UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE: PROPECIA (FINASTERIDE) PRODUCTS LIABILITY LITIGATION	Master File No.: 1:12-md-02331-JG-VVP MDL No. 2331
This Document Relates to: ALL CASES	Honorable Brian Cogan Magistrate Judge Peggy Kuo **SUPPLMENTAL STATUS REPORT**

On March 14, 2016 the Court entered a Minute Order noting, "Plaintiffs are directed to file a single status report by March 25, 2016 advising the Court of the proposed timeline for their commencing to propose bellwether cases." Following entry of the Order, Plaintiffs' Counsel contacted the Court for clarification regarding the Minute Order's directive in relation to Procedure and Practice Order ("PPO") No. 10. Based on consultation with the Clerk, it is the Plaintiff's Executive Committee's ("PEC") understanding the Court requires guidance on the current status of the Discovery and Trial Plan (PPO No. 10) and, in particular, whether the dates in that Order should be accelerated.

In response to the Court's directive, the PEC met and conferred with Counsel for Merck on March 18, 2016. The purpose of the meet and confer was to assess the viability of accelerating the deadlines set forth in in PPO No. 10 (Amended). In addition, the PEC supplied Merck a copy of this Status Report for comment prior to submitting it to the Court. Merck may or may not reply to this Status Report at a later date. Ultimately, the Parties' collective belief is as follows: PPO No. 10 sets forth an aggressive schedule with workable, but extremely tight deadlines. After thoroughly reviewing the current Trial Plan, the PEC's view is that the

proposed discovery time-table and trial date does not allow an opportunity to meaningfully alter the time-table for trial. The purpose of this Status Report is to identify the tasks that the Parties have completed to date and that are required to be completed in the next eighteen (18) months so as to provide the Court with an overview of the amount of anticipated work to be completed prior to trial.

AN OVERVIEW OF THE WORK CONDUCTED TO DATE
IN THE *In Re: Propecia* MDL

There are approximately 1,373 cases currently pending before this Court and in State Court in New Jersey for pre-trial and trial purposes. To date, the Parties have completed the following work:

1. *Plaintiff Profile Form ("PPF") Process:* Plaintiffs in this MDL (and in New Jersey) completed—or are in the process of completing—well over one thousand PPFs. The Plaintiff's PPF is an agreed-to form of discovery comprising of approximately 26 pages and roughly 160 questions**.** PPFs are routinely used in mass actions (most notably in mass tort actions) in lieu of formal written discovery. Specifically, in exchange for conducting formal written discovery, the Parties negotiate an agreed-to set of questions and document requests. Unlike with formal written interrogatories or document requests, Plaintiffs forego their right to object to specific questions and/or production of documents. Additionally, where an individual Plaintiff's PPF is materially deficient, the process entitles the defendant (in this case Merck) to challenge any purported deficiency and requires the plaintiff to cure the deficiency within a negotiated time-table. *See generally PPO No. 5*, Dkt. No. 128. Since commencing this MDL, Plaintiffs supplied Merck nearly one thousand PPFs and responded to thousands of deficiency letters claiming there were issues with the completeness of the various responses. This PPF

process is a time consuming and important aspect of all MDLs because it: a) identifies those cases that may or may not have merit; and b) ultimately leads to the selection of representative bellwether selections.

2. *Defendant Discovery*: At the same time, the PEC issued formal document requests to Merck seeking access to potentially relevant documents. To date, Merck has produced approximately three million pages of documents from over seventy custodian's individual files and shared databases. In addition, Merck likely reviewed two to three times that number of documents to evaluate whether the documents were relevant and to assess potential claims of privilege. The time to review the amount of documents—by both Parties—was a massive undertaking. The following provides an overview of the document production process and related issues:

   a. Entry of the ESI Order and Deposition Protocol: Immediately after formation of this MDL the Parties commenced negotiations over the manner governing Merck's document production and the scope of depositions. On July 2, 2013, the Court entered the *Revised ESI Order*. *See Revised ESI Order*, Dkt. No. 105. Completion of the Electronically Stored Information ("ESI") protocol is a critical step in mass tort MDL litigation given the massive number of documents and pages that are produced. Specifically, the ESI protocol governs the method in which Merck produces documents, including the type of meta-data the defendant is required to supply to the plaintiff's leadership team. Prior to approval of an ESI protocol, the parties are effectively unable to start discovery because the Order governs the method the defendant is required to follow when supplying documents to the plaintiff. The negotiations involving entry of an ESI Protocol are often time-consuming given the

highly technical nature and scope of the anticipated document collection.

b. The Original Trial Schedule and Unanticipated Delay: As is common in large scale mass tort litigation, the Parties encountered certain obstacles throughout the process that resulted in unanticipated delay of the original trial schedule. Pursuant to Judge Gleeson's and Magistrate Pohorelsky's original Discovery and Trial Plan, trial was set for October of 2016. *See PPO No. 10*, Dkt. No. 207. The original PPO No. 10 required Merck to provide "written certification" when a custodial file production was "complete" in the form of a Certification of Completion ("Certifications"). *See PPO No. 10* at ¶ 3(a). The Certification process is an important step in the discovery process because it is designed to ensure that deposition occur *once and only once.*[1]

c. Discovery Motion Practice: PPO No. 10 included two important provisions regarding document production and deposition practice. First, it directed Merck to supply the PEC with the initial Certifications "on or before December 15, 2014". *See PPO No. 10* at ¶ 3(a). Second, it precluded the PEC from conducting depositions until it received Merck's Certification from its initial custodial production. *Id.* at ¶ 3(c). In December of 2014, Merck notified the PEC that it uncovered several million pages of potentially responsive documents and, as a result, was unable to satisfy its certification obligations. At the same time, the PEC uncovered approximately thirty (30) additional custodians it believed possessed relevant information related to the

[1] And, even with a Certification process, errors can, and do, still occur. For example, in this MDL Merck supplied the PEC with Certification for Paul Knoflicek and Thomas Casola. Based on those Certifications, the PEC took Mr. Knoflicek's deposition on November 18, 2015 and scheduled Mr. Casola's deposition for March 29, 2016. On or about, February 19, 2016, Merck contacted the PEC to alert them of additional documents in uncovered in a construction area from both witnesses' custodial files. The disclosure of these documents required the Casola deposition be rescheduled; the Parties are currently negotiating whether Mr. Knoflicek will need to be re-deposed.

scope of the case. The disclosure of these additional documents and custodians not only caused the original Trial Plan to be scrapped, but also resulted in motion practice by Merck seeking a Protective Order regarding the production of additional custodial files and by the PEC seeking to compel Merck to supply the Certifications and additional custodians. *See e.g., Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion for a Protective Order and in Support of Motion to Compel Discovery*, (January 6, 2015) Dkt. No. 215; *Defendant's Letter Brief*, (December 19, 2014) Dkt. No. 213**.** Following several Case Management Conferences and numerous meet and confers, the Parties successfully negotiated a resolution whereby Merck agreed to produce twenty-four (24) of the thirty (30) additional custodial files and the Parties reached a consensus on the time-table for completion of Merck's document production.

d. The Trial Plan Amendment Process—PPO No. 10 (Amended): The discovery of the additional documents and custodial files meant that the schedule set forth in PPO No. 10 could not be achieved. Accordingly, the Court directed the Parties to supply it with an amended PPO No. 10 setting forth new dates for completion of discovery and trial. In response, Merck filed a motion to vacate PPO No. 10, proposing several substantive changes. Merck's proposals ultimately resulted in motion practice where each Party submitted letter briefs urging the Court to adopt its version of PPO No. 10. *See Parties Briefs on the Discovery and Trial Plan, PPO No. 10 (Amended)*, Dkt. Nos. 248, 259, and 260. The motion practice resulted in additional delay given the original PPO No. 10 precluded the PEC from commencing deposition practice *until* it received Merck's Certifications of Completeness. The Parties appeared before.

Following the hearing the Court entered PPO No. 10 (Amended) setting the start date for deposition practice as October 15, 2015. *See generally PPO No. 10*, Dkt. No. 274. Additionally, pursuant to PPO No. 10 (Amended), the Court Ordered that deposition practice could commence on October 15, 2015. *Id.* at ¶ 3(b).

AN OVERVIEW OF THE WORK TO-BE COMPLETED PRIOR TO TRIAL

1. *PPO No. 10 and the Status of Discovery*: As noted above, deposition practice opened on October 15, 2015. Pursuant to PPO No. 10 (Amended), the Discovery and Trial Plan contemplates the first case will be trial ready within twenty-two months of starting depositions. The purpose of this section is to provide an overview of the anticipated work the Parties will complete (or have completed) prior to trial:

a. Deposition Practice.

i. *Completed Depositions*: Since entry of PPO No. 10 (Amended), the PEC has conducted the following depositions of Merck employees: 30(b)(6) deposition related to Electronically Stored Information I (deponent: Felipe Verdelho (ESI, 12/18/2013)); 30(b)(6) deposition related to Electronically Stored Information II (deponent: Andrew Zager (ESI, 4/29/2014)); 30(b)(6) deposition related to Marketing and Sales Practice I (deponent: Dan Hauber, 1/38/2014)); 30(b)(6) deposition related to Marketing and Sales Practice II (deponent: Scott Summers (6/10/2014)); Paul Knoflicek (11/18/2015); Robert Silverman (12/10/2015); Elizabeth Round (12/17/2015); Phyllis Palmer (1/6/2016); and Frank Mellina (2/23/2016).

ii. *Future Depositions:* Additionally, the following depositions are scheduled or

are in the process of being scheduled: Grif Bates (5/9/2016); Tom Casola (postponed); Christine Alberts (unscheduled); Ruth Desmon (5/10/2016); Paul Howes (4/1/2016); Charlotte Merrit (5/19/2016); Kevin Nalty (4/21/2016); Cynthia Silber (4/19/2016); Elizabeth Stoner (4/28/2016); Shailaja Suryawanshi (5/5/2016); Keith Kaufman (unscheduled); and Siyoung Ahn (5/26/2016).

iii. *Third Party Depositions:* Finally, the PEC anticipates that it will conduct third-party depositions of several advertising agencies and hair-clubs.

In total, between October 15, 2015 and June 24, 2016 the PEC anticipates taking no less than twenty four to thirty general liability depositions (i.e., approximately one deposition every ten days).

b. Expert Discovery: As the Court is aware, expert discovery will play a significant role in this litigation. PPO No. 10 (Amended) contemplates that expert reports be produced by December 15, 2016. Given the complexity of mass tort litigation, the PEC anticipates that each side will secure no less than six to eight experts who will testify on issues of general and case-specific causation.

i. *General Causation Expert Reports:* Given the nature of the injury in this case, the experts will likely encompass a wide array of disciplines including Urology, Endocrinology, Pharmaco-vigilance, Regulatory Affairs, and Epidemiology. *This is not to suggest* each of these witnesses will testify in each trial or that either Party intends to advance testimony in violation of Rule 403's prohibition of cumulative testimony. *However,* given the fact that this is an MDL, *and* that remand is always a possibility, both Parties will likely secure experts with

duplicative disciplines so as to ensure that an expert is available to testify in future trials. Further, because the Court's rulings on the Parties' Rule 702 motions will result in ramifications for *all* cases pending in the MDL, each Parties' reports will likely be extremely thorough.

ii. *Case Specific Expert Reports:* In addition to the general causation reports, PPO No. 10 (Amended) requires the Parties to select three cases each (for a total of six cases) as potential representative candidates for inclusion in the initial Case Pool. *See PPO No. 10* at ¶ 10. From this group of cases, the Order contemplates the Court will select four (4) representative cases on or before October 28, 2016. Each of these cases will likely require some form of case-specific expert report, which must be completed (by Plaintiffs) on or before December 15, 2016 and requires Merck's opposition on or before February 1, 2017. These reports will then, be subject to Rule 702 motion practice set forth in Paragraph 12.

c. An Overview of Rule 702 Motion Practice: Following completion of the expert reports and depositions, the Parties will likely engage in Rule 702 motion practice. The motion practice will, invariably, be extensive given the fact the outcome will impact not just the individual plaintiff's cases, but also the broader population of claimants within this MDL. To put this in perspective, over the course of the next fifteen months (the date the final reply brief related to Rule 702 motion practice is filed with the Court) assuming each side retains six experts (there may be more) and that each expert's report is twenty to thirty pages in length, the PEC (and Defendants) will likely shepherd the completion of several hundred pages of expert reports per side between now and February of 2017. *See PPO No. 10* at ¶ 12. Following

submissions of the expert reports, each expert will be deposed during a sixty-day (60) period in what will likely be highly technical, complex depositions. *Id.* Eighteen (18) days after completion of expert depositions, PPO No. 10 requires the Parties submit their respective Rule 702 motions. *Id.* at ¶ 13(a). The proposed amendments to PPO No. 10 (Proposed Second Amended) contemplate seventy-five (75) pages collectively per side in the opening opposition briefs for all case-specific and general causation reports (roughly ten to twelve pages per general causation and case-specific expert), seventy-five (75) pages per-side for opposition briefs, and forty (40) pages for rebuttal briefs. *See PPO No. 10 (Proposed Second Amended),* Dkt. No. 295 at ¶ 13.[2] It is likely that the Parties combined *Daubert* briefs will exceed three-hundred (300) pages of total briefing plus hundreds of pages in relevant exhibits, reports and deposition citations. All of this work must be completed within a fifteen month window.

d. Bellwether Discovery: During much of this same time period, the Parties will be engaged in case-specific discovery of the bellwether selections. Pursuant to PPO No. 10 (Proposed Second Amended) the Parties will make their bellwether selections on May 20, 2016. Both PPO No. 10 (Amended and Proposed Second Amended) require

[2] The Parties submitted a Joint Proposed Second Amended PPO No. 10 on March 16, 2016. *See PPO No. 10 (Proposed Second Amended),* Dkt. No. 295. Ultimately, PPO No. 10 (Proposed Second Amended) contemplates two date revisions (neither of which will impact the proposed trial schedule). The first amendment extends the Case Pool selection date from May 13, 2016 to May 20, 2016. *Id.* at ¶ 7. The amendment is requested to accommodate deposition scheduling conflicts of Merck witnesses the week of May 9-13, 2016. The second amendment alters the briefing schedule for Rule 702 motions extending the time to prepare opposition briefs from fourteen to thirty days and allowing each side seventy-five pages of total briefing for opening and opposition briefs (as opposed to fifty), and allow forty pages for the reply brief (as opposed to twenty-five). *See PPO No. 10 (Proposed Second Amended)*, Dkt. No. at ¶ 13; *cf. PPO No. 10 (Ameded),* Dkt. No 207 at ¶ 13 (to compare briefing schedules and page limitations).

each side to select five (5) cases as bellwether picks for a total of ten (10) cases. Paragraph 9 governs "Case-Specific Discovery". It includes two key provisions: 1) *all* case-specific discovery will be completed between May 30, 2016 and September 15, 2016 (approximately 105 days); and 2) the Order contemplates up-to five depositions for each case. In other words, assuming each side elects to take the minimum number of eligible depositions, the Parties will likely take *at least* fifty (50) depositions over a one-hundred-five (105) day period.

e. Summation of to-be Completed Discovery: In total, the Parties will likely conduct the following discovery over the next eighteen months:

i. *General Merits Discovery*: Fifteen (15) to twenty (20) current and former Merck employees related to the PEC's general liability theory. The PEC will also likely take three to five third-party deponents by June 24, 2016.

ii. *Case-Specific Discovery:* Forty (40) to fifty (50) depositions of doctors, plaintiffs, and Merck sales representatives between May 30, 2016 and September 15, 2016.

iii. *General Causation Expert Discovery*: Six to eight general causation experts per-side (total twelve to sixteen) prepared by December 15, 2016.

iv. *Case Specific Expert Reports*: Six or more case-specific reports (per side for a total of at least twelve reports) between October 28, 2016 and February 1, 2017.

v. *Rule 702 Motion Practice*: The Parties will likely take in excess of twenty (20) expert depositions between general and case specific experts. Additionally, the Parties will likely submit a combined three-hundred plus (300+) between May 1, 2017 and July 14, 2017.

vi. *Post Daubert Work*: Following resolution of Rule 702 motion practice PPO No. 10 contemplates the Parties will conclude all discovery required for trial and engage in *Motion in Limine* practice.

CONCLUSION

The PEC submits this Status Report pursuant to the Court's Minute Order requesting an update on the bellwether process. Based on the anticipated work prior to trial, the PEC's position is that the current deadlines set forth in PPO No. 10 (Proposed Second Amended) set forth an extremely aggressive time-table leading to an anticipated trial date in September of 2017. This schedule, while aggressive, appears workable. Accordingly, it is the PEC's recommendation that the Court not accelerate the deadlines contained in PPO No. 10 (Proposed Second Amended).

Dated: March 25, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document has been electronically filed with the Court using the CM/ECF system which will send notification of such filing to all attorneys of record.

/s/ Timothy J. Becker
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