UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PRO PUBLICA, INC. and PG PUBLISHING COMPANY, Plaintiffs, - against – FOOD AND DRUG ADMINISTRATION, Defendant.	:	**COMPLAINT** Civil Action No.: 23-CV-3365

Plaintiffs PRO PUBLICA, INC. ("ProPublica") and PG PUBLISHING COMPANY (collectively, the "Press"), by their undersigned attorneys, allege as follows:

INTRODUCTION

1. This is an action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, seeking the disclosure of public records that are of deep and urgent public importance. They will shed light on how Defendant U.S. Food and Drug Administration ("FDA") has overseen the June 2021 recall of 15 million ventilators and other breathing devices by Philips Respironics, Inc. ("Philips")[1] for serious defects that could impact life-saving care.

2. Disclosure of these records will enable the Press to provide critical reporting on whether the FDA is sufficiently supervising this process and protecting public health, whether Philips, many months after this recall, is finally providing adequate notice to millions of consumers about the dangers of its products, and whether the company took proper steps before the recall to mitigate harm.

[1] Philips is a U.S.-based subsidiary of the Dutch multinational conglomerate Koninklijke Philips N.V.

3. The health of millions of Americans is at stake. The FDA has designated this a Class 1 recall, the most serious type of recall, because it involves a reasonable probability that the use of these devices will cause serious adverse health consequences or death.[2] Corporate records and FDA reports show that foam placed inside Philips' respirators and ventilators to lessen noise broke down into tiny carcinogenic particles that are potentially lethal when inhaled by patients. Since April 2021, the FDA has received more than 98,000 reports linking the Philips devices to serious injuries, including 346 reports of death.[3]

4. According to the FDA, the company's efforts to notify patients, healthcare providers, and distributors have been "insufficient" and "ineffective," and "it is likely that a significant portion of patients and consumers" using these products are unaware of the risks.[4] In the months following the recall, the FDA received "a number of calls from patients and consumers" complaining of problems with the recalled devices but unaware of the recall. *Id.* at 2. Nine months after the recall, the FDA estimated that only half of affected patients had registered to obtain a replacement device. *Id*. In March 2022, the FDA took the unusual step of ordering Philips to provide sufficient notice of the recall. *Id.*

5. Philips has been so slow to provide replacement devices that the FDA proposed issuing an order requiring it to submit a plan for the repair, replacement, or refund of the recalled devices.[5] It is unclear how, if at all, Philips responded. On information and belief, the FDA never issued the order. Yet the delays have continued. Philips promised consumers it would

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[2] *See* FDA FAQs on Philips Respironics Ventilator, BiPAP Machine, and CPAP Machine Recalls ("FDA FAQs"), https://www.fda.gov/medical-devices/safety-communications/faqs-philips-respironics-ventilator-bipap-machine-and-cpap-machine-recalls#healthrisks.

[3] *See* FDA Update: Certain Philips Respironics Ventilators, BiPAP Machines, and CPAP Machines Recalled Due to Potential Health Risks, https://www.fda.gov/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due#risk.

[4] FDA, 518(a) Notification Order at 2-3 (Mar. 10, 2022), https://www.fda.gov/media/156811/download.

[5] *See* Proposal for FDA to Issue an Order for Device Repair, Replacement, and/or Refund (May 2, 2022), https://www.fda.gov/media/158129/download.

repair its machines and replace them by September 2022, but at the time of this filing, patients are still waiting. It is unclear whether the FDA has acted. In the meantime, Philips has issued multiple additional recalls for other ventilators and related devices,[6] and the FDA has indicated that Philips may have known as far back as 2015 about the problematic foam in its devices, while continuing to sell them.[7]

6. The Press seeks to report on this public health crisis and the adequacy of the government's response and oversight. Between January 18 and February 9, 2023, the Press submitted four requests under FOIA for records at the heart of the recall. They seek (1) status reports submitted by Philips to the FDA related to the recall, (2) supporting documentation cited by the FDA in a 2021 report related to the recall (much of which has already been summarized in that report), (3) complaints received by Philips and shared with the FDA related to this recall, and (4) certain emails between key FDA officials and Philips.

7. Despite the obvious public interest in releasing these records promptly, the FDA denied expedited review and estimated 18 to 24 months to process them. More than two months have passed since Plaintiffs submitted the last of their requests, and the FDA has now constructively denied them.

8. Plaintiffs bring this action under FOIA to enjoin the FDA from continuing to improperly withhold these records and to ensure their immediate release.

PARTIES

9. Plaintiff ProPublica is a non-partisan newsroom based in New York. It is a Delaware non-profit corporation and is exempt from taxation under Section 501(c)(3) of the

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[6] *See* FDA FAQs, *supra* n.2; *see also Philips CPAP Recall*, DrugWatch, https://www.drugwatch.com/philips-cpap/recall/.

[7] *See* FDA Form 483 re Philips at 4-5 (Nov. 9, 2021), https://www.fda.gov/media/154244/download.

Internal Revenue Code. ProPublica is dedicated to producing investigative journalism in the public interest. Its mission is to expose abuses of power and betrayals of the public trust by government, business, and other institutions, using the moral force of investigative journalism to spur reform through the sustained spotlight of wrongdoing. It has been honored with numerous awards, including six Pulitzer Prizes. ProPublica publishes its reporting through its website, www.propublica.org, and in partnership with more than 180 news organizations across the country, including The New York Times, The Washington Post, POLITICO, NPR News, The Miami Herald, The New Yorker, The Boston Globe, The Los Angeles Times, and Frontline. ProPublica is headquartered in this judicial district at 155 Avenue of the Americas, 13th Floor, New York, New York 10013.

10. Plaintiff PG Publishing Company does business as The Pittsburgh Post-Gazette ("Post-Gazette"). It is one of the oldest newspapers in the nation and is the recipient of several Pulitzer Prizes, most notably in 2019 for its "immersive, compassionate coverage" of the Tree of Life synagogue massacre that left 11 people dead and a half dozen injured. Established in 1786, it was the first newspaper established west of the Allegheny Mountains and continues to serve as the largest news organization in Western Pennsylvania. The Post-Gazette is headquartered at 358 North Shore Drive, Suite 300, Pittsburgh, PA 15212.

11. Defendant FDA is a component of the U.S. Department of Health and Human Services. It is responsible for regulating the sale of medical device products in the United States. The FDA is an agency of the federal government and has possession and control of the records that Plaintiffs seek. It is headquartered at 10903 New Hampshire Ave., Silver Spring, MD 20993.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 5 U.S.C. § 552(a)(4)(B).

13. Venue is premised on the place of business of Plaintiff ProPublica and is proper in this district under 5 U.S.C. § 552(a)(4)(B).

14. Plaintiffs have exhausted all administrative remedies available. The FDA constructively denied each of their public records requests (collectively, "Requests") by failing to make a determination on them within 20 business days as required by FOIA. 5 U.S.C. § 552(a)(6)(A)(i), (a)(6)(C)(i). Plaintiffs are entitled to seek judicial review of that denial pursuant to 5 U.S.C. § 552(a)(4)(B).

FACTS

A. The 1235 Request

15. On or about February 9, 2023, reporters at ProPublica and the Post-Gazette jointly submitted a request to the FDA (2023-1235) (the "1235 Request") seeking:

> All periodic recall status reports per (21 CFR 7.53) submitted to the FDA by Royal Philips since the 2021 Class 1 recall of CPAPs and ventilators, as referenced in the FDA acknowledgement email of event 88058. Specifically, the FDA requested monthly updates from the company that included:
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> - Number of consignees notified of the recall, and date and method of notification.
> - Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.
> - Number of consignees that did not respond (if needed, the identity of nonresponding consignees may be requested by the Food and Drug Administration).

- Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.
- Number and results of effectiveness checks that were made.
- Estimated time frame for completion of the recall. If the recall is complete, provide the date of completion.

16. The FDA acknowledged the 1235 Request on February 13, 2023, and noted that it "may take up to 18 to 24 months to process."

17. To date, it has not issued a final determination or produced any records with respect to this Request. The FDA has therefore missed the deadline of 20 business days to respond under FOIA. However, the FDA has produced certain status reports with limited redactions in connection with a different FOIA request not at issue here (2023-613), demonstrating that the requested status reports are subject to disclosure under FOIA and must be released immediately.

18. The FDA also denied the Press's request for expedited processing without analysis on February 17, 2023. The Press appealed that decision on the same day. The FDA acknowledged the appeal and claimed that "unusual circumstances" applied, suggesting that an additional processing extension of ten days might be appropriate. But the agency failed to issue a decision within 20 working days (or 30 days for situations involving unusual circumstances) as required by FOIA. 5 U.S.C. § 552 (a)(6)(A)(ii), (B)(i). As of the date of this filing, it still has not issued a decision.

B. The 764 Request

19. On January 27, 2023, reporters at ProPublica and the Post-Gazette jointly submitted a request to the FDA (2023-764) (the "764 Request") seeking:

Copies of the following documents described in the FDA's November 9, 2021 483 report[8] related to the Royal Philips recall of CPAPs and ventilators.

1. Royal Philips test report(s) -- AST282T-161438, August 30, 2016, on Trilogy 200 series.
2. Royal Philips test report(s) -- AST 282T-161459, November 25, 2016, on PE-PUR and other foam performance.
3. Royal Philips test report(s) -- AST 282T-182160, December 12, 2018, on foam degradation in Trilogy devices.
4. Royal Philips test report, unidentified, May 22, 2019, on PE-PUR foam performance.
5. Documents submitted to the FDA in relation to Royal Philips CAPA INV 0988, initiated on April 12, 2018, including the closing of the investigation.
6. Royal Philips biological risk assessment, ER 2241475 v00, July 2, 2020, "Exposure to Polyester-Polyurethane Foam Particulates from System One Foam Degradation."
7. Final GLP reports – 20-03961-G2, 20-03961-G[5][9], 20-03961-G1 – on PE-PUR foam.
8. Royal Philips biological risk assessment, May 22, 2018, "Exposure to Polyester-Polyurethane Foam Particulates from Trilogy 100 Inlet Air Path Foam Degradation."
9. Royal Philips Health Hazard Evaluation ER2227646 V06, June 15, 2018, conducted as part of CAPA INV 0988.
10. Internal emails from Royal Philips, dated August 24, 2018, stating that testing confirmed foam breakdowns in heat and humidity.
11. Royal Philips report, December 12, 2018, on PE-PUR foam.
12. Royal Philips report, May 22, 2019, on PE-PUR foam.
13. Documents submitted to the FDA in relation to Royal Philips CAPA 7211, initiated in June 2019, including closing documents.
14. Royal Philips biological risk assessment on PE-PUR foam, July 2020.
15. Royal Philips biological risk assessment on PE-PUR foam, December 2020.
16. Royal Philips biological risk assessment on PE-PUR foam, January 2021.
17. Royal Philips corrective action plan on PE-PUR foam, April 2021.
18. Royal Philips notification to the FDA, April 23, 2021, on PE-PUR foam risks.

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[8] The 764 Request linked to this 483 report: https://www.fda.gov/media/154244/download. *See supra* n.7.

[9] This request appears to have included a small administrative error, referencing a report ending in "GS" when it should have referenced a report ending in "G5."

19. FDA notification to Royal Philips, October 29, 2021, detailing concerns that consumers had not been notified about the CPAP and ventilator recall.

20. On February 1, 2023, the FDA acknowledged the 764 Request and advised that it "may take up to 18 to 24 months to process."

21. More than two months after receiving this request, the FDA has not issued a final determination or produced any documents. It has therefore missed FOIA's deadline of 20 business days to respond.

22. The FDA also denied the Press's request for expedited processing and affirmed this denial on appeal.

C. The 1154 Request

23. On or about February 8, 2023, reporters at ProPublica and the Post-Gazette jointly submitted a request to the FDA (2023-1154) (the "1154 Request") seeking the following:

> MDR information for the 220,000 consumer complaints cited in the FDA November 2021 inspection report.

24. For clarity, the 1154 Request seeks the referenced consumer complaints, or, to the extent they are in a database, the relevant MDR information contained therein. MDR refers to "medical device reports" and is "one of the postmarket surveillance tools the FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessment of these products."[10] Device manufacturers like Philips are required to submit to the FDA certain reports of adverse events and product problems about medical devices.

[10] FDA, *Medical Device Reporting (MDR): How to Report Medical Device Problems*, https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

25. The 1154 Request cited an FDA report, dated November 9, 2021, in which an agency inspector stated that "a query" of Philips' consumer complaints since January 1, 2008, for certain keywords related to the defective foam, "resulted in over 222,000 complaints."[11] The 1154 Request seeks these complaints. As this Request explained, it appears most of these consumer complaints are still not publicly available in the Manufacturer and User Facility Device Experience database.

26. The 1154 Request also stated in bold:

> **If copies or records of such complaints were NOT kept by the FDA, please indicate this in your response.**

27. On February 9, 2023, the FDA acknowledged this request without addressing whether it had possession of the requested records or addressing the request for expedited processing.[12] It merely noted that the 1154 Request "may take up to 18 to 24 months to process."

28. On February 14, 2023, the FDA denied expedited processing without analysis.

29. Plaintiffs appealed the denial of expedited processing on February 16, 2023. The FDA acknowledged the appeal the next day and claimed that "unusual circumstances" applied, suggesting that an additional processing extension of ten days might be appropriate.

30. The FDA failed to decide Plaintiffs' appeal on the expedited processing issue within 20 business days (or 30 days for situations involving unusual circumstances), as required

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[11] FDA Form 483 re Philips at 12 (Nov. 9, 2021), https://www.fda.gov/media/154244/download.

[12] ProPublica reporter Debbie Cenziper sought confirmation from the FDA's Office of Media Affairs that the agency has the requested consumer complaints from Philips, but the FDA refused to provide an answer, responding on April 7, 2023, that this information "is not publicly releasable at this time as this matter remains ongoing." However, the FDA did acknowledge that "[g]enerally, FDA field inspectors collect evidence," which "can include copies of company records" and "print outs of a company's electronic records such as complaint databases." Accordingly, Plaintiffs have a good faith belief that the FDA does, in fact, have the requested complaints.

under FOIA. *See* 5 U.S.C. § 552(a)(6)(A)(ii), (B)(i). As of this filing, the FDA has still not decided the issue.

31. More than two months after this request was filed, the FDA has failed to issue a final determination or produce any documents. It has therefore missed FOIA's deadline of 20 business days (or even 30 days for unusual circumstances) to respond.

D. The 614 Request

32. On January 18, 2023, reporters at ProPublica and the Post-Gazette jointly submitted a request to the FDA (2023-614) (the "614 Request") seeking the following:

> From January 1, 2020 to the date this request is processed, all email communications sent or received by the following current and former individuals at the FDA:
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> Commissioner Stephen M. Hahn
> Commissioner Robert M. Califf
> Amy Abernethy, principal deputy commissioner
> Janet Woodcock, principal deputy commissioner
> Dara Corrigan, deputy commissioner for global regulatory operations
> Walter Harris, deputy commissioner for operations and chief operating officer
> Jeff Shuren, director, Center for Devices and Radiological Health
> William Maisel, director, Office of Product Evaluation and Quality, Center for Devices and Radiological Health
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> to/from Koninklijke Philips N.V, which goes by other names, including, but not limited to, Philips, Philips Respironics and Royal Philips, and
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> containing any of these keywords – pe-pur, polyester-based polyurethane, foam, ventilator, CPAP, recall.
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> With all responsive records, please include any email attachments and all email messages contained in the thread/chain with the responsive record.

33. On January 24, 2023, the FDA acknowledged the 614 Request and advised that it "may take up to 18 to 24 months to process."

34. More than two months later, the FDA has not issued a final determination or produced any documents. It has therefore missed FOIA's deadline of 20 business days to respond.

35. The FDA also denied the Press's request for expedited processing and affirmed this denial on appeal.

36. Therefore, Plaintiffs have exhausted their administrative remedies with respect to each of the Requests. *See* 5 U.S.C. §§ 552(a)(6)(A)(i); 552(a)(C)(i).

COUNT I (As to the 1235 Request)

37. Plaintiffs reallege and incorporate the allegations in the foregoing paragraphs as though fully set forth herein.

38. Defendant FDA is subject to FOIA and must therefore release in response to a FOIA request any disclosable records in its possession at the time of the request and provide a lawful reason for withholding any materials as to which it claims an exemption.

39. The FDA has failed to make any decision on Plaintiffs' 1235 Request or produce any responsive records. Plaintiffs have a legal right under FOIA to obtain the agency records they requested, and there exists no exceptional circumstances or legal basis for the FDA's failure to respond to this request or to make these records available.

40. The FDA's failure to make promptly available the records sought by Plaintiffs' 1235 Request violates FOIA, 5 U.S.C. §§ 552(a)(3)(A) and (a)(6)(A)(i), and applicable regulations promulgated thereunder.

41. Plaintiffs are entitled to an order compelling the FDA to immediately produce the records sought by the 1235 Request without further delay.

COUNT II (As to the 764 Request)

42. Plaintiffs reallege and incorporate the allegations in the foregoing paragraphs as though fully set forth herein.

43. Defendant FDA is subject to FOIA and must therefore release in response to a FOIA request any disclosable records in its possession at the time of the request and provide a lawful reason for withholding any materials as to which it claims an exemption.

44. The FDA has failed to make any decision on Plaintiffs' 764 Request or produce any responsive records. Plaintiffs have a legal right under FOIA to obtain the agency records they requested, and there exists no exceptional circumstances or legal basis for the FDA's failure to respond to this request or to make these records available.

45. The FDA's failure to make promptly available the records sought by Plaintiffs' 764 Request violates FOIA, 5 U.S.C. §§ 552(a)(3)(A) and (a)(6)(A)(i) and applicable regulations promulgated thereunder.

46. Plaintiffs are entitled to an order compelling the FDA to immediately produce the records sought by the 764 Request without further delay.

COUNT III (As to the 1154 Request)

47. Plaintiffs reallege and incorporate the allegations in the foregoing paragraphs as though fully set forth herein.

48. Defendant FDA is subject to FOIA and must therefore release in response to a FOIA request any disclosable records in its possession at the time of the request and provide a lawful reason for withholding any materials as to which it claims an exemption.

49. The FDA has failed to make any decision on Plaintiffs' 1154 Request or produce any responsive records. Plaintiffs have a legal right under FOIA to obtain the agency records

they requested, and there exists no exceptional circumstances or legal basis for the FDA's failure to respond to this request or to make these records available.

50. The FDA's failure to make promptly available the records sought by Plaintiffs' 1154 Request violates FOIA, 5 U.S.C. §§ 552(a)(3)(A) and (a)(6)(A)(i), and applicable regulations promulgated thereunder.

51. Plaintiffs are entitled to an order compelling the FDA to immediately produce the records sought by the 1154 Request without further delay.

COUNT IV (As to the 614 Request)

52. Plaintiffs reallege and incorporate the allegations in the foregoing paragraphs as though fully set forth herein.

53. Defendant FDA is subject to FOIA and must therefore release in response to a FOIA request any disclosable records in its possession at the time of the request and provide a lawful reason for withholding any materials as to which it claims an exemption.

54. The FDA has failed to make any decision on Plaintiffs' 614 Request or produce any responsive records. Plaintiffs have a legal right under FOIA to obtain the agency records they requested, and there exists no exceptional circumstances or legal basis for the FDA's failure to respond to this request or to make these records available.

55. The FDA's failure to make promptly available the records sought by Plaintiffs' 614 Request violates FOIA, 5 U.S.C. §§ 552(a)(3)(A) and (a)(6)(A)(i) and applicable regulations promulgated thereunder.

56. Plaintiffs are entitled to an order compelling the FDA to immediately produce the records sought by the 614 Request without further delay.

REQUESTS FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court:

57. Declare that the records sought by the Requests, as described in the foregoing paragraphs, are public under 5 U.S.C. § 552 and must be disclosed;

58. Order the FDA to immediately disclose all responsive records to Plaintiffs and enter an injunction prohibiting the FDA from continuing to withhold them;

59. Award Plaintiffs the costs of this proceeding, including reasonable attorneys' fees, as expressly permitted by FOIA; and

60. Grant Plaintiffs such other and further relief as this Court deems just and proper.

Dated: New York, New York

April 21, 2023

Respectfully submitted,

/s/ Sarah Matthews

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