

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: ORAL SODIUM PHOSPHATE SOLUTION-BASED PRODUCTS LIABILITY ACTION	:	
	:	Case No. 1:09-SP-80000
	:	(MDL Docket No. 2066)
 THIS DOCUMENT RELATES TO ALL ACTIONS	 :	
	:	JUDGE POLSTER
	:	
	:	<u>CLAIMS REVIEW</u>
	:	<u>PROTOCOL ORDER</u>

In this Court's *Order Regarding Claims Processing Schedule* (master docket no. 99) ("Claims Order"), the Court set out certain deadlines for Claimants to opt in to the Master Settlement Agreement. Nearly 600 Claimants have opted in. The *Claims Order* also set out certain procedures regarding the processing of claims, including procedures that apply if Fleet (and/or the Applicable Insurers) and the Participating Claimant disagree on the settlement value of a claim pursuant to the settlement construct ("Settlement Construct Valuation"). *See Claims Order* §2 at 8-9.

This Order sets out more fully the protocol that will apply regarding Settlement Construct Valuation and the processing of a Participating Claimant's claim. All provisions contained in the earlier *Claims Order* continue to be in full force and effect; the instant Order simply fleshes out those provisions and, in particular, documents in full the Claim Valuation protocol.

CLAIM VALUATION PROTOCOLS

I. Modification of Protocols.

The parties may agree to modify the protocols set out in this Order as the claim valuation process unfolds, and may also move the Court for modification if they cannot agree. Any circumstances not addressed by the Master Settlement Agreement (“MSA”), the *Claims Order*, and this *Protocol Order* will be decided by the Court. Similarly, any disagreement between the parties regarding the meaning or effect of any of the provisions contained in the MSA, the *Claims Order*, and this *Protocol Order* will be decided by the Court.

II. Measurement of Time.

All computations of time set forth in this Order shall be made in accordance with Rule 6 of the Federal Rules of Civil Procedure. All deadlines listed in this Order may be extended by agreement of the parties or by Order of the Court or Special Master. A motion to extend a period of time set forth in this Order must be made prior to the expiration of the time period sought to be extended. Regardless of the deadlines and time periods set forth in this Order, all parties will endeavor to fulfill their responsibilities and obligations connected with claim valuation and payment as soon as reasonably possible.

III. Good Faith.

The obligation to act reasonably and in good faith is imposed upon Fleet, all Insurers, and all Claimants in connection with every provision contained in the MSA, the *Claims Order*, and this *Protocol Order*.

IV. Zero Value Claims.

If the Claimant has filed his or her claim with any state or federal court, and the parties agree that the claim does not “pass threshold,” is excluded, or has a zero Settlement Construct Valuation, then the Claimant shall provide to Fleet an executed Stipulation of Dismissal pursuant to §4.14 of the MSA.

If the Claimant *has not* filed his or her claim with any state or federal court, and the parties agree that the claim does not “pass threshold,” is excluded, or has a zero Settlement Construct Valuation, then the parties shall file with this Court a “Notice of Agreed Zero Value” acknowledging that the Claimant’s claim has been fully resolved pursuant to the MDL settlement process.

V. Supplement to *Claims Order* §2.1.¹

Subject to any deficiency process resolution² and/or other extension of time, if Fleet and/or the Applicable Insurer(s)³ have not informed the PEC and the Claimant’s attorney that they agree or disagree with the Claimant’s Settlement Construct Valuation on or before the relevant deadline (November 19, 2010 for Track A Claims, and December 15, 2010 for Track B Claims), then Fleet and the Applicable Insurer(s) will be deemed to have agreed with the Claimant’s Settlement Construct Valuation.

¹ *Claims Order* §2.1 states: “If Fleet, or the Applicable Insurer(s), disagree with a Participating Claimant’s Settlement Construct Valuation, they must promptly inform the Participating Claimant’s lawyer and the PEC as to the precise basis of the disagreement and simultaneously provide the Participating Claimant’s lawyer with their Settlement Construct Valuation Work Sheet, together with all pertinent documents supporting their Settlement Construct Valuation. The notice shall be by email with copies to the PEC.”

² Procedures for addressing deficiencies in the documentation of a claim submission are set out at *Claims Order* §1.

³ Because the phrase “Fleet and/or the Applicable Insurer(s)” is so unwieldy, the Court uses only the term “Fleet” in the remainder of this Order. Every use of the term “Fleet,” however, should be construed to mean “Fleet and/or the Applicable Insurer(s),” unless context makes clear that the Court is referring only to Fleet.

If Fleet and the Applicable Insurer agree with the Claimant’s Settlement Construct Valuation, the valuation process is over and the Claimant shall be paid the agreed-upon Settlement Construct Valuation in accordance with the MSA and the Orders of this Court.

If Fleet disagrees with the Claimant’s Settlement Construct Valuation, then Fleet shall promptly provide to the Claimant and to the PEC a “Notice of Disagreement.” The Notice of Disagreement shall include: (1) Fleet’s Settlement Construct Valuation Worksheet, (2) Fleet’s Proposed Value, and (3) a written explanation of the precise reasons for disagreement with Claimant’s Proposed Value, together with (and/or referring specifically to) all pertinent documents that were submitted with the Claim that support Fleet’s Proposed Value.

Within seven days of receipt of Fleet’s Notice of Disagreement, the Claimant shall advise Fleet and the PEC whether the Claimant agrees to or disagrees with Fleet’s Proposed Value. If Claimant agrees with Fleet’s Proposed Value, the valuation process is over and the Claimant shall be paid the agreed-upon Settlement Construct Valuation in accordance with the MSA and the Orders of this Court. Fleet shall have seven (7) days to provide Claimant with a Notice of Confirmation of Agreed Value.

If Claimant disagrees with Fleet’s Proposed Value, Claimant and Fleet shall meet and confer within 14 days of Claimant’s receipt of Fleet’s Notice of Disagreement and try to reach agreement on Settlement Construct Valuation. During this period, Claimant and Fleet may request, obtain, and exchange additional information, records, and documents to support their positions, including expert reports and medical literature, but only if: (1) the party first obtains agreement from the other party, which shall not be unreasonably withheld, or (2) the party obtains leave from the Special Master, after trying unsuccessfully to obtain agreement.

If the parties agree on the Settlement Construct Valuation during the meet-and-confer process, the

valuation process is over and the Claimant shall be paid the agreed-upon Settlement Construct Valuation in accordance with the MSA and the Orders of this Court.

If the parties do not agree on the Settlement Construct Valuation during the meet-and-confer process, they shall proceed to the claims processing protocols set out in §2.2 of the MSA.

VI. Supplement to *Claims Order* §2.2.⁴

If the parties cannot agree on the Settlement Construct Valuation during the meet-and-confer process, then the Claimant shall send a “Request for Claims Committee Review” to Fleet and the PEC. The Request for Claims Committee Review shall include: (1) the Notice of Disagreement, (2) all documents exchanged with or correspondence between Claimant and Fleet pertaining to Settlement Construct Valuation; (3) both parties’ Settlement Construct Valuation Worksheets, and (4) all records, information, and documents that support each party’s Settlement Construct Valuation. To the extent the Claimant does not supply records, information, or documents relied upon by Fleet in reaching its Settlement Construct Valuation, Fleet may provide such records to the PEC in supplementation of the Claimant’s Request for Claims Committee Review.

The Claimant’s Request for Claims Committee Review shall be sent to Fleet and the PEC within

⁴ *Claims Order* §2.2 states: “The Claims Committee shall meet and confer telephonically as soon as practicable, but not later than fifteen (15) days from the notice that there is a disagreement as to the valuation. If the meet and confer results in an agreed Settlement Construct Valuation, the claim shall be paid within thirty (30) days of Fleet’s receipt of the executed stipulation of dismissal and/or discontinuance and a signed release in the form attached to the MSA by the Participating Claimant.”

14 days of the Claimant's receipt of a Notice of Disagreement.⁵ Failure of the Claimant to timely submit a Request for Review shall be construed to mean the Claimant agrees with Fleet's Proposed Value.

Within three days of receipt of a timely Request for Claims Committee Review, representatives of Fleet and the PEC shall confer and choose: (1) a mutually convenient date to designate the members of a Claims Committee pursuant to the MSA; and (2) a date for the Claims Committee to meet for the purpose of attempting to reach agreement on the Claimant's Settlement Construct Valuation. The Claims Committee may meet by telephone.

In attempting to reach agreement on the Claimant's Settlement Construct Valuation, the Claims Committee shall consider only the Request for Claims Committee Review and associated written materials considered by the parties, including: (1) the Notice of Disagreement, (2) all documents exchanged with or correspondence between Claimant and Fleet pertaining to the valuation; (3) both parties' Settlement Construct Valuation Worksheets, and (4) all records, information, and documents that support each party's

⁵ The Claims Committee and its membership is defined in §3.2 of the Master Settlement Agreement. The Request for Review shall be sent to all of the following addresses:

Fleet@Pepperlaw.com
Fleet@hpmb.com
Fleet@Climacolaw.com

Denise A. Holzka
Heidell, Pittoni, Murphy & Balch, LLP
99 Park Avenue
New York, NY 10016

Dawn Marie Chmielewski
Climaco, Wilcox, Peca, Tarantino & Garofoli, L.P.A.
55 Public Square, Suite 1950
Cleveland, Ohio 44113

Fleet shall be responsible for forwarding the Request for Review to the Applicable Insurer(s), as appropriate.

valuation.

Fleet may obtain additional documentation, which it determines in good faith is needed to support its valuation, but only if Fleet: (1) first obtains agreement from the PEC or from the Claimant, which shall not be unreasonably withheld, or (2) obtains leave from the Special Master, after trying unsuccessfully to obtain agreement. The Claims Committee shall issue its decision regarding a Claimant's Settlement Construct Valuation within five days of meeting to address that claim.

If the Claims Committee reaches a unanimous Valuation, Fleet and the Claimant shall each have seven days to notify the Claims Committee whether they accept the Committee Valuation. If Fleet and the Claimant both accept the Committee Valuation, the valuation process is over and the Claimant shall be paid the Committee Valuation in accordance with the MSA and the Orders of this Court. Failure to timely notify the Claims Committee shall be construed as agreement with the Committee Valuation.

If either Fleet or the Claimant does not accept the Committee Valuation, or if the Committee is unable to reach a unanimous Committee Valuation, the claim shall be automatically appealed to the Special Master. If the Claims Committee fails to reach unanimous agreement on the Claimant's Settlement Construct Valuation, the Claims Committee shall issue a Report to the Special Master, which shall state the value that each member of the Claims Committee determined should be given to the claim and shall

include all documents considered by the Claims Committee.⁶

VII. Supplement to *Claims Order* §2.3.⁷

If agreement on a Claimant's Settlement Construct Valuation is not reached by the Claims Committee, or if Fleet or the Claimant chose to appeal the Committee's Valuation decision to the Special Master, Fleet and the Claimant may provide the Special Master a Position Letter, not exceeding four pages in length, setting forth their position on the Claimant's Settlement Construct Valuation. The parties' Position Letters shall be provided to the Special Master within seven days of the issuance of the Claims Committee's Report to the Special Master.

The Special Master may, at his discretion, direct the Claimant or Fleet to provide any additional records, information, or documents. Neither the Claimant nor Fleet shall provide to the Special Master any supplemental materials not previously submitted to the Claims Committee, unless requested by the

⁶ It may occur that: (1) Fleet asserts a claim does not "pass threshold," or is excluded, and (2) the Claims Committee does not unanimously agree with Fleet's assertion. In such a case, because Fleet believed the claim did not "pass threshold," or was excluded, Fleet may not have otherwise provided to the Claimant a Proposed Value. In these circumstances, before an appeal is taken to the Special Master, Fleet shall, without waiver of its position on threshold or exclusion issues, provide to the Claimant a Settlement Construct Valuation that includes Fleet's further valuation. To the extent possible, the parties shall then engage in the above-described processes and protocols and attempt to reach an agreed conditional Valuation. This procedure is included so that the Claims Committee shall review issues of threshold, exclusion, and valuation before the matter is presented to the Special Master on Appeal. If the Special Master concludes the Claim is not excluded and passes threshold, the Special Master may remand the matter for further Valuation review by the parties and the Claims Committee.

⁷ *Claims Order* §2.3 states: "Should the meet and confer [process] not resolve the dispute, both Fleet and the Participating Claimant's lawyer shall notify the Special Master by email, with copies to the PEC, of the impasse. The notification shall state the precise Settlement Construct factors or criteria in dispute, and each party shall provide a letter not to exceed four (4) pages supporting its position in the dispute. Each party shall also provide the Special Master with all documentation supporting its position. This notice shall be filed with the Special Master no later than seven (7) days from the last meet and confer by the Claims Committee. The Special Master will promptly issue a written decision and notice shall be provided to all parties including the PEC by email."

Special Master. The Special Master shall then issue a written Valuation Decision. Any party may move the Special Master for recovery of costs as a sanction for pursuing a frivolous appeal of a unanimous Claims Committee Valuation Decision, if appropriate.

Fleet and the Claimant may appeal the Special Master's Valuation Decision to the MDL Court by filing a Notice of Appeal within seven days of the date of the Valuation Decision. If neither Fleet nor the Claimant file a timely Notice of Appeal, the valuation process is over and the Claimant shall be paid the Special Master's Valuation in accordance with the MSA and the Orders of this Court.

VIII. Supplement to *Claims Order* §2.4.⁸

Within seven days of the date that Fleet or the Claimant files a Notice of Appeal of the Special Master's Valuation Decision, the parties shall provide to the MDL Court the following: (1) the Special Master's Valuation Decision; (2) all materials related to claim valuation that were submitted to the Special Master, including: (a) the parties' Settlement Construct Valuation Worksheets, (b) all records, information, and documents that support each party's valuation, (c) the Notice of Disagreement, (d) the Claims Committee's Report to the Special Master, and (e) any Position Letters.

The MDL Court will render a decision as to the Claimant's Settlement Construct Valuation, and such decision shall be final, with no right of appeal. Once the Court renders its decision, the valuation process is over and the Claimant shall be paid the MDL Court's Valuation in accordance with the MSA and the Orders of this Court. Any party may move the Court for recovery of costs as a sanction for

⁸ Claims Order §2.4 states: "The Special Master shall make every effort to render a decision within fifteen (15) days from the date of receipt of all submissions pursuant to the preceding paragraph. The decision of the Special Master may be further appealed to the MDL Court, whose decision shall be final with no further right of appeal."

pursuing a frivolous appeal of the Special Master's Valuation Decision, if appropriate.

IX. Burden of Proof.

To the extent not otherwise provided for in the Settlement Construct and/or Settlement Construct Protocol, each party has the burden of production and burden of persuasion as to its respective positions. For example: (1) the Claimant has the burden to establish that the threshold criteria are met; (2) Fleet has the burden to establish the existence of any exclusionary criteria; (3) the Claimant has the burden to establish point enhancements it wishes to apply; and (4) Fleet has the burden to establish point deductions it wishes to apply. The burden of proof for each party to establish its position is a preponderance of the evidence.

X. Lab Reports.

Determination of Claimant's compensable injury category and current medical status shall be based upon the information provided on the date of the claim submission, unless the claim has been deemed deficient by Fleet because the most recent lab report or medical status has not been provided, in which case the deficiency resolution procedures set out at *Claims Order* §1 apply. Neither the Claimant nor Fleet shall be permitted to supplement the initial claim submission with a lab report or medical status or other data obtained on or after August 3, 2010 for Track A claims, or on or after September 2, 2010 for Track B claims. A limited exception to the rule set out in the previous sentence will be considered only in cases where: (1) there is proof that the most current lab report and/or medical status had been requested prior to the claim submission, (2) the requested lab report and/or medical status were not timely supplied by the healthcare provider, and (3) the lab report and/or medical status do not pre-date June 1, 2010.

XI. Documents Required Before Payment is Made.

Once the parties have reached a final Settlement Construct Valuation, the Claimant shall promptly provide to Fleet: (1) a signed release in the form attached to the Master Settlement Agreement, and (2) if the Claimant has filed an action in a state or federal court, an executed stipulation of dismissal or discontinuance with prejudice. The Applicable Insurer shall make payment to each Claimant in accordance with the MSA and the Orders of this Court. The following conditions apply.

- A. After a final determination of Construct Value has been reached, “the Applicable Insurer and/or the escrow agent for the [Settlement Fund Escrow Account], where appropriate, will make payment within thirty (30) days of receipt of a signed release in the form attached to the MSA and executed stipulation of dismissal or discontinuance by the Participating Claimant.” *Claims Order* at 4 & 6.
- B. Notwithstanding provision XI.A above, no payment will be made until the Participating Claimant and his or her Participating Lawyer “represent and warrant that all claims by any of the . . . lien holders [listed at MSA §6(a)&(b)] have been or will be satisfied by the Participating Claimant in a manner acceptable to Fleet and the Applicable Insurers.” MSA at §6(c).
- C. Notwithstanding provision XI.A above, no payment will be made until, “[w]here relevant, Medval, LLC, Garretson Firm Resolution Group, Inc., or such other qualified entity . . . [submits] written reports of its findings and conclusions” regarding “the interests that Medicare/Medicaid or other medical provider and any other medical provider may have in connection with the Settlement of Participating Claimant’s claims,” which will include “determin[ation of] the reasonably expected

Medicare costs for future treatments related to renal injury.” MSA at §6(e).⁹

- D. Payment will be made as soon as reasonably possible, and at the latest within 14 days, after provisions XI.A, XI.B, and XI.C above are all fulfilled.

XII. Pro Rata Reductions and Holdbacks.

As to all Claimants whose claims fall in the 2008/09 policy year, and also possibly all Claimants whose claims fall in the 2004/05 policy year, the amount of the payment they should receive cannot be known until final Settlement Construct Valuations are obtained for all US and Canadian Claimants in those respective policy years, because it may be necessary to apply a pro rata reduction to their Settlement Construct Valuations. Accordingly, after sufficient information necessary to calculate whether a pro rata reduction is required for each such Claimant in the 2004/05 and 2008/09 policy years is obtained, Fleet and the PEC shall provide to the Special Master a Statement of Appropriate Payments. The Special Master shall then promptly direct the Applicable Insurer and/or the escrow agent for the Settlement Fund Escrow Account to make appropriate interim or final payments to each such listed Claimant in accordance with

⁹ The required document may, for example, be one of the following:

- (1) A statement from Claimant’s attorney that Medicare interests are not implicated in the settlement because the Claimant is deceased;
- (2) A statement from Claimant’s attorney that Medicare interests are not implicated in the settlement because the Claimant: (a) is not currently eligible for Medicare; (b) is not 65 years or older; (c) has no reasonable expectation of becoming Medicare-eligible in 30 months; (d) has not applied for or been approved for Social Security disability because of the claimed injuries; (e) has not been on Social Security disability for 24 months or more because of the claimed injuries; (f) has not been diagnosed with ESRD; (g) has not undergone a transplant or dialysis; (h) is not totally or permanently disabled because of the claimed injuries; and (i) has not been diagnosed with anemia secondary to claimed injury and is not being treated with Procrit, Aranesp, or equivalent;
- (3) a Medicare Set Aside report from Medval or Garretson or other qualified entity; or
- (4) a statement from Medval or Garretson or other qualified entity that a Medicare Set Aside is not required, with the reasons supporting that determination.

the MSA and the Orders of this Court.¹⁰

IT IS SO ORDERED.

/s/ Dan Aaron Polster

DAN AARON POLSTER

UNITED STATES DISTRICT JUDGE

DATED: October 5, 2010

¹⁰ As an example, Fleet has indicated it currently appears a holdback and pro rata reductions are necessary for the 2004/05 policy year, because the total of Claimants' *proposed* Settlement Construct Valuations for that year exceeds the amount of available insurance. As final valuations are reached, however, the parties may become satisfied that, in fact, the total of Claimants' *actual* Settlement Construct Valuations for that year will *not* exceed the amount of available insurance (even taking into account Canadian claims and eventual arbitration decisions). If and when this circumstance occurs, payment of final valuations not reduced by any pro rata amount may become appropriate. Fleet and the PEC shall keep the Special Master informed regarding this changing status. Further, in those policy years where a holdback and pro rata reductions are and continue to be appropriate, the Court may order partial interim payments pending final calculation of the necessary pro rata reductions.