May 5, 2020

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

SUBMITTED ONLINE AT  
https://www.accessdata.fda.gov/scripts/foi/FOIREquest/requestform.cfm

RE:  Freedom of Information Act Request

Dear FOIA Officer:

On behalf of Public Citizen, and pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, I request the following records:

All documents containing any data from the clinical trials and other research studies that were submitted to or considered by the Food and Drug Administration (FDA) in support of Gilead Sciences’ request for an Emergency Use Authorization (EUA) for emergency use of remdesivir for treatment of hospitalized 2019 novel coronavirus disease (COVID-19) patients, which was granted by the agency on May 1, 2020.¹

In accordance with FDA regulations at 21 C.F.R. 20.44(a)(2), I hereby request expedited processing of this FOIA request. First, Public Citizen’s Health Research Group, which I direct, is an organization that primarily engages in disseminating information through its (a) monthly print newsletter Worst Pills, Best Pills News; (b) WorstPills.org website;² (c) monthly online newsletter Health Letter;³ and (d) press statements, letters, petitions, reports and other documents that are published on Public Citizen’s webpage.⁴ Our group has the expertise to independently analyze safety and efficacy data obtained from clinical trials testing new drugs and make it understandable to the public. Second, with tens of millions of Americans susceptible to severe novel coronavirus infection (COVID-19) and therefore potentially eligible for emergency use of remdesivir, there is

an urgent need for the public to be fully informed about the data regarding the safety and efficacy of remdesivir on which the FDA relied in granting Gilead Sciences’ EUA request for the drug.

If it is your position that responsive records exist but that those records (or portions of those records) are exempt from disclosure, please identify the records that are being withheld and state the basis for the denial for each record being withheld. In addition, please provide the nonexempt portions of the records. Public Citizen seeks each document containing responsive records in its entirety. Accordingly, please do not redact portions of any document as “non-responsive,” “out of scope,” or the like.

I request that any records produced in response to this request be provided in electronic form wherever possible and sent to me by email at mcarome@citizen.org.

Public Citizen requests that all fees in connection with this FOIA request be waived in accordance with 5 U.S.C. § 552(a)(4)(A)(iii) because Public Citizen does not seek the records for a commercial purpose and disclosure “is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government.” As noted above, there is an urgent need for the public to be fully informed about the data regarding the safety and efficacy of remdesivir that was considered by the FDA prior to granting Gilead Sciences’ EUA request for the drug. Understanding the strength and rigor of the scientific evidence submitted to the FDA in support of Gilead Sciences’ EUA request will contribute significantly to public understanding of the FDA’s decision-making regarding such requests and is clearly in the public interest.

Public Citizen is a nonprofit research, litigation, and advocacy organization that represents the public interest before Congress, the executive branch, and the courts. It fights for openness and democratic accountability in government; for social and economic justice in globalization and trade policies; for clean, safe and sustainable energy; for strong health, safety and environmental protections and product safety; for safe, effective and affordable medicines and health care; and for the right of consumers to seek redress in the courts. In particular, Public Citizen works to ensure government transparency and full implementation of FOIA by federal agencies, including by submitting comments on proposed agency FOIA regulations, offering testimony on FOIA reform to Congress, and litigating FOIA lawsuits. Public Citizen itself also regularly submits FOIA requests to numerous federal agencies and uses the information obtained to support its work in several areas.

Public Citizen does not have a commercial interest in the requested records; it intends to share information received from this request with the public free of charge. It regularly publishes reports

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7 Public Citizen, Case Library – Government Transparency, https://www.citizen.org/topic/justice-the-courts/case-library/?s_tax_case_topic%5B%5D=94&s_tax_case_topic%5B%5D=115&s_tax_case_topic%5B%5D=116&s_tax_case_topic%5B%5D=117&s_start_yearmonth=NaN&s_end_yearmonth=NaN.
based upon information acquired through FOIA. Public Citizen also has a demonstrated capacity to disseminate this information. Public Citizen has several full-time staff dedicated to distributing its publications through its website, which includes a Government Transparency webpage, its newsletters, Twitter, Facebook, email listerv, and press releases. Many of Public Citizen’s reports, petitions, or other research products are covered in major newspapers, broadcast media, social media and academic journals. Nearly every day, print and broadcast media around the world mention Public Citizen or quote its experts. Public Citizen publishes a bi-monthly newspaper and issues frequent press releases. Public Citizen also makes its experts available to speak to the media, at conferences, and to testify before Congress.

Accordingly, I request that you waive all fees for locating and duplicating the requested records because Public Citizen is entitled to a public interest fee waiver. If, however, a waiver is not granted, please advise me of the amount of any proposed search, review, and reproduction charges before you conduct those activities.

I expect a response within 20 working days as provided by law. If you have any questions regarding this request, please contact me by phone at (202) 588-7781 or by email at mcarome@citizen.org.


11 https://twitter.com/Public_Citizen (Public Citizen’s Twitter page with 218,027 followers as of March 18, 2020).


17 See, e.g., Public Citizen President Robert Weissman’s Testimony before the House Financial Services Committee: https://www.citizen.org/article/robert-weissman-testimony-before-the-house-financial-services-committee/.
Thank you very much for your attention to this matter.

Sincerely,

Michael A. Carome, M.D.
Director
Public Citizen’s Health Research Group