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May 5, 2020

Daniel O'Day  
Chairman and Chief Executive Officer  
Gilead Sciences  
333 Lakeside Drive  
Foster City, CA 94404

**RE: Request for release of data submitted to the FDA in support of Gilead Sciences' request for an Emergency Use Authorization for remdesivir**

Dear Mr. O'Day:

Public Citizen, a national consumer advocacy organization, and its Health Research Group today submitted a Freedom of Information Act (FOIA) request to the Food and Drug Administration (FDA) seeking the following records (copy enclosed):

All documents containing any data from the clinical trials and other research studies that were submitted to or considered by the FDA in support of your company's 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.<sup>1</sup>

We are writing to urge you to immediately either release the information sought in our FOIA request to the FDA or inform the FDA that you consent to the agency's release of such information.

With tens of millions of Americans susceptible to severe COVID-19 and therefore potentially eligible for emergency use of remdesivir in the future, 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. 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. And Public Citizen's Health Research 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. Finally, release of information

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<sup>1</sup> Food and Drug Administration. Letter to Gilead Sciences, Inc., issuing an Emergency Use Authorization for emergency use of remdesivir for the treatment of hospitalized 2019 coronavirus disease (COVID-19) patient. May 1, 2020. <https://www.fda.gov/media/137564/download>. Accessed May 4, 2020.

sought in our FOIA request to the FDA would not harm Gilead in light of remdesivir's EUA and your company's patent on the drug, and because the information will be made public after the drug's anticipated FDA approval.

We look forward to a prompt favorable response to our urgent request.

Sincerely,

A handwritten signature in cursive script, appearing to read "Michael A. Carome".

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

Enclosure



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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.<sup>1</sup>

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,<sup>2</sup> (c) monthly online newsletter *Health Letter*,<sup>3</sup> and (d) press statements, letters, petitions, reports and other documents that are published on Public Citizen's webpage.<sup>4</sup> 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

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<sup>1</sup> Food and Drug Administration, letter to Gilead Sciences, Inc., issuing an Emergency Use Authorization for emergency use of remdesivir for the treatment of hospitalized 2019 coronavirus disease (COVID-19) patient (May 1, 2020), <https://www.fda.gov/media/137564/download>.

<sup>2</sup> *Worst Pills, Best Pills*, <https://www.worstpills.org/index.cfm>.

<sup>3</sup> Public Citizen, *Public Citizen's Health Letter*, <https://www.citizen.org/news/public-citizens-health-letter/>.

<sup>4</sup> Public Citizen, *Health Research Group Publications*, <https://www.citizen.org/article/health-research-group-publications/>.

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](mailto: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,<sup>5</sup> offering testimony on FOIA reform to Congress,<sup>6</sup> and litigating FOIA lawsuits.<sup>7</sup> Public Citizen itself also regularly submits FOIA requests to numerous federal agencies and uses the information obtained to support its work in several areas.<sup>8</sup>

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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<sup>5</sup> Public Citizen, Comments and Petitions on Agency Freedom of Information Act Regulations, <https://www.citizen.org/article/comments-and-petitions-on-agency-freedom-of-information-act-regulations/>.

<sup>6</sup> Public Citizen, Letters and Testimony to Congress re Freedom of Information Act (FOIA), <https://www.citizen.org/article/letter-to-congress-re-improvements-to-the-freedom-of-information-act-foia/>.

<sup>7</sup> 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](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).

<sup>8</sup> See, e.g., Public Citizen, How We Used FOIA to Hold Trump's Secret Service Accountable (Mar. 5, 2020), <https://www.citizen.org/news/secretsservicefoia/>.

based upon information acquired through FOIA.<sup>9</sup> 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,<sup>10</sup> its newsletters, Twitter,<sup>11</sup> Facebook,<sup>12</sup> email listserv, 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.<sup>13</sup> Nearly every day, print and broadcast media around the world mention Public Citizen or quote its experts.<sup>14</sup> Public Citizen publishes a bi-monthly newspaper<sup>15</sup> and issues frequent press releases.<sup>16</sup> Public Citizen also makes its experts available to speak to the media, at conferences, and to testify before Congress.<sup>17</sup>

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](mailto:mcarome@citizen.org).

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<sup>9</sup> See, e.g., Public Citizen, Trade Adjustment Assistance Database, <https://www.citizen.org/article/trade-adjustment-assistance-database/>; *Trump Visits Milwaukee: The Data on Wisconsin's Ongoing Trade Job Loss, Decline in Ag Exports to China* (Jan. 14, 2020), <https://www.citizen.org/news/trump-visits-milwaukee-the-data-on-wisconsin-ongoing-trade-job-loss-decline-in-ag-exports-to-china/>; *Dem Debate: The Data on Iowa's Ongoing Trade Job Loss, Decline in Ag Exports* (Jan. 14, 2020), <https://www.citizen.org/news/dem-debate-the-data-on-iowa-ongoing-trade-job-loss-decline-in-ag-exports/>; *Trump Touts 'Pledge to America's Workers' Anniversary While Participating Firms That Promised New American Jobs Outsource* (Jul. 24, 2019), <https://www.citizen.org/news/trump-touts-pledge-to-americas-workers-anniversary-while-participating-firms-that-promised-new-american-jobs-outsource-trump-rewards-outsourcers-with-billions-in-contracts/>; *Public Citizen's FOIA Leads FTC to Name Celebrities Warned Over Paid Instagram Posts* (Sept. 14, 2017), <https://www.citizen.org/news/public-citizens-foia-leads-ftc-to-name-celebrities-warned-over-paid-instagram-posts/>.

<sup>10</sup> Public Citizen, Government Transparency, <https://www.citizen.org/topic/justice-the-courts/government-transparency/>.

<sup>11</sup> [https://twitter.com/Public\\_Citizen](https://twitter.com/Public_Citizen) (Public Citizen's Twitter page with 218,027 followers as of March 18, 2020).

<sup>12</sup> <https://www.facebook.com/publiccitizen> (Public Citizen's Facebook page with 122,997 followers as of March 18, 2020).

<sup>13</sup> See, e.g., Grant Schulte, *Nebraska Lets Legislators Shift from Lawmaking to Lobbying*, AP (Jul. 28, 2019), <https://www.apnews.com/711ef7e22e414990a6560fd42a010977> (citing Public Citizen, *Slowing the Federal Revolving Door: Reforms to Stop Lobbying Activity by Former Public Officials and States that Lead the Way* (Jul. 22, 2019), <https://www.citizen.org/wp-content/uploads/Slowing-the-Federal-Revolving-Door-Report.pdf>); Anna Maria Barry-Jester, *As Temperatures Climb, a New Push to Keep Workers Safe*, Salon (Jul. 20, 2019), [https://www.salon.com/2019/07/20/as-temperatures-climb-a-new-push-to-keep-workers-safe\\_partner/](https://www.salon.com/2019/07/20/as-temperatures-climb-a-new-push-to-keep-workers-safe_partner/) (citing Public Citizen, *Unworkable: Dangerous Heat Puts Florida Workers at Risk* (Oct. 30, 2018), <https://www.citizen.org/wp-content/uploads/migration/public-citizen-et-al-report-unworkable-florida-heat-stress-october-2018.pdf>).

<sup>14</sup> See, e.g., Todd Shields & Susan Decker, *FCC Chief Reaffirms Support for T-Mobile Deal and Sets Up Vote*, Yahoo Finance (Jul. 26, 2019), <https://finance.yahoo.com/news/fcc-chief-reaffirms-support-t-181056360.html>; Paul Wiseman & Kevin Freking, *Trump Administration, Democrats Make Progress on New NAFTA*, AP (Jul. 30, 2019), <https://www.apnews.com/a56a8c6fa2f44d559207eba7e56a02e8>. For more examples of Public Citizen experts cited in news coverage, see: <https://www.citizen.org/news/type/in-the-news/>

<sup>15</sup> See, e.g., Public Citizen, Public Citizen News (Nov./Dec. 2019), <https://www.citizen.org/wp-content/uploads/Nov-Dec-PC-News.pdf>.

<sup>16</sup> Public Citizen, Press Releases, <https://www.citizen.org/news/type/press/>.

<sup>17</sup> 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,

A handwritten signature in black ink, appearing to read "Michael A. Carome". The signature is fluid and cursive, with a prominent initial "M" and a long, sweeping underline.

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