UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: FINASTERIDE (PROPECIA) PRODUCTS LIABILITY LITIGATION	)	MDL 2331
	)	12-CV-2331
THIS DOCUMENT RELATES TO:	)	HON. BRIAN M. COGAN
ALL CASES	)	

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THE PLAINTIFF EXECUTIVE COMMITTEE'S MOTION AND MEMORANDUM OF LAW FOR APPROVAL OF SETTLEMENT PLAN OF ALLOCATION

On April 9, 2018, the Parties in this MDL announced they reached a Master Settlement Agreement ("MSA") to resolve certain claims encompassed within this MDL. Pursuant to the terms of the MSA, this Court retains jurisdiction over the terms of the settlement agreement, and in particular, the Allocation Plan. The PEC now submits the proposed Allocation Plan to this Court for its review and moves this Court for an Order approving the Allocation Plan.[1]

[1] As the Parties informed the Court, they intended to file the MSA under seal. Early today, the Court directed the Parties to make a showing beyond the agreement in the MSA why the documents should remain confidential. The PEC is bound by the confidentiality in the MSA, and as such, it is unable to file the MSA absent breaching that Agreement. However, the Parties have agreed the PEC may disclose the Gross Settlement Amount in connection with this filing and the Court's review of the Allocation Plan. Nonetheless, it is the PEC's understanding that Merck no longer intends to file the MSA and will provide additional information to the Court tomorrow. In the interim, as set forth in the April 9, 2018 letter, the PEC is filing the attached Allocation Plan and accompanying documents for the Court's review and/or additional guidance.
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THE MASTER SETTLEMENT AGREEMENT

The Parties have, from time-to-time throughout this litigation, endeavored to negotiate a resolution. The negotiations involved both formal and informal discussions including a mediation session before Retired Judge Diane Welsh. Those negotiations ultimately culminated in the MSA executed this week.

For its part, the MSA resolves the claims of eligible Plaintiffs with cases filed within the MDL, and certain other jurisdictions (most notably those claims filed in the New Jersey State Court Consolidated proceedings). Pursuant to the terms of the MSA, the Parties elected to give this Court, along with a Special Master, jurisdiction over the implementation and administration of the Settlement Program. In connection with this process, the PEC retained Retired Magistrate Judge Arthur Boylan (D. Minn.) to review the claims allocation process and resolve any appeal by claimants of their individual allocations.[2] The purposes of this brief is three-fold: First, it outlines the legal standard authorizing the Court to oversee the settlement process. Second, it describes the Allocation Plan itself and the method the PEC intends to use to allocate the settlement funds for individual claimants (which will ultimately be approved by the Special Master). Third, it seeks approval of an Allocation Committee made-up of certain members of the PEC who are familiar with the litigation and represent a substantial number of Plaintiffs.

ARGUMENT

[2] Judge Boylan is highly qualified to oversee the final allocation of the settlement funds. For example, Judge Boylan was appointed to serve as the Special Master tasked with allocation of settlement funds in the following mass tort litigation: *In re: Stryker Rejuvenate and ABG II Hip Implant Products Liability Litigation*, (MDL No. 2441, D. Minn.); *In re Guidant Corp. Implantable Defibrillators Products Liability Litigation* (MDL 1708, D. Minn); *In re Levaquin Products Liability Litigation* (MDL 1943, D. Minn). *See generally* Judge Boylan's *Curriculum Vitae* and list of cases attached as Ex. 1 and 2 to Affidavit of Timothy J. Becker dated April 10, 2018 ("*Becker Aff.*").

I. THIS COURT HAS BROAD AUTHORITY TO OVERSEE AND APPROVE THE PROPOSED ALLOCATION PLAN.

As noted above, pursuant to the Parties agreement in the MSA, this Court has authority to approve the proposed Allocation Plan. The law is well settled that an MDL court has authority and discretion to approve a plan of allocation. *See generally* Fed. R. Civ. P. 16(a)(5); *see also In re Vioxx Prods. Liab. Litig.*, 650 F. Supp. 2d 549, 553 (E.D. La. 2009) (outlining case law establishing MDL courts may approve and oversee a global settlement and plan of allocation). The district court has broad supervisory powers and discretion to oversee how the settlement funds are allocated and, ultimately, to approve the proposed allocation plan. *In re "Agent Orange" Prod. Liab. Litig*., 818 F.2d 179, 181 (2d Cir.1987). In evaluating the allocation plan, the Court's primary role is to evaluate whether the plan is fair and reasonable. *In re Merrill Lynch & Co., Research Reports Securities Litig*., 246 F.R.D. 156, 170 (S.D.N.Y. 2007). Allocation plans that include an analysis of the strengths and weaknesses of each individual action—as the proposed Allocation Plan here does—are presumed to be fair and reasonable. *Id*. Further, allocation plans developed by lawyers experienced in settlement allocations to large groups of injured plaintiffs provides additional evidence that the allocation is fair and reasonable. *See In re Global Crossing Sec. & ERISA Litig*., 225 F.R.D. 436, 462 (S.D.N.Y.2004) (quoting *In re Am. Bank Note Holographics, Inc. Sec. Litig*., 127 F.Supp.2d 418, 429–30 (S.D.N.Y.2001)) (noting "When formulated by competent and experienced class counsel, an allocation plan need have only a 'reasonable, rational basis.'"). For this reason, courts give substantial weight to the opinions of experienced counsel in assessing the fairness of the proposed allocation. *See generally In re PaineWebber Ltd. P'ships. Litig*., 171 F.R.D. 104, 133 (S.D.N.Y.1997); *In re Marsh ERISA Litig*., 265 F.R.D. 128, 145 (S.D.N.Y. 2010).

The proposed Allocation Plan satisfies these requirements. As set forth in more detail below, the lawyers who resolved this case and created the Allocation Plan, were involved in all aspects of the litigation. By way of example, they took the vast majority of the depositions, retained and worked with the general and case specific causation experts to prepare the various expert reports, and were appointed by the Court to lead this case. As a result of this work, the lawyers who created the Allocation Plan were in the best position to identify the relative strengths and weaknesses of a particular claimant's case. This insight allowed for the creation of the proposed Allocation Plan.

A. An Overview of the Allocation Plan.

In order to fairly allocate settlement funds in the Propecia Settlement Program, the PEC developed the proposed Allocation Plan. *See Plan of Allocation (Proposed)* attached as Ex. 3 to *Becker Aff*. In doing so, the PEC used a variety of factors which include positive and negative modifiers to allocate the settlement proceeds among participating Plaintiffs and Claimants. These factors reflect real-life modifiers that make an individual Claimant's claim stronger or weaker in terms of the facts a plaintiff would use at trial to establish causation and damages in their individual case. This section generally discusses the factors the PEC considered to evaluate a given claim and how those factors are used to determine the final award.

1. The lawyers who created the Proposed Allocation Plan are intimately familiar with this litigation.

At the outset, the Allocation Plan was developed by the members of the PEC who are all experienced litigators in the context of drug and device MDLs. As noted above, "When formulated by competent and experienced class counsel, an allocation plan need have only a 'reasonable, rational basis.'" *In re Global Crossing Sec. & ERISA Litig*., 225 F.R.D. 436, 462 (S.D.N.Y.2004) (quoting *In re Am. Bank Note Holographics, Inc. Sec. Litig*., 127 F.Supp.2d 418,

429–30 (S.D.N.Y.2001)). In this instance, the members of the PEC, and the corresponding members of the PLC in the New Jersey litigation who developed the Allocation Plan, are well versed in both the facts of this case and the allocation of settlement proceeds in mass tort pharmaceutical MDLs.

In terms of the litigation itself, the Allocation Plan was developed by members of the PEC who conducted the bulk of the substantive depositions in this case, were responsible for securing and preparing the expert reports, and were involved in all aspects of the case. The primary architects of the Allocation Plan were Tim Becker, Trent Miracle and Victoria Maniatis. Mr. Becker is a member of the PEC, conducted more than a dozen depositions and oversaw the preparation of the primary causation and liability experts. Mr. Miracle is also a member of the PEC, participated in numerous depositions, and was responsible for overseeing completion of the primary regulatory expert report. Finally, Ms. Maniatis is Co-Lead Counsel in the Consolidated State Court action, defended and took several key depositions, and has participated in this litigation throughout the entire process. In short, these three attorneys were key members of the PEC litigation team.

Similarly, each has substantial experience in pharmaceutical and device litigation. For example, Mr. Becker was Co-Lead Counsel in the NexGen MDL in the Northern District of Illinois. Mr. Miracle currently serves as Co-Lead Counsel in the Testosterone Replacement Therapy Litigation in the Northern District of Illinois. Ms. Maniatis is a member of the Plaintiffs' Steering Committee in multiple pharmaceutical and medical device MDLs. Their work in these cases involved both litigation and settlement efforts with the various defendants. As a result of this work, the three represent seasoned litigators who are also experienced in

developing settlement plans of allocation in the context of mass tort pharmaceutical and device MDLs.

2. An overview of the mechanics of the Proposed Allocation Plan.

In terms of the Allocation Plan itself, the Plan sets forth various categories and levels of compensation based upon an individual Claimant's proof of use of Propecia and evidence of injury. The lawyers who participated in the litigation and the development of the experts in this litigation are in the best position to understand the strengths and weaknesses of the individual cases and the weight to give the various factors in the allocation plans. In short, these lawyers are most able to ascertain what is and is not a compensable claim.

In order to fairly distribute the settlement proceeds among the Plaintiffs and Claimants, the Allocation Plan employs a point system, categorizes claims and then uses various factors to adjust point awards both upwards and downwards based upon the individualized factors in the claim. The final point award will ultimately translate into settlement awards for each Claimant. In the context of a pharmaceutical MDLs, this type of point system is an often-used approach in a settlement allocation plan. *See e.g., In re Benicar (Olmesartan) Prod. Liab. Litig*. (MDL 2606, D. N.J.), Appendix J to the August 1, 2017 Master Settlement Agreement establishing the Olmesartan Settlement Program, attached as Ex. 4 to *Becker Aff*. (employing a point award system, including categories and upwards point adjustments based upon the individualized factors in each claim); *see also In re Actos (Pioglitazone) Prod. Liab. Litig*. (MDL 2299, W.D. La.), Appendix J to the April 28, 2015 Master Settlement Agreement establishing the Actos Settlement Program, attached as Ex. 5 to *Becker Aff*. (employing a point award system utilizing upwards and downwards point adjustments). In other words, the mechanism the Allocation Plan

employs to establish a given Plaintiff's award is both typical of that in other mass tort pharmaceutical MDLs and widely accepted by courts overseeing similar actions.

In this instance, utilizing a similar scheme, the base point awards will be determined using objective criteria to assess the relative merits of the types of claims encompassed within each category, with upward and downward adjustments tied to additional objective criteria. It is important to note that the PEC designed the Allocation Plan to link each award to *objective evidence* from a given Plaintiff's claim. The PEC did this in an effort to eliminate subjective criteria that could not be fairly considered across the entire spectrum of all potential claimants.[3] Finally, once all claims are submitted and reviewed, the Special Master will finalize individualized point awards for each claimant. After any appeals are exhausted and the Special Master makes any point adjustments, the value of the settlement fund will be equally divided among the total points awarded, which will then be used to determine a final value per point. The per point value will then be applied to individual point awards to determine the final settlement awards for the participating individual Plaintiffs and Claimants.

a. The Categories of Allocation.

In general terms, the Allocation Plan creates five categories from which a plaintiff is assigned a base point award. The categories directly correspond to the relative strength of a given claim. Specifically, the categories reflect the type of proof an individual plaintiff could amass to support their individual claim as if the case went to trial. Each category reflects the relative "weight" of a particular Plaintiff's proof—i.e., the better the proof corresponds to higher categories. The categories are described as follows:

[3] That said, the Allocation Plan specifically contemplates an appeal process to Special Master Boylan for any claimant who believes that he should have received additional points. The appeal process affords claimants the opportunity to review the final allocation.

Category One: The first category includes men whose primary proof of erectile dysfunction is based upon evidence the man was prescribed a PDE5-inhibitor (e.g., Viagra® or Cialis®) during or after discontinuation of Propecia. In other words, the individual started to use an erectile dysfunction drug while on or after stopping Propecia.[4] The fundamental rational for Category One is that a PDE5-inhibitor prescription is the minimal amount of proof required to establish the individual has some form of erectile dysfunction.

Category Two: The second category includes men whose primary proof of erectile dysfunction stems from a man who saw his Primary Care Provider ("PCP") who, in turn, made a diagnosis of erectile dysfunction. Unlike those claims in Category One, these men actually have a diagnosis from their medical provider diagnosing the individual with erectile dysfunction. In the PEC's experience, there are often instances where a man is prescribed a PDE-5 inhibitor without any mention or diagnosis included in the medical records and results in this distinction in the categorization of claims.

Category Three: The third category of men includes men whose primary proof of erectile dysfunction stems from a diagnosis by a specialist (e.g., urologist or endocrinologist) who diagnosed the man with erectile dysfunction. The rational for this is that the specialist, unlike a PCP, is skilled in recognizing and diagnosing erectile dysfunction issues and the additional treatment and evaluation likely performed by the specialist.

[4] As part of the PPO 16 process, most, if not all, claimants who used PDE5-inhibitors *prior to starting* Propecia dismissed their claim. The rational for this being that the core claim in this MDL is that Propecia causes men to experience sexual dysfunction while on-drug and following discontinuation of use. A man who used a PDE5-inhibitor prior to starting Propecia ostensibly had erectile dysfunction prior to starting Propecia. As set forth below, those men are included in the "Catch-All" Category Five. Conversely, a man who used a PDE5-inhibitor while on-drug and continued to use it following discontinuation of use, has a claim that Propecia caused his sexual dysfunction.

Category Four: The fourth category includes men who saw a specialist who rendered a causation diagnosis. Specifically, this includes men where the specialist attributed the man's erectile dysfunction to his Propecia use (*e.g.*, erectile dysfunction secondary to Propecia/finasteride use). The rational for this is that these men ostensibly saw a medical provider who conducted a differential diagnosis and concluded the "cause" of the man's erectile dysfunction was Propecia. This category also encompasses claims where there is additional objective evidence of the injury, including radiologic testing such as a Doppler imaging to demonstrate penile fibrosis.

Category Five: Finally, the fifth category includes men whose claims do not fall into any of the previous categories. These include claims for men whose injury include ancillary claims to this litigation (e.g., claims that Propecia caused prostate cancer, breast cancer, genital disfigurement, and gynecomastia or whose proof of harm is not sufficient to fall within Categories One through Four).

Ultimately, each of the Categories was designed to eliminate subjective determinations of evidence and, instead, is predicated on objective evidence (i.e. the individual has definitive proof in the medical or pharmacy records of proof of use and an injury). This type of evaluation will allow the Allocation Committee and Special Master to assess each man's claim from an objective determination predicated upon the records the individual claims submits in connection with the allocation process.

b. Factors impacting an individual claim.

The Allocation Plan includes not only categories, but methods to adjust points both upwards and downwards based upon the individual factors in each claim. Like the Category designation, the factors are predicated upon objective evidence. *See generally Allocation Plan*

(Proposed) attached to *Becker Aff.* as Ex. 3. Specifically, each modifier will be identifiable in the materials a claimant is required to submit in connection with the claims process.[5] This type of evaluation of the individualities of each claim, including the strengths and weaknesses of a case, are precisely the characteristics used by other Courts in determining a plan of allocation is a fair and reasonable plan. *In re Merrill Lynch & Co., Research Reports Securities Litig.*, 246 F.R.D. 156, 170 (S.D.N.Y. 2007) (a settlement plan must be fair and reasonable). *Id.* Further, a district court has considerable discretion in determining what to consider in approving a settlement allocation. *See In re "Agent Orange" Prod. Liab. Litig.*, 818 F.2d 179, 181 (2d Cir.1987). As such, the Allocation Plan considers other evidence and factors in an individual Plaintiff or Claimant's medical records, including:

(1) the proof of Propecia use;
(2) documentation of injury following drug use;
(3) the duration of time between drug use and injury;
(4) age at time of injury[6]; and
(5) alternative causes for the injury.

Certain of these factors were identified based upon evidence uncovered in the MDL including Merck documents and witness testimony, general causation expert reports and testimony, and support in the medical literature with respect to the medical causation of the individual claims. Similarly, downward modifiers were incorporated to take into consideration certain defenses

[5] As set forth in the Allocation Plan, each Claimant is required to produce the following: 1) a claim form; 2) the Plaintiff's Profile Form (even if not previously required to be completed); 3) all pharmacy records; and 4) the diagnosis record establishing proof of injury (if such a record exists). These records will allow the Special Master and Allocation Committee to make objective determinations of the various factors that modify a particular Plaintiff's point determination.

[6] By way of example, the "age" at the time of injury is relevant to the merits of a particular Plaintiff's claim. As men age, the percentage of men who experience naturally occurring age-related erectile dysfunction increases. Put another way, men in their seventies experience erectile dysfunction at a higher rate then men in their twenties. As such, younger men receive a positive modified to their base award, whereas older men receive a negative modifier.

available to Merck, including Propecia usage after the warning label was updated or filing dates with expired statutes of limitations.

Finally, to ensure any allocation of the settlement proceeds are performed in a fair and reasonable manner, the Allocation Plan contemplates a committee of Plaintiffs' attorneys to review the claim submissions and work in connection with the Special Master to finalize approve the allocation of the settlement proceeds. It also includes an appeal process for the Special Master to reconsider any awards before final allocations are awarded and paid.

B. Appointment of a Settlement Allocation Committee.

In order to implement the attached Proposed Allocation Plan, the PEC further moves the Court for an Order appointing an Allocation Committee, consisting of three Plaintiffs' Firms of the PEC who will work with the Special Master to apply the objective criteria encompassed within the Allocation Plan so as to determine the final allocation of the settlements funds among the Plaintiffs and Claimants consistent with the MSA, the Allocation Plan, and any further Orders of this Court. An Allocation Committee appointed by the Court to work with a Special Master on settlement claims is a frequent part of a settlement allocation process. *See e.g. In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.* (MDL 1708, D. Minn) August 1, 2008 Order Appointing Claims Review Committee, attached as Ex. 6 to *Becker Aff.*; *see also In re Medtronic, Inc. Implantable Defibrillators Prod. Liab. Litig.* (MDL 1726, D. Minn) February 11, 2008 Order Appointing Claims Review Committee and Adoption of Settlement Claims Review Protocol, attached as Ex. 7 to *Becker Aff.* The identified Firms have considerable experience working on pharmaceutical and medical device settlement allocations and will work with the Special Master to ensure any allocation of the settlement proceeds is fair and reasonable and consistent with the approved allocation plan.

CONCLUSION

As set forth throughout, the Proposed Allocation Plan is reasonable and fair; was designed by lawyers familiar with the case and experienced in mass tort litigation. In creating the Proposed Allocation Plan, the architects endeavored to utilize factors predicated upon objective evidence that coincide with a given Claimant's case. Finally, the PEC ensured the overall allocation will be fair by retaining a seasoned and experienced Special Master. Ultimately, the Proposed Allocation Plan satisfies the requirements Court evaluate when overseeing global resolution of multi-district litigation. Accordingly, the Court ought to approve the Proposed Allocation Plan.

Dated: April 10, 2018

Respectfully submitted,

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