United States Senate
WASHINGTON, DC 20510

May 11, 2023

VIA ELECTRONIC TRANSMISSION

The Honorable Robert M. Califf, M.D.
Commissioner of Food and Drugs
Food and Drug Administration

Dear Dr. Califf:

The U.S. Food and Drug Administration (FDA) is required by regulation to respond to citizen petitions "within 180 days of receipt of the petition."[1] Citizens cannot have their matter adjudicated until administrative remedies have been exhausted.[2]

In *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, a Federal District Judge opined that the FDA had not handled the citizen petition process in an acceptable manner.[3] Over twenty years ago, the FDA approved the use of mifepristone for chemical abortion.[4] Shortly thereafter, in 2002, Christian Medical & Dental Associations and American Association of Pro-Life Obstetricians & Gynecologists (AAPLOG) filed a petition with FDA challenging the approval.[5] Those parties ultimately brought suit in the Northern District of Texas in November of 2022.[6]

In that case, the court stated the following with respect to the FDA's conduct:

> Simply put, FDA stonewalled judicial review — until now. Before Plaintiffs filed this case, FDA ignored their petitions for over sixteen years, even though the law requires an agency response within "180 days of receipt of the petition." But FDA waited 4,971 days to adjudicate Plaintiffs' first petition and 994 days to adjudicate the second. Had FDA responded to Plaintiffs' petitions within the [allotted time], this case would have been in federal

[1] 21 C.F.R. § 10.30(e)(2).
[2] The exhaustion of administrative remedies doctrines instructs that an aggrieved party cannot seek "judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted." *McKart v. United States*, 395 U.S. 185, 193 (1969) (quoting *Myers v. Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 50-51 (1938)). Under the CFR, "Final agency action exhausts all administrative remedies and is ripe for preenforcement judicial review as of the date of the final decision…." 21 C.F.R. § 10.45(d)(1)(i). The FDA makes a "final agency action" when it makes a final decision on a citizen petition. 21 C.F.R. § 10.45(c).
[3] *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, No. 2:22-CV-223-Z, 2023 WL 2825871 (N.D. Tex. Apr. 7, 2023).
[4] *Id*. at *1.
[5] *Id*. at *2.
[6] Complaint, *Alliance for Hippocratic Med. v. U.S. Food and Drug Admin.*, No. 2:22-CV-223-Z, 2023 WL 2825871 (N.D. Tex. Apr. 7, 2023) No. 2:22CV00223.

> court *decades* earlier. Instead, FDA postponed and procrastinated for nearly 6,000 days.[7]

I have fought to improve the petition process in Congress recently by sponsoring the Stop STALLING Act to crack down on branded pharmaceutical companies that file sham petitions with the FDA in an effort to interfere with the regulatory approval of generics and biosimilars. It is bad enough that some drug companies have abused the process by using it as a tool to prolong monopolies over medication and keep lower-cost alternatives off the market. To read that the FDA is stonewalling legitimate citizen petitions is likewise unacceptable.

Citizen petitions exist to promote safety and efficacy of prescription drugs. For Congress to better understand the FDA's practices and resources allocated to citizen petitions, please provide answers to the following questions by May 25, 2023:

1. Why was there such a lengthy delay in addressing the citizen petition from 2002 mentioned in *Alliance for Hippocratic Med. v. U.S. Food and Drug Admin.*?[8]

2. How many FDA employees are responsible for reviewing citizen petitions? Provide a list of all employees organized by grade and title.

3. How many FDA employees are responsible for responding to citizen petitions that are on file with the FDA for more than 180 days with no response or final agency action? Provide a list of all employees organized by grade and title.

4. Please provide all records[9] between and among the FDA, Department of Health and Human Services, and Department of Justice regarding the citizen petition.

Thank you for your attention to this important matter. If you have any questions, please contact my Committee staff at (202) 224-0642.

Sincerely,

Charles E. Grassley
Ranking Member
Committee on the Budget

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[7] *Alliance for Hippocratic Med. v. U.S. Food and Drug Admin.*, *supra* note 3, at *1 (emphasis in original) (internal citations omitted).
[8] *Id*.
[9] "Records" include any written, recorded, or graphic material of any kind, including letters, memoranda, reports, notes, electronic data (e-mails, email attachments, and any other electronically-created or stored information), calendar entries, inter-office communications, meeting minutes, phone/voice mail or recordings/records of verbal communications, and drafts (regardless if they resulted in final documents).