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June 1, 2015

**BY ECF AND FACSIMILE**

The Honorable Lynne A. Sitarski  
United States District Court,  
Eastern District of Pennsylvania  
601 Market Street, Room 3015  
Philadelphia, Pennsylvania 19106  
Fax: (267) 299-5060

Re: *United States ex rel. Krahlung v. Merck & Co., Inc.* (No. 10-4374)

Dear Judge Sitarski:

We write on behalf of Relators to move the Court to compel Merck to respond to certain Interrogatories and Requests for Admission (RFA) on which the parties have reached impasse.

The first set of disputed discovery requests centers around the question of what Merck understands to be the current efficacy of its mumps vaccine. This is one of the key areas of dispute in this case. Yet, Merck refuses to answer any questions on the subject, instead hiding behind a facade of confusion and obfuscation as to what efficacy means. Merck does so even though efficacy is a common term used throughout the industry to identify how well a vaccine works. It is also a term Merck has, until now, freely used throughout these proceedings to describe how well its vaccine works.

The second disputed request is simply for Merck to identify the names and titles of the individuals involved in responding to Relators' Interrogatories and RFAs. Ignoring the clear precedent in this Circuit for such an interrogatory, Merck refuses to provide the requested information claiming privilege and that the information would be duplicative of other discovery already provided.

**Current Efficacy**

This case is about Merck's ongoing efforts to misrepresent to and conceal from the government what Merck knows about the significantly diminished efficacy of its mumps vaccine. *See* Judge Jones Decision Denying Merck's Motion to Dismiss at 1 ("Relators allege . . . [Merck] fraudulently misled the government and omitted, concealed, and adulterated material information regarding the efficacy of its mumps vaccine"); United States Statement of Interest

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on Merck's Motion to Dismiss at 2 (Relators allege "Merck has knowingly failed to disclose the vaccine's diminished efficacy").

From the outset of this case, Merck has denied any such misrepresentations and concealment, instead arguing its mumps vaccine works "phenomenally" and "enormously" well, with "tremendous efficacy." Merck MTD, Doc No. 45-1 at 5 n.2, 8 and 30 n.17. Merck did so in its unsuccessful motion to dismiss where Merck argued it "remains indisputably true" its vaccine "confer[s] a high degree of protective efficacy against the mumps." *Id.* at 8. Merck did so again in its Answer to the operative complaint where it denied "the efficacy of the vaccine is falsely represented" on the product's labeling. Doc. No. 62 at ¶ 80. And Merck did so again in the Joint Rule 26(f) Report where in the summary of its defenses to this action Merck argued it "has full confidence" in the efficacy of the vaccine and that the product labeling "accurately reflects" that efficacy. Doc. No. 63 at 3-4.

Merck has likewise repeatedly argued how the efficacy of its vaccine is a critical issue in this case. In fact, at oral argument on the motion to dismiss, Merck at least a half-dozen times protested (unsuccessfully) to the Court that the complaint fails to allege "what the actual efficacy of the vaccine is." *See* Transcript of MTD Hearing at 6-10. And in its Rule 26(a) Initial Disclosures, Merck identified as among the limited categories of documents "likely to support Merck's claims and/or defenses," those relating to the efficacy of the vaccine.

But now, when asked to confirm what Merck believes that efficacy to be, Merck refuses to answer or acknowledge it does not know. This is readily apparent in Merck's refusal to answer *Interrogatory No. 1* (First Set) which asks Merck to "[s]tate, as a percentage, the current Efficacy of the mumps component of Merck's MMRII vaccine . . . ." <sup>1</sup> Rather than answer this interrogatory, however, Merck merely identifies the vaccine's efficacy as Merck measured it roughly 50 years ago when the vaccine was originally licensed. Merck refuses to identify the current efficacy, arguing "there are no 'current' efficacy' clinical trials involving Merck's mumps vaccine and [] it is not now possible to conduct such double-blind controlled studies."

Merck has taken an equally evasive approach in its blanket refusal to answer Relators' RFAs on the vaccine's current efficacy:

*RFA Nos. 1 and 2* ask Merck to admit (i) "Merck does not know the current Efficacy of the mumps component of Merck's MMRII vaccine," and (ii) "the current Efficacy . . . is less than 96%."

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<sup>1</sup> To avoid any confusion or disagreement as to how the term "Efficacy" should be defined, Relators defined the term in both its Interrogatory and RFA requests to mean "efficacy as the term is used in the current package insert for Merck's MMRII Vaccine." Notably, Merck made no objection to this definition. Nor did it offer an alternative definition.

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*RFA Nos. 12 and 14* ask Merck to admit: (i) "the current package insert for Merck's MMRII vaccine . . . accurately represents the current Efficacy of the mumps component of the vaccine," and (ii) "Merck does not know whether the current package insert . . . accurately represents the current Efficacy . . . ."

*RFA Nos. 27 and 28* ask Merck to admit (i) "the current Efficacy . . . is less than that found for Merck's Mumps Vaccine in the 'field trials' referenced . . . in the current package insert," and (ii) "Merck does not know whether the current Efficacy . . . is less than that found . . . in the 'field trials' referenced . . . in the current package insert."

*RFA Nos. 38 and 40* ask Merck to admit (i) "Merck's website . . . accurately represents the current Efficacy of the mumps component of Merck's MMRII vaccine," and (ii) "Merck does not know whether . . . Merck's website . . . accurately represents the current Efficacy . . . ."

*RFA Nos. 55 and 57* ask Merck to admit (i) "the language 'Efficacy - 95%' on the CDC's website . . . accurately represents the current Efficacy of the mumps component of Merck's MMRII vaccine," and (ii) "Merck does not know whether the language 'Efficacy - 95%' on the CDC's website . . . accurately represents the current Efficacy . . . ."

*RFA Nos. 71 and 72* ask Merck to admit (i) "the current Efficacy of the mumps component of Merck's MMRII vaccine is less than it was at the time Merck was first licensed to sell a mumps vaccine in the U.S.," and (ii) "Merck does not know whether the current Efficacy . . . is less than it was at the time Merck was first licensed to sell a mumps vaccine in the U.S."

As with its refusal to answer Interrogatory No. 1, Merck provides the identical cut-and-paste rebuff for each of these RFAs. Rather than answering them with respect to the vaccine's current efficacy, Merck confines its response to what Merck measured it to be roughly 50 years ago, when the vaccine was originally licensed. Merck refuses to answer with respect to current efficacy, again claiming the term "current efficacy" is vague and ambiguous because "there are no 'current' efficacy clinical trials involving Merck's mumps vaccine and because it is not now feasible to conduct such double-blind controlled studies."

Either Merck knows the current efficacy of its mumps vaccine, or it does not. If it does, it should be required to answer Interrogatory No. 1 and the identified RFAs as posed. If it does not know the current efficacy, it should be required to answer the Interrogatory and RFAs accordingly. Whichever the case, Merck should not be permitted to raise as one of its principal defenses that its vaccine has a high efficacy, which is accurately represented on the product's label, but then refuse to answer what it claims that efficacy actually is.

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Merck Witnesses

Merck's absolute refusal to identify the witnesses involved in responding to Relators' Interrogatories and RFAs is equally baseless. Relators' Interrogatory No. 1 (Second Set) asks Merck to identify for each Interrogatory and RFA "the individuals involved in preparing Merck's responses and objections, including their current title if still employed at Merck, their former title if previously employed at Merck, and their current place of employment and title if not currently employed at Merck." Merck will not identify any of its current or former employees who helped answer these discovery requests, claiming the request (i) seeks information protected by the attorney-client and/or work-product privilege, (ii) would constitute 85 interrogatories and thus exceed the limit imposed by the Federal Rules, and (iii) is duplicative of the organizational charts Merck has produced.

As to Merck's privilege objection, Merck can point to no case within this Circuit that protects the mere identity of these witnesses. To the contrary, as this Court has previously recognized, the Third Circuit has been very clear that interrogatories seeking "the identities of persons who provided [parties] with certain information at certain times" are proper. The Court reasoned as follows:

While these lists may provide a remote clue as to the nature and scope of [the party's] investigation, their substantive work product content is minimal. In producing this information, [the party] need not reveal any of the details of the interactions that occurred or the mental impressions, conclusions, legal theories, or opinions drawn therefrom. [The propounding party] merely seek[s] 'specific subcategory[ies] of all potential fact witnesses,' a permissible subject for discovery.

*In re: Automotive Refinishing Antitrust Litig.*, 2006 WL 1479819, at \*5 (E.D. Pa. May 26, 2006) (compelling complete answer to interrogatory on identity of plaintiffs' witnesses who helped draft the complaint). *See also Felkner v. Werner Enterprises, Inc.*, 2013 WL 6692735, at \*2 (E.D. Pa. Dec. 18, 2013) (compelling answer to interrogatory on identity of individuals "consulted while gathering information for . . . use in responding to the interrogatories"); *Kalp v. Life Ins. Co. of North America*, 2009 WL 261189, at \*10 (W.D. Pa. Feb. 4, 2009) (compelling answer to interrogatory on identity of "company representatives that provided input into the answers and objections to interrogatories").

Merck's interrogatory-limit objection is equally without merit. This is particularly so given the likelihood that a relatively limited number of Merck witnesses were involved in responding to the interrogatory and RFA requests and that each of these witnesses was involved in responding to many if not most of these requests. Relators are not seeking all facts supporting each Interrogatory and RFA response, or the basis for each response. Nor are we seeking the identity of all individuals with knowledge of the subject matter to which each Interrogatory and

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RFA relates. We are merely seeking the names of those who worked on or were consulted on the response. This should count for no more than one interrogatory. In fact, at least one court in this Circuit found that this should not be included in the interrogatory count at all, instead treating it as a proper part of the instructions for answering the requests. *See Rhoades v. Young Women's Christian Ass'n of Greater Pittsburgh*, 2009 WL 3319820, at \*4 (W.D. Pa. Oct. 14, 2009) (granting motion to compel answer to interrogatory instruction requesting the identity of all witnesses involved in preparing interrogatory response).

Finally, Merck is also off-base with its contention that this request is duplicative of other discovery Merck has already provided Relators; namely its organizational charts. Merck's voluminous yet incomplete smattering of organizational charts, many without dates, collectively identifies hundreds, if not thousands, of employees who worked at Merck over the past fifteen years. They do not even provide the identity of the Merck custodians with the most relevant information in this case, let alone provide any guidance on those employees who worked on Merck's current discovery responses. Merck's refusal to spend the few minutes it would take to identify these employees is simply a stratagem to avoid identifying those witnesses likely to have the most knowledge about the key issues in this case.

\* \* \*

For these reasons, Relators respectfully request the Court to compel Merck to answer Interrogatory No. 1 (First Set), Interrogatory No. 1 (Second Set) and RFA Nos. 1, 2, 12, 14, 27, 28, 38, 40, 55, 57, 71 and 72 *as they are posed*.<sup>2</sup> We of course are amenable to participating in a conference (either by phone or in person) to discuss this motion further if Your Honor so requests.

Respectfully submitted,



Gordon Schnell

cc: counsel of record (via Electronic Mail)

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<sup>2</sup> See Proposed Order attached as Exhibit A. By this letter we hereby certify that the parties, after reasonable effort, are unable to resolve this dispute.