United States
Consumer Product Safety Commission

November 20, 2023

Via Email
Bardia Sergent
3333 Piedmont Road, NE, Suite 2500
Atlanta, Georgia 30341
sergentb@gtlaw.com

RE: Freedom of Information Act Request #23-F-00555: Data and Materials regarding Dr. Erin M. Mannen's "Biochemical Analysis of Inclined Sleep Products" (Date Range for Record Search: From 9/1/2018 To 9/1/2019)

Dear Mr. Sergent:

The Consumer Product Safety Commission (Commission or CPSC) is in receipt of your request for information pursuant to the Freedom of Information Act (FOIA), filed on August 30, 2023.

In your request, you seek 41 categories of records, including but not limited to:

1. *Copies of all documents relating to the 2019 Study, including, but not limited to:*

    a. *All communications between Dr. Mannen, or any other University of Arkansas employees, and the CPSC regarding the 2019 Study.*

    b. *All documents reflecting payments made by the CPSC to the University of Arkansas for the 2019 Study.*

    c. *All notes from all meetings between Dr. Mannen, or other University of Arkansas employees, with the CPSC relating to the 2019 Study, including regular meetings occurring every two to four weeks throughout the pendency of the 2019 Study and meeting discussing the study's goals and outcomes.*

    d. *All "progress updates" provided to the CPSC regarding the 2019 Study as discussed on page 70 of the 2019 Study. See Exhibit A.*

    e. *Drafts of study designs and protocols for the 2019 Study, including, but not limited to:*

        i. *Study protocol 228457 "Biomechanical Evaluation of Infants in Inclined Sleep Products" submitted to the IRB;*

ii. All drafts of the 2019 IRB Study Protocol 228457;

iii. Any and all protocols or processes for selection of inclined sleep products used during the study;

iv. Any and all protocols or processes for selection of the ten (10) infant study participants, as well as exclusion of other participants;

v. Any and all protocols or processes for the frequency and assessment of infant behaviors, including, but not limited to "crying" and "significant crying;"

vi. Any and all protocols or processes for decisions to include or exclude data gathered during an infant crying event.

f. All raw and processed data, including, but not limited to:

i. Raw and processed data maintained in a secured storage space provided by the University of Arkansas for Medical Sciences, Department of Orthopaedic Surgery;

ii. Raw and processed data maintained in a secured storage space provided by the University of Arkansas for Medical Sciences, Department of Pediatrics;

iii. Contact area data collected;

iv. Data collected through electromyography (“EMG”);

v. All kinematic data and video recordings using a marker-based motion capture, including video recordings from infrared cameras and additional video recording of the entire data collection process;

vi. All data pertaining to "pressure-mapping sensors" referenced during the 2019 Study;

vii. All data pertaining to study participants' oxygen saturation;

viii. All calculations and data analysis using MATLAB code;

ix. All data used for peak-finding algorithms and results of same;

x. All data and related notes regarding weights and measurements of products used during infant testing;

xi. All data and related notes regarding weights and measurements of products not used during infant testing;

xii. All data collected pertaining to "CPSC 1" through "CPSC 11" referenced in the 2019 Study.

g. All laboratory notebooks maintained by Dr. Mannen or other co-investigators employed by University of Arkansas.

h. All notes pertaining to the 2019 Study and maintained by Dr. Mannen or other co-investigators employed by University of Arkansas.

i. All photographs and videotapes captured during the testing or evaluation of the 2019 Study.

j. All photographs and videotapes captured to assess potential participating infants in the 2019 Study.

k. All developmental screening questionnaire form(s) used for the participants of the 2019 Study.

l. All completed developmental screening questionnaires completed by the participants of the 2019 Study.

m. All photographs and videotapes captured during the testing or evaluation of the 2019 Study.

n. The 91 CPSC incident reports provided by the CPSC and reported to or investigated by the CPSC as of July 2019.

o. All notes or spreadsheets drafted, prepared, or maintained by Dr. Mannen or other University of Arkansas employees regarding the 91 CPSC incident reports provided by the CPSC and reported to or investigated by the CPSC as of July 2019.

2. Copies of all documents relating to the 2020 Study, including, but not limited to:

a. All communications between Dr. Mannen, or any other University of Arkansas employees, and the CPSC regarding the 2020 Study.

b. All documents reflecting payments made by the CPSC to Boise State University or the University of Arkansas for the 2020 Study.

c. All notes from all meetings between Dr. Mannen or other University of Arkansas employees and the CPSC, relating to the 2020 Study, including, but not limited to, notes discussing the study's goals and outcomes.

d. Drafts of study designs and protocols for the 2020 Study, including, but not limited to:

i. Study protocols submitted to the IRB;

ii. *Any and all protocols or processes for selection of sleep products used during the study;*

iii. *Any and all protocols or processes for selection of the fifteen (15) infant study participants, as well as exclusion of other participants.*

e. *All raw, processed, or re-cut data, including, but not limited to:*

i. *Raw, processed, or re-cut data maintained in a secured storage space provided by the University of Arkansas for Medical Sciences, Department of Orthopaedic Surgery;*

ii. *Raw, processed, or re-cut data maintained in a secured storage space provided by the University of Arkansas for Medical Sciences, Department of Pediatrics;*

iii. *Contact area data collected;*

iv. *Data collected through electromyography ("EMG");*

v. *All kinematic data and video recordings using a marker-based motion capture, including video recordings from infrared cameras and additional video recording of the entire data collection process;*

vi. *All data pertaining to study participants' oxygen saturation;*

vii. *All calculations and data analysis using MATLAB code;*

viii. *All data used for peak-finding algorithms and results of same;*

ix. *All data and related notes regarding weights and measurements of products used during infant testing;*

x. *All data and related notes regarding weights and measurements of products not used during infant testing;*

f. *All laboratory notebooks maintained by Dr. Mannen or other co-investigators employed by University of Arkansas.*

g. *All notes pertaining to the 2020 Study and maintained by Dr. Mannen or other co-investigators employed by University of Arkansas.*

h. *All photographs and videotapes captured during the testing or evaluation of the 2020 Study.*

i. *All photographs and videotapes captured to assess potential participating infants in the 2020 Study.*

j. All developmental screening questionnaire form(s) used for the participants of the 2020 Study.

k. All completed developmental screening questionnaires completed by the participants of the 2020 Study;

l. All photographs and videotapes captured during the testing or evaluation of the 2020 Study.

3. Copies of all documents relating to the 2021 Study, including, but not limited to:

a. All communications between Dr. Mannen, or any other University of Arkansas employees, and the CPSC regarding the 2021 Study.

b. All documents reflecting payments made by the CPSC to Boise State University or the University of Arkansas for the 2020 Study.

c. All notes from all meetings between Dr. Mannen or other University of Arkansas employees and the CPSC, relating to the 2021 Study, including, but not limited to, notes discussing the study's goals and outcomes.

d. Drafts of study designs and protocols for the 2021 Study, including, but not limited to:

i. Study protocols submitted to the IRB;

ii. Any and all protocols or processes for selection of sleep products used during the study;

iii. Any and all protocols or processes for selection of the fifteen (15) infant study participants, as well as exclusion of other participants.

e. All raw, processed, or re-cut data, including, but not limited to:

iv. Raw, processed, or re-cut data maintained in a secured storage space provided by the University of Arkansas for Medical Sciences, Department of Orthopaedic Surgery;

v. Raw, processed, or re-cut data maintained in a secured storage space provided by the University of Arkansas for Medical Sciences, Department of Pediatrics;

vi. Contact area data collected;

vii. Data collected through electromyography ("EMG");

viii. All kinematic data and video recordings using a marker-based motion capture, including video recordings from infrared cameras and additional video recording of the entire data collection process;

ix. All data pertaining to study participants' oxygen saturation;

x. All calculations and data analysis using MATLAB code;

xi. All data used for peak-finding algorithms and results of same;

xii. All data and related notes regarding weights and measurements of products used during infant testing;

xiii. All data and related notes regarding weights and measurements of products not used during infant testing;

f. All laboratory notebooks maintained by Dr. Mannen or other co-investigators employed by University of Arkansas.

g. All notes pertaining to the 2021 Study and maintained by Dr. Mannen or other co-investigators employed by University of Arkansas.

h. All photographs and videotapes captured during the testing or evaluation of the 2021 Study.

i. All photographs and videotapes captured to assess potential participating infants in the 2021 Study;

j. All developmental screening questionnaire form(s) used for the participants of the 2021 Study;

k. All completed developmental screening questionnaires completed by the participants of the 2021 Study;

l. All photographs and videotapes captured during the testing or evaluation of the 2021 Study.

4. Any and all communications and/or disclosures between you and Dr. Erin Mannen regarding her retention as an expert witness in civil lawsuits involving claims against the Fisher-Price Rock 'n Play Sleeper.

Your request as stated does not constitute a proper FOIA request. Under the FOIA and the Commission's regulations, a request for access to records must reasonably describe the records being requested. *See* 5 U.S.C. § 552(a)(3)(A); 16 C.F.R. § 1015.3(b). Determining whether a request meets this requirement hinges upon the ability of an agency's staff to reasonably ascertain exactly which records are being requested and to locate them. Requests which are so overly broad, sweeping or lacking in specificity are not reasonably described. *See e.g., Sai v. TSA,* 315 F. Supp. 3d 218, 249 (D.D.C. 2018) (holding that "it is difficult to imagine" a request broader in scope and more burdensome than a "request for all 'policy and/or procedures documents,' past and present"); *Pinson v. DOJ*, 245 F. Supp. 3d 225, 244-45 (D.D.C. 2017) (request for "documents 'concerning the activities of the California Mexican Mafia and Aryan brotherhood gangs within federal prisons generated since 2007'" not reasonably described); *Cable News Network, Inc. v. FBI*, 271 F. Supp. 3d 108, 112 (D.D.C. 2017) (finding that language "'relate in any way to'" certain memos was too vague).

Courts have explained that "the rationale for this rule is that FOIA was not intended to reduce government agencies to full-time investigators on behalf of requesters," or to allow requesters to conduct "fishing expeditions" through agency files. *See Dale v. IRS,* 238 F. Supp. 2d 99, 104-05 (D.D.C. 2002) (concluding that request seeking "'any and all documents . . . that refer or relate in any way'" to requester failed to reasonably describe records sought and "amounted to an all-encompassing fishing expedition of files at offices across the country, at taxpayer expense").

As a corollary to the "reasonably described" inquiry, courts have held that agencies are not required to conduct wide-ranging, "unreasonably burdensome" searches for records. *See AFGE v. Dep't of Commerce*, 907 F.2d 203, 209 (D.C. Cir. 1990) (holding that "while might identify the documents requested with sufficient precision to enable the agency to identify them . . . it is clear that these requests are so broad as to impose an unreasonable burden upon the agency," because agency would have "to locate, review, redact, and arrange for inspection a vast quantity of material"); *Leopold v. DOJ*, 301 F. Supp. 3d 13, 23-24 (D.D.C. 2018) (finding that, because request used word "'including'" when referencing topic, request was broader than just topic, but also finding that FBI credibly explained that such a literal construction of request "would be 'overly broad, unduly burdensome, and inadequate to describe the records sought,' such that the FBI 'would have been unable to craft a reasonable search for such non-investigative records"); *Bailey v. Callahan*, No. 3:09MC10, 2010 WL 924251, at *4-5 (E.D. Va. March 11, 2010) (holding that request is so overbroad that only if requester specified particular component of interest could agency conduct a search without an "unreasonable amount of effort"). *Van Strum v. EPA*, Nos. 91-35404, 91-35577, 1992 WL 197660, at *1 (9th Cir. 1992) (accepting agency justification denying or seeking clarification of overly broad requests because agency not required to conduct search which would place inordinate burden on agency resources); *Dixon v. DOJ*, 279 F. Supp. 3d 1, 2 (D.D.C. 2017) ("Where . . . an agency's response to a FOIA request calls for 'an unreasonably burdensome search,' . . . the agency need not honor the request.") (aff'd, 2018 WL 4610736 (D.C. Cir. 2018).

As your request is overly broad and unduly burdensome, your request is improper, and is denied. You may re-submit a request. For assistance with formulating a reasonable FOIA request, you may contact a FOIA Liaison as instructed below.

FOIA Administrative Procedures

Right to appeal. If you are not satisfied with the response to this request, you may administratively appeal in writing, addressed to: FOIA APPEAL, Office of the General Counsel, ATTN: Division of Information Access, U.S. Consumer Product Safety Commission, 4330 East West Highway, Room 820, Bethesda, MD 20814-4408. Your appeal must be postmarked or electronically transmitted (cpscfoiarequests@cpsc.gov) within 90 days of the date of the response to your request. You may also fax your appeal to 301-504-0127. You may contact us Monday – Friday from 8:00AM – 4:30PM EST, by telephone at: 1-800-638-2772, or by fax to: 301-504-0127.

Before filing a formal appeal with the CPSC, you may contact me, or one of CPSC's Public FOIA Liaisons, Korinne Super (ksuper@cpsc.gov) or Robert Dalton (rdalton@cpsc.gov), via email or at 1-800-638-2772, for further assistance or to discuss any aspect of your request. Assistance may include guidance on possible reformulation of your request or an alternative time frame for processing the request.

Right to Mediation. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they

offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, MD 20740-6001; email at: ogis@nara.gov; telephone at: 202-741-5770; toll free at: 1-877-684-6448; or facsimile to: 202-741-5769.

Fees. We are not charging you fees in this instance per our regulations that no fee will be charged when the total fee is equal to or less than $25. *See* 16 CFR § 1015.9(g)(2)(vii).

Sincerely,

Amanda Civins

Digitally signed by Amanda Civins
Date: 2023.11.20 15:34:03 -05'00'

Amanda Civins
Attorney
Office of the General Counsel
Division of Information Access
P: 301-504-7630
E: acivins@cpsc.gov