IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, *ex rel.* STEPHEN A. KRAHLING AND JOAN A. WLOCHOWSKI, Plaintiffs, v. MERCK & CO., INC. Defendant.	Civil Action No. 10-4374 (CDJ)

MERCK'S RESPONSE TO RELATORS' WRITTEN STATEMENT OF OBJECTIONS TO JUDGE SITARSKI'S JULY 31, 2015 ORDER

Relators have requested that the Court reverse Judge Sitarski's July 31, 2015 Order ("Order") as it relates to Interrogatory No. 1 of Relators' First Set of Interrogatories. Judge Sitarski's ruling can be reversed only upon a showing of clear error. Relators' objections reveal nothing of the kind, and Judge Sitarski's Order should stand.

BACKGROUND

On February 20, 2015, Relators served their First Set of Interrogatories and 78 related Requests for Admission ("RFAs"). Relators' discovery requests focused on three scientific concepts – efficacy, effectiveness, and seroconversion – and the specific interrogatory at issue here focused on what Relators refer to as "current efficacy." Merck provided detailed responses to the discovery requests. Relators moved to compel, and Judge Sitarski rejected their arguments based principally on Merck's argument that the foregoing terms each have distinct meanings when used in a scientific manner and that Merck answered the Interrogatories and RFAs appropriately under the Federal Rules of Civil Procedure. Relators now object to Judge

Sitarski's ruling with respect to Interrogatory No. 1, which asks Merck to "[s]tate, as a percentage, the current Efficacy" of Merck's vaccine.

"Current efficacy" is a term invented by Relators solely during the course of this litigation. As addressed at the oral argument, the term "efficacy" is, in scientific terms, a measure of the vaccine's ability to protect against disease as determined by a well-controlled clinical trial. That is the way Merck defines the term, the way it is used in the FDA-approved label at issue in this litigation,[1] the way it is used by the CDC,[2] and the way it is used by the United States government.[3] *See, e.g.*, Transcript of July 22, 2015 Argument (Dkt. 85) at 32:15 – 34:9. Relators cannot point to any time at which Merck, the FDA, the CDC, or the government has used the term "current efficacy" in describing the mumps vaccine, or any other vaccine for that matter. *See* Dkt. 84 at 3. And, as Judge Sitarski noted, it is not even a defined term in Relators' First Set of Interrogatories, which instead defines "efficacy" "as that term is used in the current package insert for Merck's MMRII Vaccine," *i.e.*, "[e]fficacy of measles, mumps, and rubella vaccines [] established in a series of double-blind controlled field trials which

---

[1] M-M-R®II Package Insert, Clinical Pharmacology 2 (2014) (attached as Exhibit 1) ("Efficacy of measles, mumps, and rubella vaccines was established in a series of double-blind controlled field trials which demonstrate a high degree of protective efficacy afforded by the individual vaccine components.").

[2] Centers for Disease Control and Prevention, *Manual for the Surveillance of Vaccine-Preventable Disease*, Definition of Terms (5th ed. 2012), http://www.cdc.gov/vaccines/pubs/surv-manual/front-portion.pdf (efficacy is defined as "[t]he ability of a vaccine to provide protection against disease under ideal circumstances (e.g., during a clinical trial)).

[3] Susan Thaul, Cong. Research Serv., R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness* 4 (2012) (efficacy "refers to whether a drug demonstrates a health benefit over a placebo or other intervention when tested in an ideal situation, such as a tightly controlled clinical trial").

demonstrate a high degree of protective efficacy afforded by the individual vaccine components." Order (Dkt. 83) at 3-4, n.3.

"Current efficacy" is devoid of any scientific meaning. A clinical trial to measure a vaccine's ability to protect against disease, an efficacy trial, can only be conducted when the disease is prevalent in the community and the vaccine has not yet been proven to work – meaning, here, at a time where the mumps virus is prevalent in the population and children are not being vaccinated. Once a vaccine has dramatically reduced the incidence of the disease, it is neither feasible, as there is too little disease circulating in the population, nor ethical, as it would be inappropriate to withhold the proven treatment, to conduct a placebo-controlled clinical efficacy trial. *See* Merck's June 15, 2015 Letter to Judge Sitarski (Dkt. 77) at 2-3. It does not appear that Relators dispute this fact.

Thus, when Relators asked Merck to: "State, as a percentage, the current Efficacy of the mumps component of Merck's MMRII vaccine, and the basis for your answer, including any Tests on which it is based," Merck, in good faith, responded by objecting to the term "current Efficacy" as vague and ambiguous and as not being susceptible to a straightforward response. Merck further objected that the "Interrogatories define 'efficacy' by reference to the use of that term in the current package insert" and the "current package insert uses 'efficacy' in the context of specific double-blind controlled trials, which is how the term is often used." Subject to its objections, Merck further stated that:

> the efficacy of Merck's mumps vaccine is described in various papers, including:
>
> Hilleman, M.R.; Buynak, E.B.; Weibel, R.E.;et al: Live, Attenuated Mumps Virus Vaccine 4. Protective Efficacy as Measured in a Field Evaluation, *N. Engl. J. Med.* 276:252-258, 1967;
>
> Weibel, R.E.; Buynak, E.B.; Stokes, J.; et al: Evaluation Of Live Attenuated Mumps Virus Vaccine, Strain Jeryl Lynn, First International Conference on Vaccines

AgainstViral and Rickettsial Diseases of Man, World Health Organization, No. 147, May 1967; and

Suggs, W.C.; Finger, J.A.; Levine, R.H.; et al: Field evaluation of live virus mumps vaccine, *J. Pediatrics* 72:461-466, 1968.

In addition, Merck stated that: "The protective efficacy reported in the Hilleman paper was 97% if only laboratory-proved cases were considered and about 95% if later cases that occurred in families where there was not yet a laboratory diagnosis were taken into account. The protective efficacy reported in the Weibel paper was about 97%. The protective efficacy reported in the Suggs paper was 95.6%."

Merck's responses are appropriate and scientifically accurate. Merck is not required under the Federal Rules of Civil Procedure to accept a false and scientifically erroneous premise in responding to Relators' interrogatory. Judge Sitarski agreed that the term "'current efficacy' is vague and confusing, and therefore Merck's explanation for answering the interrogatory with the 'efficacy' of Merck's mumps vaccine, not the 'current efficacy' is justified." *See* Order (Dkt. 83) at 5, n. 2. The Relators' Objections provide no basis to disturb Judge Sitarski's well-reasoned Order.

ARGUMENT

Federal Rule of Civil Procedure 72(a) permits a party to "serve and file objections" to a Magistrate Judge's non-dispositive order. *See* Fed. R. Civ. P. 72(a). "A District Judge may reverse a Magistrate Judge's order for a non-dispositive matter under 28 U.S.C. § 636(b)(1)(A), only if it is clearly erroneous or contrary to law." *Yarus v. Walgreen Co.*, No. 14-1656, 2015 WL 1021282, at *2 (E.D. Pa. Mar. 6, 2015) (citing Fed. R. Civ. P. 72(b)). This Court has noted that "[a] ruling is clearly erroneous if the reviewing court has 'the definite and firm conviction that a mistake has been committed.'" *Id.* (quoting *Haines v. Liggett Grp., Inc.*, 975 F.2d 81, 92

(3d Cir. 1992)). This standard is a high one, as "'[c]lear error . . . requires something more than simple disagreement.'" *Id.* (quoting *F.T.C. v. NHS Sys., Inc.*, No. 08-2215, 2011 WL 5979573, at *3 (E.D. Pa. Nov. 30, 2011)). Indeed, this Court has made clear that "[u]nder the clearly erroneous standard, the District Court shall not reverse the Magistrate Judge's determination even where the Court might have decided the matter differently." *Id.* (citation omitted).

I. AS ADDRESSED AT ARGUMENT, MERCK HAS NEVER USED THE TERM "CURRENT EFFICACY" AND ITS STATEMENTS IN FILINGS AND ARGUMENT ARE NOT INCONSISTANT WITH ITS OBJECTION TO INTERROGATORY NO. 1.

Relators contend that Judge Sitarski should permit Relators to simply make up scientific terms and require Merck to respond, irrespective of how flawed Relators' understanding of the science is. Moreover, by conflating different scientific principles, Relators argue that Merck's statements in pleadings and arguments are inconsistent with Merck's objection to Relators' Interrogatories. *See* Relators' Written Statement of Objections (Dkt. 84) at 4. As an initial matter, Relators do not cite a single case to support the contention that Judge Sitarski was obligated to reconcile each statement plucked by Relators from various pleadings and arguments with Merck's objections or to look beyond the interrogatory and response in determining whether Merck's objections were valid. But even if she was obligated to do so, Merck has never used the term "current efficacy" in any pleading or argument. This is apparent even from the examples provided in Relators' Objections. *See id.* at 3. Instead, Merck has defended that the vaccine works and discussed the proven benefits of the vaccine. Merck has said that the vaccine has a "high degree of protective efficacy," that it is "tremendously successful," and other like statements. *See id.*; *see also* Transcript of July 22, 2015 Argument (Dkt. 85) at 32:15 – 34:9, 39:18 – 41:5, 41:22 – 42:18. All of these statements are based on fact. According to the CDC, which conducts surveillance of cases of infectious diseases such as mumps, "[s]ince the pre-

vaccine era, there has been a more than 99% decrease in mumps cases in the United States." *See* Centers for Disease Control and Prevention, *Mumps Cases and Outbreaks*, http://www.cdc.gov/mumps/outbreaks.html (last updated May 29, 2015).

Because Merck has never defended its mumps vaccine by referring to "current efficacy," Judge Sitarski did not commit "clear error" by denying Relators' motion to compel as to Interrogatory No. 1. Merck cannot be compelled to adopt a faulty premise or false construction created by the use of the term "current efficacy" in Relators' interrogatory. *See, e.g.*, *Williams v. Sprint/United Mgmt. Co.*, 235 F.R.D. 494, 499 (D. Kan. 2006) (stating "[p]laintiffs are not required to phrase their response with the exact language of the interrogatory for their answer to be considered responsive if they have indicated their objection to the language used by the contention interrogatory itself"); *Struthers v. Sci. & Int'l Corp. v. Gen. Foods Corp.*, 45 F.R.D. 375, 379 (S.D. Tex. 1968) (noting that a party responding to contention interrogatories may "qualify or restrict its answer as may be necessary because of any uncertainty"). Instead, Merck properly objected that the interrogatory was vague and ambiguous, and clarified its answer to resolve the ambiguity and scientific imprecision. *High Point SARL v. Sprint Nextel Corp.*, No. 09-2269, 2011 WL 4036424, at *13 (D. Kan. Sept. 12, 2011) (holding that if, after receiving the propounding party's definitions, the responding party "is still . . . unclear as to what information is being requested, then it should identify the ambiguity, explain the interpretation chosen and why, and answer the interrogatory based upon its stated interpretation"); *see also Talbot v. Lakeview Ctr., Inc.*, No. 06-378, 2007 WL 2376066, at *1 (N.D. Fla. Aug. 16, 2007) (holding that because interrogatories one and three "are based in part on a false premise, [the responding party] will be required to answer the interrogatories in limited fashion"); *Tobacco & Allied Stocks v. Transamerica Corp.*, 16 F.R.D. 537, 541 (D. Del. 1954) ("A party is not required to file

conjectural answers to interrogatories based upon false premises. Otherwise, an answering party might be trapped into syllogistic pitfalls not based on fact but from which a false inference might be drawn.").

Where, as here, there is a sound basis for Merck to qualify is response with appropriate objections so as not to fall prey to the false logic used by Relators, Judge Sitarski acted well within her sound discretion to permit Merck's objections.

II. THE DEFINITION OF "EFFICACY" RELIED ON BY JUDGE SITARSKI IS THE DEFINITION PROVIDED BY RELATORS IN THEIR INSTRUCTIONS.

The Relators object as well to the definition relied on by Judge Sitarski in determining that the term "current efficacy" is vague and ambiguous. *See* Relators' Written Statement of Objections (Dkt. 84) 5-6. The Judge did nothing more than take the plain meaning of Relators' instructions and apply it. This is obviously not clear error.

In the "Definitions" section of the First Set of Interrogatories, Relators define the term "efficacy" "as the term is used in the current package insert for Merck's MMRII Vaccine." Relators' First Set of Interrogatories at 4. The current package insert, which is approved by the FDA, describes the efficacy of the vaccine as follows: "Efficacy of measles, mumps, and rubella vaccines was established in a series of double-blind controlled field trials which demonstrate a high degree of protective efficacy afforded by the individual vaccine components." Ex. 1, M-M-R® II Package Insert, Clinical Pharmacology 2 (2014).

As discussed earlier, the usage of the term "efficacy" in the package insert is consistent with usage elsewhere in the scientific community. For example, according to the CDC, efficacy refers to "[t]he ability of a vaccine to provide protection against disease under ideal circumstances (e.g., during a clinical trial)." Centers for Disease Control and Prevention, *Manual for the Surveillance of Vaccine-Preventable Disease*, Definition of Terms (5th ed. 2012),

http://www.cdc.gov/vaccines/pubs/surv-manual/front-portion.pdf; *see also* Susan Thaul, Cong. Research Serv., R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness* 4 (2012) (efficacy "refers to whether a drug demonstrates a health benefit over a placebo or other intervention when tested in an ideal situation, such as a tightly controlled clinical trial").

In the case of mumps, prior to licensure in the United States, two different clinical trials were conducted to determine the vaccine's efficacy. *See* M.R. Hilleman et al., *Live, Attenuated Mumps-Virus Vaccine—Protective Efficacy as Measured in a Field Evaluation*, N. Engl. J. Med. 276: 252–58 (1967); W.C. Suggs et al., *Field Evaluation of Live Virus Mumps Vaccine*, J. Pediatr. 72(4):461–66 (1968); *see also* Stanley A. Plotkin et al., *Vaccines* 419–46 (6th ed. 2012). These clinical studies "demonstrated that a single dose of the live, attenuated mumps vaccine was 95% to 96% effective in preventing mumps in people who were followed for as many as 20 months after vaccination." Plotkin, *supra*, at 434. The efficacy rate for the mumps vaccine was calculated using these controlled studies.

Given that the Relators define "efficacy" "as the term is used in the current package insert" and because the efficacy statements in the current package insert depend upon the M.R. Hilleman study published in 1967, it is, as Judge Sitarski found, confusing and vague to combine the words "current" with the term "efficacy" "as the term is used in the current package insert."

CONCLUSION

Nothing about Judge Sitarski's Order is "clearly erroneous." The objections lodged here were duly considered by Judge Sitarski and rejected by her in a thoughtful opinion reached after considering all arguments. This Court has no basis to reverse her Order.

Dated: August 27, 2015

/s/ Lisa C. Dykstra
Lisa C. Dykstra (PA ID No. 67271)
Eric W. Sitarchuk (PA ID No. 39082)
R. Brendan Fee (PA ID No. 91382)
Morgan Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103-2921
215-963-5000 – Telephone
215-963-5001 – Fax

Dino S. Sangiamo (admitted *pro hac vice*)
Sally W. Bryan (admitted *pro hac vice*)
Venable LLP
750 E. Pratt Street, Suite 900
Baltimore, MD 21202
410-244-7400 – Telephone
410-244-7742 – Fax

Attorneys for Defendant Merck Sharp & Dohme Corporation (formerly known as Merck & Co., Inc.)