UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: Acetaminophen – ASD-ADHD Products Liability Litigation This Document Relates To: All Actions	Docket Nos.: 22-md-3043 (DLC)

STIPULATED ORDER REGARDING PHASE ONE DISCOVERY

Pursuant to the Court's December 7, 2022 Order (DE 246) directing prioritization of discovery related to the issue of general causation, specifically whether prenatal exposure to acetaminophen products causes ASD and ADHD, Plaintiffs and Defendant Johnson & Johnson Consumer Inc. ("JJCI") hereby stipulate and agree that Phase One discovery shall proceed as set forth below. Timing and scope of Phase Two discovery, which shall include sales and marketing issues, shall be decided by the Court. The parties will be prepared to discuss this with the Court during the conference on Friday, January 13, 2023.

November 18 Requests for Production

1. Plaintiffs' November 18 Requests for Production to JJCI are hereby withdrawn, subject to the custodial and non-custodial production agreements, below. Plaintiffs shall have the right to serve Requests for Production as part of Phase Two discovery.

Phase One Custodial Productions and Depositions

2. Defendant JJCI will produce custodial files, based on agreed search terms, for five initial Phase One custodians relevant to the issue of ASD/ADHD prenatal acetaminophen exposure medical causation. Defendant JJCI will identify the five initial Phase One custodians within one week of entry of an order memorializing this agreement, specify each custodian's relevancy to the issue of ASD/ADHD prenatal acetaminophen exposure medical causation, and thereafter will meet

and confer with plaintiffs on any questions or issues regarding the five initial Phase One custodians to ensure that the parties reach agreement concerning the initial Phase One custodians. The parties will meet and confer on a reasonable timeline for rolling productions based on timing of agreed search terms and the Court's discovery schedule.

3. Thereafter, plaintiffs may request custodial files for up to five additional Phase One custodians relevant to the issue of ASD/ADHD prenatal acetaminophen exposure medical causation. If JJCI believes that a custodian selected by plaintiffs is not relevant to the issue of ASD/ADHD prenatal acetaminophen exposure medical causation, JJCI reserves the right to object to that selection. Plaintiffs reserve the right to request more than five additional Phase One custodians for good cause shown.

4. Defendant JJCI will produce up to five Phase One custodians for deposition (one day/7 hours pursuant to Fed. R. Civ. P. 30(d)(1)) on a mutually convenient date, and cross noticed in all jurisdictions as applicable. The subject matter of the depositions will encompass the witnesses' work and/or knowledge relevant to the issue of ASD/ADHD prenatal acetaminophen exposure, and each witness will only be produced for deposition once (*i.e.*, no second deposition during Phase 2), unless good cause is shown to retake any deposition based upon the later production of documents concerning the same deponents, if such documents should have been produced in Phase 1. The parties will meet and confer on a reasonable timeline for the scheduling of depositions based on entry of a protective order, rolling productions, and deposition guidelines order.

Phase One Non-Custodial Productions

5. In addition to the NDA, which will be produced in full without search terms applied, with its interrogatory responses, Defendant JJCI will provide a list of non-custodial

document and data sources relevant to the issue of ASD/ADHD prenatal acetaminophen exposure medical causation. The parties will meet and confer on a reasonable timeline for rolling production of these non-custodial sources, which shall include any responsive modern attachments per the ESI protocol, based on timing of agreed search terms, the Court's discovery schedule, and entry of the ESI protocol and protective order.

November 18 Interrogatories

6. JJCI will respond and/or object to the following November 18 Interrogatories as part of Phase One discovery related to ASD/ADHD prenatal acetaminophen exposure medical causation. This staging agreement does not concede the relevancy of the requests or information sought, reflect any agreement to produce specific documents or information, nor is it a waiver of any objections.

Interrogatory No.	Interrogatory Request
1	With respect to these interrogatories, please identify the person answering them and all persons assisting in answering them and specify which interrogatories they so assisted in answering.
2	Identify all ACETAMINOPHEN PRODUCTS sold by YOU or on YOUR behalf from 2010 through present.
3	Identify any individual person, as well as any department, group, or entity, with relevant information concerning the claims or defenses in this case, including any persons responsible for the design, review, approval, and modification of warnings and/or labels and/or monographs for YOUR ACETAMINOPHEN PRODUCTS.
4	Identify all Scientific Research, studies, tests, trials, or analysis that YOU relied on to test the safety or efficacy of each of YOUR ACETAMINOPHEN PRODUCTS or that YOU relied on as a basis for any marketing concerning the safety or efficacy of each of YOUR ACETAMINOPHEN PRODUCTS. For each such Scientific Research, study, clinical trial, or analysis identify: a. Whether the testing involved PRENATAL USE of acetaminophen; b. The duration for which the patient population was given or took acetaminophen;

Interrogatory No.	Interrogatory Request
	c. The dose of acetaminophen given to or taken by the patient population.
5	Identify any and all studies that found that acetaminophen is safe for PRENATAL USE.
6	Identify any Persons employed by YOU, or who received compensation or anything of value from YOU, including any former employees, who reviewed or analyzed data regarding the use . . . of acetaminophen for PRENATAL USE and/or who reviewed or analyzed data regarding the possible risks or adverse effects of acetaminophen for PRENATAL USE.
7	Identify any data systems or sources of data that YOU have used to study, review or analyze causes, contributing factors, and/or medical and developmental research regarding ASD, ADHD and/or other neurodevelopmental disorders, including data regarding ASD, ADHD and/or other neurodevelopmental disorder histories and trends.
8	Identify any data systems or sources of data that YOU have used to study, review or analyze risk factors or adverse events relating to ACETAMINOPHEN PRODUCTS.
9	Identify any scientific research, STUDIES, tests, clinical trials, or analysis regarding the safety and efficacy of acetaminophen that YOU decided not to publish and the reasons for that decision.
11	Identify all potential side effects of taking acetaminophen, including the date and manner upon which YOU became aware of such potential side-effect(s).
12	Identify any and all companies or affiliates, foreign or domestic, which performed any of the following functions with respect to the safety of acetaminophen for PRENATAL USE from 1968 to the present: a. Research and development (including animal and human testing and in vitro and in vivo studies); b. Industry and/or Regulatory Relations; c. Regulatory Compliance; . . . e. Safety Surveillance and Risk Management; f. Adverse event identification and collection; and g. Pharmacovigilance.
13	Identify any and all THIRD-PARTIES or consultants who performed any of the following functions for YOU with respect to the safety of ACETAMINOPHEN PRODUCTS for PRENATAL USE and/or POSTNATAL USE from 1968 to the present:

Interrogatory No.	Interrogatory Request
	a. Research and development (including animal and human testing and in vitro and in vivo studies); b. Industry and/or Regulatory Relations; c. Regulatory Compliance; . . . f. Safety Surveillance and Risk Management; g. Adverse Event identification and collection; and h. Pharmacovigilance.
14	Identify any individual person, as well as any department, group, or entity, associated with the FDA, EMA, or any other governmental organization or entity with relevant information concerning the claims or defenses in this case, including any persons responsible for the design, review, approval, and modification of warnings and/or labels and/or monographs for YOUR ACETAMINOPHEN PRODUCTS.
15	Identify any persons at the J&J family of companies, including YOU, and YOUR attorneys, or any other entity acting on YOUR behalf, including any related corporate entity and their employees, or a third party, who have communicated with the FDA or any other governmental entity, including the dates of the communications, specifically about FDA drug safety communications about pain medicine use during pregnancy and generally about acetaminophen and neurodevelopmental disorders such as ASD and/or ADHD.
16 ***Limited as to neurodevelopmental research.	Identify any non-profit or charitable organizations or entities with whom YOU, or by any other entity acting on YOUR behalf, including any related corporate entity and their employees, or third party, communicated regarding YOUR ASD, ADHD, and other neurodevelopmental research, outreach and efforts.
17 ***Limited as to neurodevelopmental research.	Identify any non-profit or charitable organizations or entities funded, either in whole or in part, by YOU, or by any other entity acting on YOUR behalf, including any related corporate entity and their employees, or a third party, regarding their ASD, ADHD, and other neurodevelopmental research, outreach and efforts.
18	Identify any advisory committees or task forces YOU have formed or consulted with, whether internal or external, regarding acetaminophen for PRENATAL USE and the potential risk of ASD and/or ADHD. For each advisory committee or task force, identify the date of formation; the members of the committee; and the identity of any documents generated by the committee.
19	At any point since 1968, has the board of directors of JJCI, including any committee or subcommittee discussed, communicated about, or considered issues related to the safety of acetaminophen for

Interrogatory No.	Interrogatory Request
	PRENATAL USE? If the answer is "yes," please describe the nature of the communication(s), the date(s) on which the communication(s) took place, the individuals involved, the topics and issues discussed, and the details of the communications.

7. This Order may not be modified absent agreement of the parties or further order of the Court for good cause shown.

IT IS SO ORDERED.

Dated: New York, New York

January 12, 2023

HON. DENISE COTE
United States District Judge