UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

IN RE: DEPO-PROVERA (DEPOT MEDROXYPROGESTERONE ACETATE) PRODUCTS LIABILITY LITIGATION	Case No. 3:25-md-3140
This Document Relates to: All Cases	Judge M. Casey Rodgers Magistrate Judge Hope T. Cannon

PRETRIAL ORDER NO. 14
(Supplemental Order Governing Production of Documents and Electronically Stored Information—Defendant Pfizer, Inc. Search & Validation Protocol)

In accordance with Paragraph 21 of Pretrial Order No. 13 ("Order Governing Production of Documents and Electronically Stored Information"), Plaintiffs and Defendant Pfizer, Inc. ("Pfizer") have met and conferred regarding a protocol for the collection and identification of potentially responsive documents for review by Pfizer and ultimate production in this MDL. The agreed-upon protocol (*see* **Exhibit A)** sets forth the processes and procedures Pfizer will use for the collection and identification of potentially responsive documents for review and ultimate production herein, as well as the validation processes Pfizer will employ with regard to its search for potentially responsive documents. The agreed-upon protocol is approved and adopted herein.

Counsel for authorized generic Defendants Prasco LLC, Greenstone LLC, and Viatris Inc. must meet and confer with Plaintiffs regarding an analogous search and validation protocol appropriate for the collection and identification of their potentially responsive documents for review and ultimate production herein. The proposed protocol is due on or before **March 21, 2025**.

SO ORDERED this 14th day of March, 2025.

M. Casey Rodgers

M. CASEY RODGERS
UNITED STATES DISTRICT JUDGE

EXHIBIT A

PROTOCOL FOR THE USE OF SEARCH TERMS AND VALIDATION IN THE IDENTIFICATION, REVIEW, AND PRODUCTION OF PFIZER DOCUMENTS

Guiding Principles

This document sets forth the process Pfizer will use for the collection and review of documents for ultimate production in *In re Depo-Provera Products Liability Litigation*, MDL No. 3140, as well as the validation processes Pfizer will employ to ensure that it has met its discovery obligations under the Federal Rules of Civil Procedure.

Although each litigation is unique, all Pfizer discovery efforts are guided by a number of principles. These include that the results of any review of documents for litigation production must be accurate, reasonable, and proportional to the needs of the case.

The search-term procedure described below for use in this litigation employs an iterative process through which sampling and statistical estimation is used both to determine and to demonstrate the effectiveness and sensitivity of the chosen search terms. Matters may vary in terms of how many iterations and sampling may be required. Through a validation process, the Producing Party will share high-level volume metrics pertaining to burden, plus statistical information indicating the efficacy of a given set of search terms, but will not share non-relevant documents that are unrelated to the issues being addressed in the case.

It should be noted that search terms will be applied as sets of terms. In most instances, documents will contain hits on multiple individual terms from the overall set. It is more useful to assess recall and precision for the comprehensive set of documents returned by the entire set of terms, as opposed to individually focusing on one of many terms being run in concert.

Search Process & Validation

Except as otherwise set forth in the Order Governing Production of Documents and Electronically Stored Information (the "ESI Protocol"), as agreed to among the Parties, or as otherwise Ordered by the Court, below are the steps that will be followed by Pfizer to identify potentially responsive documents for review and production in this litigation. They take into account, and have been adapted to fit, the needs of the In re: Depo-Provera Products Liability Litigation, MDL 31400.

1. Collection of Documents. Pfizer will prepare the starting universe of documents by comprehensively collecting applicable classes of documents from custodial and non-custodial sources without application of any search term or other limitation. Consistent with the ESI Protocol, Pfizer will segregate materials subject to identification by search terms versus other identification/review processes.

2. Development of Search Terms. Pfizer will develop a list of proposed search terms likely to identify as many responsive documents as reasonably possible for proportionate effort. These terms shall include known names of products and all known code names or synonyms, plus terms that are likely to be related to issues identified in the matter. Pfizer will prepare and present a proposed list of search terms to Plaintiffs on or before March 17, 2025; Plaintiffs will present an initial proposed supplemental list of search terms on or before March 24, 2025.

3. Application of search terms.
    a. Pfizer will run the proposed set of search terms to assess the comprehensive return of potentially responsive documents, as well as the impact of individual terms. Individual terms often offer an opportunity for the Producing Party to begin deploying "judgmental sampling" of returned documents to see if it can learn of obvious issues with specific terms. Judgmental sampling is not designed to make statistical assertions or estimations but rather to learn something either useful or not (e.g., a term unexpectedly hits on the email signature line use by a custodian). As such, there is no predetermined sample size, confidence level, or margin of error to consider when using judgmental sampling.

b. Upon application of the search terms to the universe of documents subject to search term use, the documents that contain such search terms will be subjected to human review of the full search-hit population to assess responsiveness.

4. Statistical sampling. Pfizer will draw the following simple random samples of documents from the full collection. Pfizer's statistical samples will contain 2400 documents (commonly referred to as using "a 95% confidence level with a margin of error of +/- 2%"). 1200 of the documents will be randomly drawn from the set of search-term hits and 1200 documents will be randomly drawn from the set of search-term misses. The two samples will be randomly interspersed and a full responsiveness review will be performed by a blind reviewer who is provided with no information about the source of the documents. An estimation will be made of the recall and precision achieved by the application of the proposed list of search terms. The recall and precision will be assessed in light of proportionality considerations. There is no predetermined level of recall or precision that is considered de facto acceptable, but rather a determination of what is acceptable will be based on a reasonable overall balance of the two metrics, including the expected burden of review versus fruitfulness of the effort. Pfizer will share the statistically determined recall and precision estimates with the Requesting Party, and will also share the responsive documents identified through the sampling exercise.

5. Pfizer will modify the search terms, as necessary to decrease false-positive search-term hits (i.e., hits on non-responsive documents) and false-negative search-term misses (i.e., responsive documents not identified using the current list of search terms). New search terms identified through review of the responsive documents missed by the previous search terms will be evaluated and added as appropriate. Any changes to the search terms implemented during this step (either to decrease false-positives or false negatives) will be disclosed to the Requesting Party.

   a. Sampling search term hits for responsiveness. Pfizer may prepare a new statistical sample to assess the responsiveness rate for the revised set of search terms, and may review, estimate responsiveness rate, and assess the revised set of search terms for acceptability.

b. Sampling of dropped documents for responsiveness. Pfizer may review a sample of the documents dropped from review by the modifications of the prior iteration of search terms to determine if responsive documents have been inadvertently dropped. This information may be used to determine the acceptability of modifications and resulting responsiveness rates and to determine whether further modifications of the search terms are necessary. In other words, if an attempt to raise responsiveness rates causes responsive documents to drop from review, then that modification is reconsidered in the determination of acceptable responsive rate for the review.

6. Repetition as Necessary. Steps 4 and 5 above are repeated until an acceptable combination of recall and precision are reached. The number of iterations will depend on when an appropriate balance between recall and precision (i.e., comprehensiveness and burden) is met.

7. Search Validation.

a. When Pfizer has achieved a comfort level with its results by the processes set forth in paragraphs 4-6 above, Pfizer will validate its search process by drawing a new random sample of documents (the "Validation Sample") drawn from each of the following three strata and in the following sizes: (a) 1,500 random documents drawn from the set of documents that the search terms did not hit on; (b) 750 random documents drawn from the documents that the search terms hit on that were determined by reviewers to be responsive; and (c) 750 random documents drawn from the documents that the search terms hit on that were determined to be non-responsive. The documents will be randomly interspersed, and a full responsiveness review will be performed on the combined sample by a reviewer blinded to the source and strata from which the documents were drawn and any prior review determinations. From this review, an overall estimated recall and precision based on the Validation Sample will be determined. Pfizer will share the statistically determined recall and precision with the Requesting Party, and will share the responsive documents identified through the validation process including the strata from which they were drawn.

b. Any found responsive documents will be assessed and further modifications to the search terms will be prepared and tested in an attempt to sweep similar documents in the review population by repeating step 4 and 5 above.

c. Upon completion of new rounds of testing, a subsequent sample of the "non-hit" population can be performed until such time as the amount of expected responsive documents as determined by the statistical sample and estimation meets agreeable levels of comprehensiveness. Step 7 can be repeated, with subsequent additional validation in steps 4 and 5 until such time as comfort is achieved. There is no pre-set number of iterations until that comfort level is met.

d. When Pfizer has completed the validation process in step 7, including such subsequent iterations of steps 4 through 7 as may be appropriate, and has achieved a comfort level with the recall and precision indicated by its final Validation Sample, the Parties will meet and confer to try to reach agreement based on the reported recall and precision, and the responsive documents surfaced through validation, about whether the relevant production is adequate.

8. Supplemental Terms/Requests. Pfizer will reasonably comply with Plaintiffs' reasonable requests for supplemental search terms; alternative means to identify potentially responsive documents or information not well suited to identification by search terms or omitted during the review process; and/or targeted requests for specific documents.

9. Conferral & Disputes. To the extent the Parties have any disputes with regard to the implementation of the process hereunder, they shall promptly meet and confer in an effort to reach resolution. Absent agreement, the Parties may present their dispute to the Court for resolution.