IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

MICHAEL D. NELSON,

Plaintiff,

v.

MATRIXX INITIATIVES, a Delaware Corporation, and ZICAM, LLC, an Arizona limited liability company,

Defendants.
_____/

No. C 09-02904 WHA

ORDER GRANTING DEFENDANTS' MOTIONS TO EXCLUDE TESTIMONY OF DRS. GREG DAVIS AND PETER HWANG AND HOLDING IN ABEYANCE DEFENDANTS' MOTION FOR SUMMARY JUDGMENT BASED ON LACK OF PROOF OF CAUSATION

INTRODUCTION

In this action for personal injury, defendants move to exclude the testimony of two of plaintiff's experts and move for summary judgment based on lack of causation. Defendants' motions to exclude are, to the extent stated below, **GRANTED**. Dr. Davis will be permitted to revise his expert report, subject to the conditions stated below. Defendants' motion for summary judgment based on lack of proof of causation is **HELD IN ABEYANCE**.

STATEMENT

Plaintiff Michael D. Nelson, a lawyer, proceeding *pro se*, claims loss of his sense of smell and taste resulting from his use of Zicam Cold Remedy Nasal Gel swabs and spray, a homeopathic cold remedy. Both products are produced and marketed by or with express consent of defendants Matrixx Initiatives, Inc., and Zicam, LLC. The operative complaint alleges claims for manufacturing defect, design defect, failure to warn, intentional misrepresentation and false promise, fraudulent concealment, and negligence, all of which require plaintiff to show causation. This order follows full briefing and a hearing.

There are four points to note at the outset. *First*, the second amended complaint is the operative one. Although the complaint alleges injury from plaintiff's use of Zicam swabs and spray, the evidence on the issue of specific causation goes only to Zicam spray. The experts do not opine on plaintiff's use of the swabs and smell loss. Nor does plaintiff address this issue in his brief in opposition to defendants' motion for summary judgment on the issue of causation or in his briefs in opposition to the motions to exclude, addressed herein. Thus, no claim based on plaintiff's use of Zicam swabs can survive summary judgment.

Second, while the complaint alleges loss of smell and taste, the evidence relevant to the motions at issue in this order does not address taste in any way.

Third, the parties filed a total of four motions for summary judgment, five motions to exclude, and one motion to dismiss, all in the span of a week. In an effort to effectively manage this action, the Court notified the parties that it would rule on defendants' motion for summary judgment based on lack of causation and any motions to exclude relevant to deciding that motion. All other motions would then be held in abeyance pending the outcome on the causation motion. To resolve the motion for summary judgment based on lack of causation, the Court has found it necessary to also rule on the motions to exclude the testimony of Drs. Greg Davis and Peter Hwang. This order grants defendants' motions to exclude the testimony of Drs. Davis and Hwang and holds in abeyance defendants' motion for summary judgment on the issue of causation to allow Dr. Davis an opportunity to submit a revised expert report and to allow a second round of briefing on a motion to exclude Dr. Davis's opinions, if necessary.

Fourth, this action was remanded from the MDL court in September 2011. The relevant MDL rulings are set forth below.

1. THE PRODUCT AND USE.

Zicam is a viscous gel applied to the nose with either a spray pump or a swab resembling a Q-Tip. The active ingredient is zinc gluconate (Dkt. No. 81 ¶ 2). The volume of Zicam gel administered into each nostril under ordinary use is approximately 130–140 microliters, containing 1.6% concentration of the active ingredient zinc gluconate, amounting to 260–280 micrograms of zinc with each squirt (Def. Exh. 58 at 8).

Zicam spray is designed to deliver gel to the lower nasal opening and remain there. The instructions on the side of the box for Zicam spray state (Def. Exh. 54 at 19):

> 1. Remove cap and safety clip.
>
> 2. Hold with thumb at bottom of bottle and nozzle between your fingers.
>
> 3. Before using the first time, prime pump by depressing several times.
>
> 4. Place tip of nozzle just past nasal opening (approximately 1/8").
>
> 5. While inside nasal opening, slightly angle nozzle outward.
>
> 6. Pump once into each nostril. To avoid irritation, do not sniff up gel.
>
> 7. After application, press lightly on outside of each nostril for about 5 seconds.

2. ANATOMY OF THE NASAL CAVITY.

A brief study of the anatomy of the nasal cavity will serve the reader. The nasal cavity is lined by tissue called mucosa. "Cilia line the mucosa and carry the mucous through the cavity. The parts of the mucosal lining that contains sensory cells that detect smell are called olfactory epithelium (Def. Exh 54 at 6):

> The nasal cavity is divided by the nasal septum into left and right halves. Beyond the entrance to each nostril ("the nasal opening") is a constriction in the airway (sometimes called the "nasal valve") located adjacent to the internal ostium . . . . Typically, anatomists identify an inferior (lower), middle and superior (upper turbinate) with a narrow airway or meatus between each one. Above the superior turbinate, a portion of the ceiling of the nasal cavity is densely covered by olfactory receptors. This areas is termed the olfactory region.

The olfactory nerve receptors that transmit smell signals, ie., the olfactory epithelium, are concentrated in the olfactory cleft, which is located in the roof of each nostril, near the midline of the eyes. Isolated patches of smell tissue can sometimes be found in individuals in areas adjacent to the olfactory cleft (Def. Exh. 66 at 9).

3. PLAINTIFF'S MEDICAL HISTORY.

Plaintiff testified that he used Zicam swabs in December 2006 to treat a cold and that he "do[es] not believe the swabs caused," his loss of sense of smell (Def. Exh. 5 at 144). He used

Zicam spray in December 2008, sometime between Christmas and New Years, because he felt the onset of a cold. He used the product mostly in accordance with the instructions on the box, except that he sniffed up the gel, contrary to a direct instruction on the box, and thereafter felt a strong burning sensation that lasted ten to fifteen minutes (*id*. at 165–67). He then blew his nose to expel the gel. Plaintiff did not use the product again (*id*. at 173). Plaintiff's cold lasted approximately six to ten days. For that period of time, he was congested and his sense of smell became inhibited, which plaintiff testified happens "when you have a cold." Sometime in January, "several days" or a "few days" after recovering from the cold, plaintiff noticed he could not smell (*id*. at 173, 211; Def. Exh. 49 at 27). *All of plaintiff's claims stem from this one-time use of Zicam spray* (given that plaintiff does not put in any evidence specifically regarding his use of Zicam swabs in 2006, ignores the issue in his briefing, and has admitted that he does not believe the swabs caused his smell loss).

Plaintiff first sought medical treatment for his smell loss on February 23, 2009, when he saw ear, nose, and throat Dr. David Stone. At that time, plaintiff was 64 years old. Dr. Stone's medical chart from the February 23 visit indicates that plaintiff's anosmia, smell loss, "was noted beginning gradually 4 months ago," which would have been in October 2008, two months *before* plaintiff used Zicam spray (Def. Exh. 70). Plaintiff, however, testified during his deposition that Dr. Stone was mistaken and wrote four months instead of four weeks, which would have put the "gradual" smell loss beginning toward the end of January 2009 (Def. Exh. 5 at 175–76). Dr. Stone's chart makes no mention of Zicam or the burning sensation plaintiff allegedly experienced when he used Zicam. Dr. Stone's chart is the only pre-litigation documentation of the history of plaintiff's smell loss.

Dr. Stone testified that plaintiff had a visit with him again in September 2011, after he had filed suit. Dr. Stone has no opinion whether Zicam caused plaintiff's anosmia (Def. Exh. 70 at 36–37).

In September 2010, plaintiff administered a smell function test, which he graded himself. Dr. Davis later agreed to score another of plaintiff's self-administered tests and scored plaintiff as anosmic (Def. Exhs. 5 at 134, 136–37; 49 at 10). In January 2012, plaintiff was referred to

Dr. Peter Hwang, who opined that plaintiff's loss of smell was most likely caused by Zicam. Also in January 2012, plaintiff took an allergy test, which tested negative for allergic rhinitis (Def. Exh. 49 at 69). Plaintiff also had an MRI, which was normal (Def. Exh. 70 at 33).

4. MDL RULINGS.

The MDL court issued two orders relevant here: (1) an order on summary judgment related to the issue of general causation and (2) an order on *Daubert* motions, also related to the general causation issue. These orders are important because they define the scope of the MDL's rulings on issues relevant to our plaintiff. Specifically, what is important is that the MDL court ruled on the issue of general causation, but not on the issue of specific causation, which was left to the transferor courts. To meet his prima facie burden of showing causation, and to survive summary judgment, plaintiff must put forward enough evidence on general and specific causation. This order focuses on the issue of specific causation, not addressed by the MDL court, as shown below.

A. Summary Judgment.

Plaintiff originally filed this action in state court in June 2009, alleging defective design, defective product manufacture, and negligence. The action was removed to this district the same month and then transferred to the multidistrict litigation panel in Arizona in November 2009. The MDL plaintiffs alleged that their use of Zicam Cold Remedy Intranasal Gel spray or swabs caused them to lose their sense of smell. The MDL court issued an order on defendants' motion for summary judgment on the issue of general causation. The MDL court held as follows (Def. Exh. 83 at 13–14) (citations omitted):

> In sum, we conclude that the totality of plaintiffs' evidence regarding the toxicity of Zicam, distribution and deposition of Zicam and zinc in the nasal cavity, and the location of OE [olfactory epithelium], is sufficient to create a triable issue of fact as to whether Zicam can cause anosmia. A reasonable fact-finder could conclude that ordinary use of Zicam can cause plaintiffs' alleged injuries. Therefore, defendants are not entitled to summary judgment on the issue of causation.

This holding was based on several key conclusions made by the MDL court, which are relevant to understanding the issues at play here. *First*, the MDL court concluded (Def. Exh. 83 at 9) (internal citations and quotations omitted):

> that to establish general causation, plaintiffs need not prove a toxic dosage of Zicam. Instead, plaintiffs' must demonstrate Zicam is toxic to humans given substantial exposure. Plaintiffs need not provide precise information concerning the exposure necessary to cause specific harm to humans. Rather, they must put forth sufficient evidence from which a reasonable person could conclude that it is more probable than not that Zicam caused their anosmia. A qualitative, rather than quantitative, analysis can suffice.

Second, on the issue of the distribution and reach of Zicam in the nasal cavity, the MDL court concluded that "plaintiffs' experts opinions about the reach of Zicam and zinc within the nasal cavity contribute to the sufficiency of plaintiffs' evidence that the product can cause anosmia" (*id*. at 13). This conclusion was based on the MDL court's reliance on the expert opinions of Drs. Steven Pike and Ashim Mitra.

Third, on the issue of the location of the olfactory epithelium, the MDL court concluded that "Dr. Davis's opinion about the location of the OE may support a trier of fact's finding that it is scientifically possible for Zicam to have caused a plaintiff's anosmia" (Def. Exh. 83 at 13). Plaintiff offers Dr. Greg Davis as a retained expert in this action.

Defendants' motion for summary judgment on the issue of causation argues that plaintiff has put forward insufficient evidence to show general and specific causation. The MDL court already resolved the issue of whether the plaintiffs had enough evidence on the issue of general causation to survive a motion for summary judgment. While our defendants raise arguments on the issue of general causation that were struck down by the MDL court, they have not brought a formal motion before this Court to reconsider the MDL court's order on the motion for summary judgment on the issue of general causation (though they did bring a motion to reconsider before the MDL court, which has not yet been adjudicated). Thus, this Court will apply the holding of the MDL court as to the issue of general causation. Indeed, the purpose of the MDL court is to resolve common issues. General causation was one such issue.

B. Daubert Order.

The MDL court also issued an order on defendants' motion to exclude expert reports and testimony of plaintiffs' general causation experts (Def. Exh. 89). On transfer back to this Court, plaintiff designated Dr. Davis to testify as an expert on both general and specific causation. The MDL court limited Dr. Davis's expert testimony on the issue of general causation, holding that

"Dr. Davis may testify about (1) his theory of the diffuse location of the OE and (2) the toxicity of Zicam, but without reference to FDA reports. Dr. Davis may not testify about (1) the distribution of Zicam within the nose and (2) the efficacy of Zicam" (*id.* at 36–37).

ANALYSIS

1. SUMMARY JUDGMENT STANDARD.

Summary judgment is proper when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FRCP 56(a). Where the party moving for summary judgment would bear the burden of proof at trial, that party bears the initial burden of producing evidence that would entitle it to a directed verdict if uncontroverted at trial. *See C.A.R. Transp. Brokerage Co. v. Darden Rests., Inc.*, 213 F.3d 474, 480 (9th Cir. 2000). Where the party moving for summary judgment would not bear the burden of proof at trial, that party bears the initial burden of either producing evidence that negates an essential element of the non-moving party's claims, or showing that the non-moving party does not have enough evidence of an essential element to carry its ultimate burden of persuasion at trial. If the moving party satisfies its initial burden of production, then the non-moving party must produce admissible evidence to show there exists a genuine issue of material fact. *See Nissan Fire & Marine Ins. Co. v. Fritz Cos.*, 210 F.3d 1099, 1102–03 (9th Cir. 2000).

The issue here is whether plaintiff has put forward sufficient evidence of specific causation to carry his ultimate burden of proof at trial on all of his claims. This is so because as stated, the MDL court concluded that there was sufficient evidence in the summary judgment record on the issue of general causation to allow that issue to go to a jury. This Court will not undo or undermine the MDL court's order. Of course, if this case were to go to trial, plaintiff would still need to put in evidence on the general causation issue. The focus of this order, then, is on defendants' challenges on summary judgment related to the issue of specific causation.

To prevail on his alleged claims, plaintiff must show a causal link between his alleged injury, anosmia, and his use of Zicam. This is different from general causation. "General causation" means "whether the substance at issue had the capacity to cause the harm alleged." *In re Hanford Nuclear Reservation Litig.*, 292 F.3d 1124, 1133 (9th Cir. 2002). (Plaintiff's

argument that *Hanford* is distinguishable because the court applied Washington law is unavailing because our court of appeals recognized in *Hanford* that Washington and California state causation standards are "virtually the same," and did not state any meaningful difference whatsoever.) The general causation inquiry is "whether exposure to a substance . . . is capable of causing a particular injury or condition in the general population." *Ibid.* Specific causation, however, "refers to whether a particular individual suffers from a particular ailment as a result of exposure to a substance." *Ibid.*

Causation must be proven "within a reasonable medical probability based upon competent expert testimony. Mere possibility alone is insufficient to establish a prima facie case." *Jones v. Ortho Pharmaceuticals Corp.*, 163 Cal. App. 3d 396, 402 (1985). Plaintiff must provide enough evidence at this stage to show that he was exposed to a sufficient amount of Zicam to cause his alleged injury. *See In re Hanford*, 292 F.3d at 1133–34; *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liability Litig.*, 524 F.Supp. 2d 1166, 1172–75 (N.D. Cal. 2007) (Breyer, J.). "In cases claiming personal injury from exposure to toxic substances, it is essential that the plaintiff demonstrate that she was, in fact, exposed to harmful levels of such substances. However, precise data on the exact degree of exposure to each chemical is not required." *Abuan v. Gen. Elec. Co.*, 3 F.3d 329, 333 (9th Cir. 1993).

To be clear, the MDL court did not decided whether our plaintiff has enough evidence on the specific causation issue to prove his case at trial. Unlike general causation, where the focus of the inquiry is whether use of the product can cause the injury, the specific causation inquiry requires more. The specific causation inquiry is whether Zicam more likely than not caused the harm plaintiff alleges he suffered. "This determination is highly individualistic." *In re Hanford*, 292 F.3d at 1133.

2. DIFFERENTIAL DIAGNOSIS.

Plaintiff attempts to survive summary judgment by relying on the differential diagnosis offered by Drs. Greg Davis and Peter Hwang, two doctors offered by plaintiff, to prove specific causation. The testimony of both, however, is inadmissible because, as shown below, their opinions are not based on reliable methods reasonably applied to the facts of this action. And in

the case of Dr. Hwang, his limited qualifications undermine the reliability of his opinion altogether.

Differential diagnosis is "the determination of which of two or more diseases with similar symptoms is the one from which the patient is suffering, by a systematic comparison and contrasting of the clinical findings." *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1057 (citing Stedman's Medical Dictionary 474 (26th ed.1995)). The first step to conducting a differential diagnosis is to rule in a list of potential causes of the injury. Then, the expert must engage in a process of eliminating, or ruling out, the identified potential causes. The "expert must provide reasons for rejecting alternative hypotheses using scientific methods and procedures and the elimination of those hypotheses must be founded on more than subjective beliefs or unsupported speculation." *Clausen*, 339 F.3d at 1058. Drs. Davis and Hwang fail at both steps.

At oral argument and in his briefing, plaintiff pointed to a decision by the United States Court of Appeals for the Sixth Circuit, called *Best v. Lowes Homes Centers*, 563 F.3d 171 (6th Cir. 2009), in support of the sufficiency of the expert opinions of Drs. Hwang and Davis. In *Best*, the plaintiff claims to have developed anosmia from pool chemicals spilling on his face and clothes while lifting a perforated product container from the shelf at Lowes. In *Best*, the court of appeals allowed the physician to provide causation expert testimony even though the physician did not know the precise amount of the chemical that plaintiff had been exposed to and was not able to determine the threshold level of exposure that could cause harm. As stated, although in our court of appeals and district, precise data on the exact degree of exposure to the allegedly harmful substance is not required, plaintiff must put forward enough evidence to show that he was exposed to a sufficient amount of a substance to cause the alleged injury. *See In re Hanford*, 292 F.3d at 1133–34; *In re Bextra*, 524 F.Supp. 2d at 1172–75; *Abuan v. Gen. Elec. Co.*, 3 F.3d at 333. Moreover, in *Best*, the court found the differential diagnosis to be reliable and the causation opinions admissible where the clinician had performed an objective test to confirm the plaintiff's injuries *and* there were no other established causes of anosmia put forward by the defendant. These are not the facts of our case.

Regarding our specific causation inquiry, plaintiff has not produced admissible evidence that he was exposed to an amount of zinc sufficient to cause anosmia. Instead, plaintiff contends that the MDL court ruled such information was not required. Not so. The MDL court ruled that such evidence was not required to survive summary judgment on the issue of *general* causation. The MDL court did not rule that such evidence was not required to establish *specific* causation — that issue was not before the MDL court. Again, plaintiff conflates the general and specific-causation inquiry, the latter of which necessarily requires more. Even if plaintiff had marshaled admissible evidence sufficient to show he was exposed to a harmful level of Zicam, he would still need to prove that said exposure was the cause of his injury by ruling out other potential causes — namely age and a cold virus. Plaintiff's experts have not reliably applied the differential diagnosis methodology to the facts of this case and Dr. Hwang's limited qualifications undermine the reliability of his opinion. The opinions of the two experts —the sole expert opinions offered by plaintiff to prove specific causation — must, therefore, be excluded.

A. Daubert Standard.

Rule 702 governs the admissibility of expert opinions. It provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Courts must ensure that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrill Dow Pharms.*, 509 U.S. 579, 589 (1993). The expert's opinion must be based on "scientific knowledge;" opinions based on unsubstantiated generalizations or opinions not derived by the scientific method must be excluded. *Daubert v. Merrell Dow Pharms.*, 43 F.3d 1311, 1316 (9th Cir. 1995).

Plaintiff has offered two experts on the issue of specific causation: Dr. Davis, who is retained, and Dr. Hwang, who is non-retained. Dr. Davis opines that Zicam, more likely than

not, caused plaintiff's likely permanent smell loss. Dr. Hwang opines that plaintiff's loss of smell is "likely related to Zicam use." Defendants move to exclude the experts' opinions on the issue of specific causation. For the reasons stated below, they are so excluded.

B. Dr. Davis.

Based on differential diagnosis, Dr. Davis, who did not examine plaintiff himself, opined that plaintiff's one-time use of Zicam in December 2008, more likely than not caused anosmia, which is likely permanent in plaintiff. As stated, a differential diagnosis is a systematic method used to identify a cause where multiple causes are likely. This is the methodology Dr. Davis relied on to form an opinion regarding specific causation in this action.

Both age and the cold virus are well-established, common causes of smell loss (Def. Exhs. 49 at 35–37; 49–50; 77 at 755). A substantial percentage of cases of anosmia are classified as idiopathic, meaning the cause is unknown to medical science (Def. Exh. 76 at 8). Yet, Dr. Davis has not explained his procedure for ruling out the cold plaintiff developed as the cause of his anosmia, which plaintiff noticed a few days after his cold subsided. Neither does Dr. Davis's expert report consider age as a possible or likely cause of plaintiff's anosmia; at the time plaintiff used Zicam in 2008, he was 64 years old. Many over sixty have lost all or most of their sense of smell and would say to plaintiff, "Welcome to the sixties."

In addition to his unexplained method for ruling out the cold virus and age, if indeed he did rule out age, as likely causes of plaintiff's anosmia, Dr. Davis does not sufficiently explain his scientific method for ruling Zicam in. For example, the report does not state that one pump of Zicam spray into each nostril, would have produced the level of Zicam exposure needed to cause smell loss. What is more, Dr. Davis does not address the issue of how he accounted for adverse facts — namely the fact that Dr. Stone's medical chart states that plaintiff's smell loss was gradual and started four months prior to his doctor visit, which would have also been prior to plaintiff's use of Zicam.

(1) Opinion.

Dr. Davis's expert report concludes (Def. Exh. 48 at 5):

> Zicam, when used under conditions of ordinary use, more likely than not caused anosmia, likely permanent in Michael D. Nelson.

> My differential diagnosis, based on the results of his normal MRI, two normal nasal endoscopies, normal (negative) allergy testing, and past medical history leave Zicam induced anosmia as more likely than not the cause for his complete olfactory loss. The only other possible source for his olfactory loss, albeit much less likely, would be post-viral induced smell loss.
>
> Fortunately, post-viral anosmia is an uncommon event. We know that the virus that eventually caused Mr. Nelson's "common cold" did not cause his "strong burning sensation" immediately when he sprayed Zicam in his nostrils. We do know that Zicam is cytoxic. More likely than not, the Zicam's toxicity caused tissue destruction (necrosis) to his olfactory epithelium. Given that this olfactory function has not improved in over three years, his complete olfactory loss is likely permanent.

In reaching this conclusion, Dr. Davis reviewed the following:

> 1. History and Background Fact provided by Mr. Nelson.
>
> 2. Plaintiff Fact Sheet for Personal Injury Actions completed by Mr. Nelson.
>
> 3. Clinic note including nasal endoscopy by Dr. Peter Hwang dated 1/9/12.
>
> 4. Clinic note including nasal endoscopy by Dr. David Stone, an otolaryngologist, dated 2/23/09.
>
> 5. Clinic note including allergy testing by Dr. Matthew Lodewick, dated 1/5/12.
>
> 6. University of Pennsylvania Smell Identification test (UPSIT) completed by Mr. Nelson.
>
> 7. MRI Brain of Mr. Nelson dated 3/18/09.
>
> 8. Phone discussion with Mr. Nelson on 11/22/11.

(2) Unreliability.

Dr. Davis's opinion that plaintiff's smell loss was more likely than not caused by his use of Zicam is unreliable. Experts employing differential diagnosis must use scientifically valid methods and procedures for ruling in and out each significant possible cause of the alleged injury. *Clausen*, 339 F.3d at 1057. Otherwise, an expert's opinion could risk being based on subjective beliefs or unsupported speculation. Dr. Davis's opinion on specific causation is excluded for the following reasons. As stated, he will be allowed to revise his report to cure the problems identified herein.

First, Dr. Davis has not sufficiently explained his method for ruling in Zicam as a

possible cause of plaintiff's anosmia.

Second, Dr. Davis's expert report does not indicate that age was considered as part of the differential diagnosis. It is possible that when Dr. Davis considered plaintiff's past medical history he took into account plaintiff's age and considered it as a possible cause of his anosmia. But, it is not the place of courts to engage in such guesswork. The expert must lay bare in his report the basis for his opinions (*see* Dkt. No. 29 ¶ 6 ("At trial, the direct testimony of experts will be limited to the matters disclosed in their reports. Omitted material may not ordinarily be added on direct examination. This means the reports must be complete and sufficiently detailed.")).

It is undisputed that age is an important factor in reaching opinions on specific causation of smell loss and that the possibility of smell loss increases with age (Def. Exh. 49 at 48–49). Approximately 25 percent of individuals over the age of 60 have smell dysfunction (Def. Exhs. 72, 78). Dr. Davis did not explain in his report how he factored this into his differential diagnosis. There is no mention of age in his report. Plaintiff *argues* that Dr. Davis ruled plaintiff's age out based on the suddenness of plaintiff's smell loss and the fact that age-related smell loss usually occurs gradually. Again, this is not stated in the expert report.

However, appended to plaintiff's opposition brief is a declaration by Dr. Davis dated July 11, with no year stated, that he "ruled out any age related anosmia since age related smell dysfunction is slow and gradual over many years and not sudden as reported by Mr. Nelson" (Dkt. No. 146-1 at ¶ 6). Dr. Davis offers no support for this assertion that age-related smell loss is gradual. Also problematic, is the fact that this information was not included in his expert report. Another complication is that, Dr. Stone's contemporaneous chart entry taken during plaintiff's February 2009 visit stated that plaintiff's anosmia started "four months" prior and was "gradual" (Dkt. No. 165-1 at 5). Dr. Stone has testified to a reliable and accurate history documentation practice. Thus, to the extent Dr. Davis ruled out age-related anosmia as a possible cause of plaintiff's anosmia (even assuming age-related anosmia occurs gradually), there would be no foundation for such an opinion. This problem is addressed in detail below, but is noted here, as it is yet another factor that is not explained in Dr. Davis's report as having

been factored into his decision to rule out age-related anosmia. Possibly, the Court could cure this deficiency by limiting him to assuming that plaintiff's anosmia was sudden in onset. But, again, Dr. Davis has offered no basis for his assertion or plaintiff's argument that age-related smell loss is gradual, not sudden. Finally, and of great significance, is the fact that plaintiff's argument and Dr. Davis's recent declaration stating that he ruled out age-related anosmia is wildly inconsistent with Dr. Davis's previous sworn-to testimony where he clearly stated he had *not* ruled out age (Def. Exh. 49 at 50). Whatever his opinion regarding age, it lacks foundation and is unreliable.

Third, a cold virus is a well-known cause of smell loss. Post-viral anosmia classically presents as smell dysfunction during the course of a cold, with the patient noticing smell was not regained after having recovered from the cold (Def. Exh. 49 at 34–35). Dr. Davis did not rule out a cold as the cause of plaintiff's anosmia, though, he opined it was less likely. The basis for Dr. Davis's opinion that post-viral anosmia is less likely the cause of plaintiff's anosmia is unstated in the report, except for Dr. Davis's statement that post-viral anosmia is an uncommon event. This is not a scientific explanation. It is not reliable. There is no clear basis in the report for this assertion.

Fourth, as stated, there were inconsistencies between the pre-litigation history recorded by Dr. Stone and the post-litigation history, involving the critical issue of whether plaintiff's smell loss started before or after he used Zicam. Dr. Davis accepted the latter as true — that plaintiff's smell loss occurred after he used Zicam, and the former as a mistake. *He did so without explanation*. Rule 702 requires that expert opinions be based on sufficient and reliable facts and data and a reliable methodology applied in a valid and reliable manner. Dr. Davis's handling of the factual inconsistencies in plaintiff's critical medical history is not merely a factual dispute to be left for trial, as plaintiff suggest, but it is a problem with the reliability of Dr. Davis's methodology and scientific rigor of his expert opinion.

Dr. Davis did not inquire into an important discrepancy. Indeed, in failing to do so, he deviated from his own methodology of "tak[ing] people at their face value until I have a reason to think otherwise" (Def. Exh. 49 at 70). This goes to the core of the reliability of Dr. Davis's

opinion and the sufficiency of facts and data underlying his opinion. Unexplained selective use of the facts fails to satisfy the scientific method. *See Pac. Gas & Elec. Co. v. Zuckerman*, 189 Cal. App. 3d 1113, 1128 (1987) ("Where an expert bases his conclusion upon assumptions which are not supported by the record, upon matters which are not reasonably relied upon by other experts, or upon factors which are speculative, remote or conjectural, then his conclusion has no evidentiary value).

Ultimately, Dr. Davis points to three reasons for attributing plaintiff's smell loss to Zicam. The first is that Zicam is cytotoxic. But as stated, Dr. Davis did not address the threshold questions of whether plaintiff's olfactory epithelium or isolated patches of smell tissue were exposed to an amount of Zicam sufficient to destroy enough smell tissue to cause anosmia (Def. Exh. 49 at 107–08). Second, although in his expert report, Dr. Davis cited plaintiff's post-litigation description of a burning sensation after using Zicam, during his deposition, Dr. Davis acknowledged that he would have reached the same decision without the burning sensation and that he merely found it to be "supportive." Dr. Davis acknowledges himself that a burning sensation is not pathognomic for smell loss from a toxic exposure (Def. Exh. 49 at 37). The third reason Dr. Davis attributed plaintiff's smell loss to Zicam was reliance on a temporal relationship between plaintiff's smell loss and his use of Zicam. But Dr. Davis ignores the temporal relationship between plaintiff's cold and his smell loss. Even crediting plaintiff's post-litigation assertion that Dr. Stone made a mistake in his chart and plaintiff's smell loss occurred four weeks, not four months prior to his February 23 exam, this would still yield a delay of at least two weeks between the time plaintiff used Zicam and the time he experienced smell loss. In between the use of Zicam and the smell loss, plaintiff developed a cold. Arguably, the temporal relationship does not support an opinion that Zicam rather than the cold caused plaintiff's anosmia.

Dr. Davis's failure to rule out objectively valid reasons for plaintiff's anosmia is fatal to his specific causation opinion. *Clausen*, 339 F.3d at 1058. Dr. Davis's choice of Zicam as the more than likely cause of plaintiff's anosmia is, for the aforementioned reaons, unreliable. Thus, Dr. Davis's opinions on specific causation are **EXCLUDED**.

Dr. Davis will be permitted to amend his expert report. Plaintiff must pay for all expenses incurred by reason of allowing Dr. Davis a second opportunity to submit a viable expert opinion, including attorney's fees, expert fees, and other related costs, along with the expense of a second round of briefing (if appropriate as to the adequacy of Dr. Davis's revised opinions). These amounts shall be paid prior to any ruling on the adequacy of Dr. Davis's revised report. These amounts will not include fees incurred with respect to the initial motions to exclude. Proceeding in all other pending motions will be **STAYED** pending resolution of the adequacy of Dr. Davis's revised opinions. Dr. Davis's revised report, together with all supporting material, must be served not later than **SEPTEMBER 4, 2012.** Within seven calendar days after service of the revised report, Dr. Davis may be deposed by defendants' counsel for seven hours. Within seven calendar days of the deposition, defendants must file any *Daubert* motion to the revised report, to be heard on a shortened track as follows: defendants' opposition shall be filed seven calendar days after the motion is served and the reply shall be filed four calendar days thereafter. Filings are due at noon. The Court will set a hearing date if one is needed.

C. Dr. Hwang.

Dr. Peter Hwang, a treating physician, offered by plaintiff as a non-retained expert, saw plaintiff once in January 2012, approximately three years after plaintiff took Zicam. He performed an endoscopic examination of plaintiff's nasal cavity, revealing a left septal spur, reviewed an MRI and allergy study done by another doctor, which found plaintiff was not allergic to twenty five standard allergens (Pl. Exh. 80 at 42–43). He talked to plaintiff and reviewed his statement of background and facts (Pl. Exh. 104). Based on his clinical judgment, and review of two articles written by Dr. Terrence Davidson, given to him by plaintiff, Dr. Hwang opines, that plaintiff's loss of smell is "likely related to Zicam use" (Dkt. No. 165-2 at 6). Dr. Hwang's weak qualifications to offer an opinion on the cause of plaintiff's anosmia coupled with unsupported speculation and unreliable methodology make his opinions on the issue of specific causation unreliable.

(1) Qualifications.

Defendants argue that Dr. Hwang's limited qualifications undermine the reliability of his opinions. This order agrees. Dr. Hwang is an otolaryngologist, and diagnoses ear, nose, and throat conditions. He has no specialized epidemiological or toxicological training or credentials (*See* Def. Exh. 71 at 14–19, 21). He has performed no independent scientific research on the issue of Zicam's ability to produce smell loss. He has never studied zinc gluconate, the active ingredient in Zicam or Zicam itself (*id.* at 15–19).

Plaintiff has not shown that Dr. Hwang has an understanding of the field of toxicology or epidemiology and is capable of evaluating the strengths and weakness of toxicological research and determining whether an individual has been harmed by exposure to a particular chemical. Yet Dr. Hwang attempts to offer an opinion that plaintiff's smell loss is likely related to his exposure to Zicam. Dr. Hwang does not possess the relevant skill, knowledge, or training to render such an opinion on the *cause* of plaintiff's smell loss.

(2) Reliability.

Dr. Hwang testified that the basis for his opinions on causation were two articles by Dr. Terrence Davidson and his own clinical judgment. The first problem is that the two articles Dr. Hwang reviewed were given to him by plaintiff. Dr. Hwang did not do an independent review of scientific studies or research. This litigation-driven review of two studies purportedly supportive of plaintiff's theory that Zicam caused his smell loss does not withstand Rule 702 scrutiny and, in this instance, is devastating to the reliability of Dr. Hwang's opinion.

But there is another reason to doubt the reliability of Dr. Hwang's opinion. The MDL court held that Dr. Davidson's case series, one of the Davidson studies Dr. Hwang relied on, "is not admissible evidence of causation" and excluded all opinions "to the extent they were based on the Davidson study." *In re Zicam Cold Remedy Marketing, Sales Practices, and Prods. Liab. Litig.*, 2011 WL 798898, *17 (D. Ariz. 2011). This Court will not readjudicate the MDL court's ruling. Neither has plaintiff rebutted the unreliability of Dr. Davidson's case study.

Finally, like Dr. Davis, Dr. Hwang used differential diagnosis in reaching his opinion on the issue of specific causation. An "expert must provide reasons for rejecting alternative

hypotheses using scientific methods and procedures and the elimination of those hypotheses must be founded on more than subjective beliefs or unsupported speculation." *Clausen*, 339 F.3d at 1057. Dr. Hwang acknowledged during his deposition that there are many different causes for smell loss and that a common cause is the cold virus (Def. Exh. 71 at 28–30; 54). He apparently ruled out plaintiff's cold as the cause of his smell loss because of the burning sensation plaintiff experienced shortly after using Zicam (*id.* at 49). But Dr. Hwang does not point to reliable evidence showing that a burning sensation in the nasal area indicates damage to smell tissue.

Dr. Hwang ruled out age as the cause of plaintiff's anosmia because plaintiff relayed a history of immediate smell loss after using Zicam (*id.* at 51). But like Dr. Davis, Dr. Hwang turns a blind eye to the records in plaintiff's medical file noting the gradual loss of smell beginning four months prior to plaintiff's use of Zicam. This goes to the issue of unreliable methodology.

In sum, Dr. Hwang, who is not trained in epidemiology or toxicology rendered an opinion on the cause of plaintiff's smell loss based, in part, on his "clinical judgment." But clinical judgment does not provide an adequate basis for an opinion on an issue foreign to his clinical practice. This is the type of subjective belief and unsupported speculation that *Daubert* guards against. Moreover, Dr. Hwang did not faithfully adhere to the scientific method; he did not account for the possibility that Dr. Stone's report that plaintiff's smell loss was gradual and occurred four months prior to plaintiff's use of Zicam was possibly correct. He did not offer a scientifically supported basis for reliably ruling out age or/and plaintiff's cold as the cause of plaintiff's anosmia. Nor did he offer a reliable basis for ruling in Zicam as the cause of anosmia. Dr. Hwang is qualified to testify that plaintiff has anosmia. He is not qualified to render opinions about the causal relationship between Zicam and plaintiff's smell loss. Dr. Hwang's opinions on the issue of specific causation are **EXCLUDED**.

3. PLAINTIFF CANNOT SHOW SPECIFIC CAUSATION BASED ON MDL COURT'S DIRECT-CAUSATION ANALYSIS.

Plaintiff argues that he can establish a prima facie case of causation based on the direct causation analysis conducted by the MDL court. But the MDL court made very clear that the

only issue before it was the issue of general causation (Def. Exh. 83 at 3). The issue of specific causation was reserved for transferor courts. Thus, plaintiff's reliance on the MDL court's orders as supplying direct proof of causation is misplaced. Even assuming there is a triable issue on general causation, this does not create a genuine issue on specific causation. This is because there is a difference between determining whether scientific evidence supports an inference that the alleged exposure is capable of causing the type of injury in humans versus whether it was the most likely cause of the alleged injury in plaintiff. Plaintiff attempts to relax this standard by pointing to the substantial factor standard that California courts have applied in asbestos cases. But asbestos cases are *sui generis*, particularly in the causation context. *See Miranda v. Bomel Constr. Co.*, 187 Cal. App. 4th 1326, 1337–38 (2010). Even under the substantial factor test, which requires that the alleged cause significantly contribute to producing the injury, beyond mere speculation, there is no support that Zicam, in combination with another cause, produced plaintiff's anosmia. Plaintiff's effort to import the MDL court's rulings on general causation to meet his burden of proof on specific causation is unavailing.

4. BURDEN SHIFTING.

Plaintiff seeks to shift the burden of proving causation and require defendants to carry the burden of disproving causation. *First*, plaintiff contends that under California law the burden of proof shifts when there is a violation of public safety laws, citing *McGee v. Cessna Aircraft Cessna*, 139 Cal. App. 3d 179 (1983); *Haft v. Lone Palm Hotel*, 3 Cal. 3d 756 (1970). No such clear-cut rule is discernible from the two decisions plaintiff relies on for this proposition. These decisions stand for the proposition that under the doctrine of negligence *per se*, burden shifting may be appropriate where defendant's violation of a statute or regulation intended to safeguard against the injury plaintiff suffered has unfairly or unreasonably heightened the difficulty of proving causation. *But see Jones v. Ortho Pharm. Corp.*, 163 Cal. App. 3d 396, 406 (1985) (rejecting burden shifting because of difficulty of proving drug caused cancer).

Plaintiff also cites the decision in *Summer v. Tice*, 33 Cal. 2d 80 (1948), involving hunting and joint-liability where the court shifted the burden to defendants, who were both negligent in firing in the direction of plaintiff, to prove which one fired the bullet that hit

plaintiff. Plaintiff does not explain how the situation in *Summers*, where plaintiff was not able to establish which of two hunters fired the shot that injured him, is similar to the situation here. Finally, plaintiff cites to another decision involving risk-benefit theory and proof of defect. Plaintiff offers no analysis as to the applicability of this line of cases here. There is no cogent reason to shift the burden in this case.

CONCLUSION

For the above-stated reasons, the motions to exclude the expert testimony of Drs. Davis and Hwang, to the extent stated herein, are **GRANTED.** Dr. Davis will be permitted to revise his expert report, subject to the conditions stated above. Defendants' motion for summary judgment on all claims based on lack of causation is **HELD IN ABEYANCE.** The pretrial conference set for **AUGUST 27, 2012** and the trial date of **SEPTEMBER 17** are hereby **VACATED**. A status conference will be held on **SEPTEMBER 6, 2012**, to reset the pretrial and trial dates.

IT IS SO ORDERED.

Dated: August 21, 2012.

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE