines Company sought approval of cangrelor (brand name Kengreal)**
- **CHAMPION PHOENIX, registered to ClinicalTrials.gov as NCT01156571, included in NDA 204958, in which The Medicines Company sought approval of cangrelor (brand name Kengreal)**

For each of the three trials named above, BuzzFeed News requests the following records:

- **Data on each individual event specified as a component of each trial's primary endpoint(s). For example, if the primary endpoint is composite of death, myocardial infarction, ischemia-driven revascularization, and stent thrombosis, please provide an individual record for each death, each myocardial infarction, each ischemia-driven revascularization, and each stent thrombosis. The data provided on each event should include — but not be limited to — study site name and location, name of investigator, relevant dates, participant identification number, designation of the treatment arm (cangrelor-then-clopidogrel or clopidogrel-only) to which the participant was assigned, the patient diagnosis/clinical presentation (for example, stable angina, unstable**

Exhibit G

angina, NSTEMI, STEMI, or any other classification used), time relative to angiography and time relative to PCI when the drug was administered to patient, dose of drug given (for example, 300 mg or 600 mg of clopidogrel or dummy tablets), and type of procedure undergone by patient (for example, angiography-only, angioplasty, angioplasty with stent, angioplasty with drug-eluting stent, CABG, or any other classification used).

- **All meeting minutes pertaining to meetings of each trial's Data Safety and Monitoring Board or Interim Analysis Review Committee.**
- **All IND Safety Reports (as required by 21 CFR 312.32(c)) and all documents submitted pursuant to 21 CFR 312.55(b).**
- **Each individual site's IRB approval documents and each site's particular informed consent form (the template form approved for use at each site).**
- **All documents memorializing communications between the FDA and the sponsor (including both employees of The Medicines Company and people working on the trial but not directly employed by The Medicines Company) related to each trial's protocol and all protocol amendments, including, but not limited to, meeting minutes, sponsor submissions, and FDA responses.**

Format: we prefer to receive records in the following formats, listed in order of preference:

(1) an electronic data format such as a spreadsheet, delimited data set, database file, or similar;
(2) other non-proprietary electronic format;
(3) word processing file, text-based PDF, or similar;
(4) paper copies.

Please also provide any and all documentation related to such electronic records, including but not limited to data dictionaries, database documentation, record layouts, code sheets, data entry instructions, and similar printed or electronic documentation materials.

Please respond within 20 working days, as the Act provides, or notify me if "unusual" or "exceptional" circumstances apply (as the Act uses those terms).

Scope and breadth of request

Please interpret the scope of this request broadly. The department is instructed to interpret the scope of this request in the most liberal manner possible short of an interpretation that would lead to a conclusion that the request does not reasonably describe the records sought.

Exemptions and segregability

Under the FOIA Improvement Act of 2016, agencies must adopt a presumption of disclosure, withholding information "only if . . . disclosure would harm an interest protected by an exemption" or "disclosure is prohibited by law."

The FOIA Improvement Act of 2016 also amended the FOIA as follows (5 USC 552(a)(8)):

(A) An agency shall—
(i) withhold information under this section only if—
(I) the agency reasonably foresees that disclosure would harm an interest protected by an exemption described in subsection (b); or
(II) disclosure is prohibited by law; and
(ii) (I) consider whether partial disclosure of information is possible whenever the agency determines that a full disclosure of a requested record is not possible; and
(II) take reasonable steps necessary to segregate and release nonexempt information. . .

If it is your position that any portion of the requested records is exempt from disclosure, I request that you provide an index of those documents as required under Vaughn v. Rosen, 484 F.2d 820 (D.C. Cir. 1973), cert. denied, 415 U.S. 977 (1974). As you are aware, a Vaughn index must describe each document claimed as exempt with sufficient specificity "to permit a reasoned judgment as to whether the material is actually exempt under FOIA."

Moreover, the Vaughn index "must describe each document or portion thereof withheld, and for each withholding it must discuss the consequences of disclosing the sought-after information." Further, "the withholding agency must supply 'a relatively detailed justification, specifically identifying the reasons why a particular exemption is relevant and correlating those claims with the particular part of a withheld document to which they apply.'"

In the event some portions of the requested records are properly exempt from disclosure, please disclose any reasonably segregable non-exempt portions of the requested records. If it is your position that a document contains non-exempt segments, but that those non-exempt segments are so dispersed throughout the document as to make segregation impossible, please state what portion of the document is non-exempt, and how the material is dispersed throughout the document. Claims of non-segregability must be made with the same degree of detail as required for claims of exemptions in a Vaughn index. If a request is denied in whole, please state specifically that it is not reasonable to segregate portions of the record for release.

Further, "the withholding agency must supply 'a relatively detailed justification, specifically identifying the reasons why a particular exemption is relevant and

correlating those claims with the particular part of a withheld document to which they apply.'"

In addition, I ask that your agency exercise its discretion to release records which may be technically exempt, but where withholding serves no important public interest.

Request for fee reduction and fee waiver as a representative of the news media

If there are any search, review, or duplication fees greater than $25, inform me before you fill the request. But first please consider BuzzFeed News' requests for fee reduction and fee waiver:

BuzzFeed was founded as a social news and entertainment media company, but its mission broadened in 2012 to include traditional news reporting. BuzzFeed now employs about 190 reporters and editors in bureaus around the U.S. and the world. Reporters in the Washington, D.C., bureau report on Congress, the White House and the U.S. Supreme Court. BuzzFeed News has departments dedicated to longform journalism and investigative reporting.

This request is being made in connection with BuzzFeed's newsgathering functions and not for any other commercial purpose. BuzzFeed intends to produce one or more original investigative reports based on analysis of the requested information.

In addition, BuzzFeed News requests a waiver of all duplication fees for this request as permitted under the Act. Disclosure of the requested information to BuzzFeed News is likely to contribute significantly to public understanding of the operations or activities of the government by illuminating the FDA approval process and FDA oversight of clinical trials related to an important drug.

In reference to our request I am providing the following information addressing the six factors listed in the Department of Justice's FOIA Guide (March 2007): Fees and Fee Waivers, as found online at www.usdoj.gov/oip/foia_guide07/fees_feewaivers.pdf.

1) The subject matter of the requested records concerns the "operations or activities of the government," specifically of the FDA.

2) Release of the requested information "is likely to contribute" to the understanding of your agency by the public. Our research will be advanced by the release of the requested information. Prior to any action on this FOIA request, this information is not freely available to the public.

3) and 4) The disclosure under our FOIA request will "contribute to the understanding of the public at large" and "contribute 'significantly' to public understanding of government operations or activities." Using the information produced through this FOIA request and other sources, we intend to produce one or more original investigative reports that explain the actions and operations of government to the general public. Our reports will be posted on our website, www.buzzfeednews.com, and will be read by hundreds of thousands of people worldwide.

5) and 6) The disclosures we request under the Freedom of Information Act primarily serve the public interest and not any commercial interest. As stated above, the requested information will be used only in connection with BuzzFeed's newsgathering functions.

Production on a rolling basis

If a portion of the responsive records become available before the entire request is complete, I respectfully request that your agency provide records on a rolling basis.

Please feel free to contact me about any aspect of this request. In principle, BuzzFeed News is willing to consider ways in which the request might reasonably be narrowed.

Thank you for your attention to this request.

Sincerely,
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