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I.
INTRODUCTION/SUMMARY OF ARGUMENT

Plaintiff Gayle Rose (“Rose” or “Plaintiff”) offers Dr. Terence M. Davidson (“Dr. Davidson”) to testify that a toxic dose of Zicam® Cold Remedy No Drip Liquid Nasal Gel (“Zicam®”) caused her smell dysfunction. Dr. Davidson’s causation opinion lacks reliable foundation and lacks a valid scientific connection to the facts concerning Rose’s injury. It is inadmissible under Rule 702.

Dr. Davidson has no reliable foundation for his causation opinions. He admits that Zicam could be the cause of Rose’s smell loss only if she used the product in both nostrils and sniffed it up to her smell tissue in both nostrils. Rose testified unequivocally, and has stated consistently, that she only used Zicam® in her right nostril, and she has testified that she does not recall sniffing at all. Thus, there is no substantial evidence that Rose (1) applied Zicam® to her right nostril, and (2) sniffed at all, only Dr. Davidson’s speculation. Moreover, there is no scientific evidence whatsoever that a sniff, of any type or magnitude, can pull a viscous gel like Zicam® up to the smell tissue, much less a toxic dose of Zicam®. To the contrary. All available scientific evidence (much of which Dr. Davidson has not reviewed) indicates that sniffing has little influence on where solutions are distributed in the nose. Finally, even if some type of sniff was capable of delivering a viscous gel like Zicam® to the smell tissue and there were evidence of a sniff here, Dr. Davidson has no basis for concluding that Rose sniffed in a way that exposed her smell tissue to Zicam®, much less a toxic dose (which Dr. Davidson has never identified). Because Dr. Davidson tries to bridge these multiple analytical gaps with serial assumptions devoid of record or scientific support – that Rose used the product in both nostrils, that she sniffed in both nostrils, that her assumed sniff was capable of drawing a toxic level of gel to the smell tissue – his opinions amount to no more than speculation and unfounded personal belief.

Dr. Davidson’s specific causation opinion is also speculative because he failed to reliably exclude alternative causes of smell loss solidly within Rose’s clinical picture. The cold Rose was treating with Zicam®, and the rhinitis and sinusitis with which she was diagnosed by her treating physician, are all common, established causes of smell loss, and Dr. Davidson has failed

to reliably exclude them. For this additional reason, Dr. Davidson's specific causation analysis is speculative, subjective and unreliable.

Dr. Davidson's causation opinions are also speculative and unreliable because his general causation opinion also lacks reliable foundation and his analysis is inconsistent with the scientific method and lacking in the scientific rigor ordinarily employed by experts assessing causal relationships. It is undisputed that Zicam® could only be a theoretical cause of smell loss if a toxic dose reaches the smell tissue, i.e., if there is toxic exposure. But there is no reliable scientific evidence that there is *any* exposure, let alone exposure to a still-undefined toxic dose. Moreover, Dr. Davidson relies on the types of evidence toxicologists do not rely upon to reach general causation conclusions, and his analysis, developed in the course of litigation, fails to conform to the scientific method and lacks scientific rigor.

Finally, Dr. Davidson's analysis fails the *Daubert* reliability factors. He has not scientifically tested his theories, or even thoroughly researched many of the components of his theory, preferring to rely on untested assumptions and personal belief. Only his case series was peer-reviewed and published; peer review of a case series (as opposed to a scientific study) adds nothing in the way of reliability. A subjective analysis relying on untested assumptions is obviously highly prone to error and lacks standards and controls. And Dr. Davidson's opinion relies on principles and methods of analysis which do not merely lack general acceptance; they are inconsistent with the generally accepted methods of investigating general and specific causation.

In sum, Dr. Davidson's causation opinions are not based on sufficient facts or data, are not the product of a reliable application of reliable scientific methods, fail to qualify as scientific knowledge, are not helpful to the trier of fact, and consequently are more prejudicial than probative. They are therefore inadmissible under Federal Rules of Evidence 702 and 403.

II. **BACKGROUND**

A. The Facts And Allegations Surrounding Rose's Smell Loss

Rose testified that she used Zicam® on the morning of May 18, 2006 to treat cold

symptoms. She purchased the product in February 2006 and read the instructions on the box and the package insert. When Rose used the product, she followed the instructions: she primed the pump, placed the tip of the nozzle just inside her left nostril, and angled it outward. She pumped one time into the left nostril.¹ She immediately felt intense pain and burning.² Because of the writhing pain, she did not apply the product to her right nostril.³ She claims that the next morning she could not smell, and that two days later, she could not taste food.⁴

Rose used Zicam® because she felt cold symptoms. As we discuss below, the common cold is uniformly considered one of the most common causes of chronic or permanent smell loss. Close behind is nasal and sinus disease, such as rhinitis and sinusitis, conditions prominent in Rose's medical profile near the time she noticed her smell loss.

B. Medical Treatment and Examinations

1. Dr. Klug

On May 21, 2006, Rose called Dr. Dean Klug, an Ear, Nose, and Throat Specialist, and reported her loss of sense of smell. Dr. Klug prescribed an oral steroid, and he examined her the following day.⁵ He took Rose's history, examined her, and performed a nasal endoscopy.⁶ Rose reported that she had used Zicam® on May 18, had experienced extreme pain and burning *in her left nostril* that lasted fifteen to twenty minutes, and later realized that she could not smell.⁷ Dr. Klug's examination revealed a septal deviation, nasal congestion, and swollen turbinates. The

¹ Exhibit ("Exh.") A (Rose Depo) at 33, 42-44, 129-133.

² *Id.* at 141-142.

³ *Id.* at 130, 138, 196.

⁴ *Id.* at 149-153.

⁵ *Id.* at 35-36.

⁶ Exh. B (Klug Depo). at 57-58.

⁷ *Id.* at 55-57; Exh. C (Klug Medical Records) at GRose-IN-DAK-00001-2.

congestion and swelling were consistent with a cold.⁸

Dr. Klug saw Rose five more times, May 30, June 20, August 8, November 28, and December 15, 2006. He repeatedly found nasal congestion, swollen turbinates, chronic rhinitis, and diminished smell, and also found sinusitis.⁹ In smell tests, on May 30 Rose scored 15 out of 40, grading anosmia (no smell); on June 20, she scored 23 out of 40, microsmia (hyposmia or diminished smell); on August 8 and November 28, she scored 29 out of 40, microsmia.¹⁰

Dr. Klug's impression was anosmia secondary to Zicam® use, based solely on the reported temporal relationship between use of Zicam® and onset of the alleged injury.¹¹ Dr. Klug has never performed any research regarding Zicam® and loss of smell, and knows very little about the product and how Rose used it, and he has no science-based opinion as to the cause of Rose's smell loss. He has no explanation for how Zicam® could be the cause of her smell loss if she only used it in one nostril.¹² He has not been designated to testify to any causation opinion.

2. Dr. Terence Davidson

On February 11-12, 2008, long after she had filed this lawsuit, Rose consulted with Dr. Terence Davidson and the Nasal Dysfunction Center at UCSD Medical Center. Dr. William Cain took Rose's history and performed a smell test. Rose reported diminished olfactory functioning and distortion of odors, which she attributed to spraying Zicam® *into her left nostril* in May 2006. Dr. Cain noted Rose's complaint of an intense burning sensation lasting about 45 minutes. Rose told him that she did not spray the product into her right nostril. She said that she had used the Zicam® to treat cold symptoms. Rose scored twelve out of forty on a smell test,

⁸ *Id.* at 58-62; Exh. C (Klug Medical Records) at GRose-IN-DAK-00002.

⁹ Exh. C (Klug Medical Records) at GRose-IN-DAK-00003-12; Exh. D (Davidson Medical Records) at GRose-TN-TD-0011-15; Exh. B (Klug Depo) at 103; Exh. E (Davidson *Rose* Depo) at 46-50.

¹⁰ Exh. B (Klug Depo) at 64- 86; Exh. D (Davidson Medical Records) at GRose-TN-TD-0011-15.

¹¹ Exh. B (Klug Depo) at 90-92, 104.

¹² *Id.* at 37-39, 46, 52-53, 56-57, 90-93.

anosmia.¹³

Dr. Davidson met with Rose on February 12, 2008 after first speaking with her attorney and discussing the causation problem presented by Rose's testimony and history of use in one nostril.¹⁴ Rose told Dr. Davidson that she used Zicam® only in her left nostril. Dr. Davidson confronted her with the fact that Zicam® could not have been the cause if that was true, and he suggested that she must have "forgotten" about the second shot. According to Davidson, upon reflection, Rose agreed that she could be mistaken.¹⁵ Dr. Davidson acknowledges that Zicam® must be used in both nostrils to cause bilateral smell loss, Rose's condition. The two nasal cavities are separate chambers, each with their own set of smell receptors, and a toxic exposure to one side will not affect function in the other.¹⁶ Only by assuming use in both nostrils, contrary to Rose's consistent testimony and history, can Davidson attribute her loss to Zicam® use.

Further, although Rose did not previously report sniffing in her use of Zicam®, and though she testified January 10, 2008 that she used the product according to the package directions (which instructs the user to avoid sniffing) and that she could not recall sniffing,¹⁷ Dr. Davidson recorded that she "sniffed" by noting in his February 12, 2008 medical chart "squirt sniff burn and total loss," a shorthand he uses for his theorized "zinc induced anosmia syndrome" diagnosis. Dr. Davidson testified that he did not recall Rose telling him that she sniffed, and assumes she did only because of the cryptic chart notation.¹⁸ Dr. Davidson assumes Rose sniffed after each "shot" of Zicam® (including the phantom second shot), but he acknowledges he does

¹³ Exh. D (Davidson Medical Records) at GRose-TN-TD-0005, 0007-0009.

¹⁴ *Id.* at GRose-TN-TD-0001-2; Exh. E (Davidson *Rose* Depo) at 14.

¹⁵ Exh. E (Davidson *Rose* Depo) at 11-14; Exh. D (Davidson Medical Records) at GRose-TN-TD-0001-2; Exh. U (Davidson *Rose* Report) at Exh. 1, p. 1 ("Ms. Rose has stated that the gel was only squirted into the left side. I questioned her about that and she realized that in the trauma and pain of the moment, she actually doesn't know whether she squirted it on one side or both sides of the nose.")

¹⁶ Exh. E (Davidson *Rose* Depo) at 12-13, 65; Exh. X (Davidson *Bruno* trial testimony) at 79-81.

¹⁷ Exh. A (Rose Depo) at 130-134, 137; Exh. I (package directions).

¹⁸ Exh. E (Davidson *Rose* Depo) at 16-18, 21-22.

not know anything about the timing of her supposed sniff. He assumes it was a vigorous sniff, because he noted it in his chart and presumably it would need to be to deliver gel to the smell tissue. He has no information about her assumed sniff, beyond these assumptions.¹⁹

Dr. Davidson does not know anything about how Rose used the product, *i.e.* the extent to which she followed the directions. He also does not know whether she used the first or second generation actuator design, and acknowledges that the latter would tend to deposit the gel lower in the nose, and in a radial pattern.²⁰

3. Dr. James A. Duncavage

Seventeen days after she met with Dr. Davidson, on February 29, 2008, Rose underwent an independent medical examination with Dr. James A. Duncavage. Rose provided Dr. Duncavage with the history of her Zicam® use, explaining that on May 18, 2006 she felt a cold coming on, squirted Zicam® once into her left nostril, and experienced pain after squirting the Zicam®. *She told him she did not spray Zicam® into her right nostril.*²¹

Dr. Duncavage performed a smell test. Rose scored 6 out of 40 for the right nostril and 12 out of 40 for the left nostril. He also examined Rose's nose. He found significant nasal obstructions in both cavities and concluded that Zicam gel could not have come into contact with her smell tissue on the left side – the one side where she squirted the gel. Dr. Duncavage confirmed the presence of a sinus infection.²²

C. The Product

Zicam® is a homeopathic cold remedy. It is a viscous gel administered in the nose with a spray pump. The active ingredient is zinc gluconate, a compound classified by the FDA as GRAS (generally recognized as safe). Typical of homeopathic remedies, the level of active

¹⁹ *Id.* at 22, 25, 28-29, 36, 64.

²⁰ *Id.* at 64-65, 86-88.

²¹ Exh. F (Duncavage IME Report) at 1.

²² *Id.* at 2-3.

ingredient is minimal, just a 1.58% concentration. Each metered dose contains 120-140 microliters of gel, approximately 1/35 of a teaspoon. At 1.58% concentration of zinc gluconate, the total amount of zinc delivered into a nasal cavity is .231% of the gel, amounting to about 240-280 micrograms of zinc.²³ There is no scientific evidence whatsoever that this amount of zinc gluconate, or zinc, is capable of causing severe and chronic smell loss in humans, nor that an equivalent dose is capable of doing so in animals.²⁴

Zicam® is designed to be delivered to the very lowest part of the nasal cavity, and, as discussed below, the available scientific evidence demonstrates that when used as directed, none of the gel reaches the smell tissue.²⁵

D. Smell Disorders

Chronic smell impairment, including complete smell loss (“anosmia”), is a fairly common condition. Dr. Davidson estimates that at least approximately 1-2% of the people in this country, and probably many more than that, have chronic smell disorders.²⁶ It is generally accepted that the most common causes of chronic smell loss are upper respiratory infections (“URIs”), such as cold and flu, and sino-nasal diseases such as rhinitis and sinusitis, and that a substantial percentage of cases are classified as idiopathic (meaning the cause is unknown to medical science or otherwise undetermined).²⁷

The nerves primarily responsible for sensing odors are the “olfactory epithelium,” a small patch of tissue approximately one square centimeter in size, tucked away in a remote portion of the roof of each nostril near the midline of the eyes. Nasal anatomy is convoluted and complex

²³ Exh. G (Halmes Report) at 13, 14, 16, 18.

²⁴ See Exh. P (Slotnick study); Exh. L (Kern Report) at 1.

²⁵ Exh. H (Dalby Report) at 8-9; Exh. I (package directions); Exh. N (Herranz Study); Exh. O (Univ. Pittsburgh study).

²⁶ Exh. J (Davidson *Bruno* Depo) at 31-33. Dr. Davidson has testified that this is a “gross” underestimate. Exh. S (Davidson *Nelson* Depo.) at 39. Recent studies suggest that the real percentage approaches 20%. Exh. K (Brämerson Study).

²⁷ Exh. J (Davidson *Bruno* Depo) at 31-33; Exh. BB (Deems, Doty Study) at 522.

and the path from the entrance of the nostril to the smell tissue is circuitous.²⁸ Access to the sheltered smell tissue is limited further where, as here, the individual has unusual narrowing of the nasal airways, a severely deviated septum, or congestion.²⁹ These characteristics make it highly unlikely that any of the viscous gel can reach the smell tissue.³⁰ It is undisputed that damage to the smell tissue from chemical exposure requires physical contact.³¹ And as noted above, each separate nasal cavity has its own independent smell tissue, and direct toxic exposure in each nostril is required to cause bilateral smell loss. Destruction from a virus such as a URI or nasal sinus disease, on the other hand, attacks the smell tissue on both sides and typically causes bilateral smell loss.³²

E. Research Regarding Zicam® And Smell Loss

Whether Zicam® can cause smell loss has been scientifically studied. In 2004, in response to the publication of a case report by Bruce W. Jafek, M.D., hypothesizing that Zicam® use can cause smell loss, Matrixx convened a Scientific Advisory Board to study the existing science and design scientific experiments to test that hypothesis.³³ Nasal distribution studies were performed to determine whether Zicam® can reach the smell tissue when used as directed or flagrantly misused; a mouse study evaluated the dose-response curve for Zicam®; and an epidemiological study investigated the medical conditions and prescription medications associated with chronic smell loss.

The distribution studies found that when Zicam® is used as directed, the gel does not

²⁸ Exh. H (Dalby Report) at 5-6; Exh. E (Davidson *Rose Depo*) at 30..

²⁹ Exh. L (Kern Report); Exh. F (Duncavage Report).

³⁰ Exh. H (Dalby Report) at 5-6, 8-9.

³¹ Exh. J (Davidson *Bruno Depo*) at 10, 127; Exh. E (Davidson *Rose Depo*) at 65.

³² Exh. E (Davidson *Rose Depo*) at 12-13.

³³ Exh. M (8K SEC Statement Filed 2/19/04).

reach the area of the smell tissue.³⁴ The animal study showed that mice experienced no smell dysfunction at doses approximately 15 times the equivalent human dose of Zicam®, and even at an extreme overdose of approximately 94 times the equivalent human dose, the researcher was unable to produce anosmia, much less permanent anosmia, and the dysfunction was temporary.³⁵ The epidemiological study confirmed that the most prominent conditions associated with smell loss included URI, rhinitis and sinusitis.³⁶

The Scientific Advisory Board reviewed this research on an ongoing basis and unanimously concluded that the hypothesis that Zicam® causes smell loss was unsupported by the scientific evidence.³⁷

F. Dr. Davidson's Connection To Zicam® Litigation

Dr. Davidson is an otolaryngologist and plastic surgeon at the University of California at San Diego, and sees patients in its Nasal Dysfunction Clinic. He has been an expert testifying for plaintiffs in Zicam® litigation since early 2005, following the publication of the Jafek case report in September 2003.³⁸ Dr. Davidson has been deposed in several similar cases against Matrixx and has testified once at trial.

In 2006, in between depositions in litigation against Matrixx, Dr. Davidson published a retrospective case series claiming discovery of a phenomenon he coined as “zinc-induced anosmia syndrome”, characterized by a pattern of “squirt, sniff, burn, anosmia.”³⁹ Dr. Davidson

³⁴ Exh. N (Herranz Study); Exh. O (Univ.Pittsburgh Study). See Exh. G (Halmes Report) at 16-18.

³⁵ Exh. P (Slotnick Study). See Exh. G (Halmes Report) at 18-19.

³⁶ Exh. Q (Jones Study).

³⁷ Exh. R (8K SEC Statement Filed 9/29/04).

³⁸ Dr. Davidson gave numerous interviews to the media in the aftermath of publicity arising from publication of the Jafek case report, and he was quickly retained to testify by attorneys for plaintiffs in various cases against Matrixx and its competitor, Quigley, the makers of Cold-Eeze®. Exh. X (Davidson Bruno Trial Testimony) at 68-69.

³⁹ Exh. T (Alexander, Davidson Study); Exh. J (Davidson Bruno Depo) at 10-11. Dr. Davidson testified that he made up the term “zinc-induced anosmia syndrome” in preparing for his first Zicam

(continued...)

claimed that patients using Zicam® who sniffed up the gel during use, contrary to package instructions, experienced a severe burning sensation in their nose and soon thereafter noticed a smell deficit. The case series was based on a retrospective review of patient files for those with a history of smell loss following use of Zicam® or Cold-Eeze®. He found 17 cases in his clinic over the years— at least half of them referred by attorneys. To retrospectively ascribe their smell loss to the nasal spray, the case series relied entirely on patient histories and temporality, and concluded that 15 of the 17 cases were examples of the “syndrome.” Dr. Davidson claimed that the histories allowed him to rule out as a cause of the loss of sense of smell the underlying medical condition for which the patients were taking Zicam®, the cold, and other conditions and medications. Ruling out the cold is critical to his opinions because the cold is known to be the most common cause of chronic smell loss.⁴⁰

A case report is not a scientifically rigorous undertaking, but discovery has revealed that even by the lax standards applied to case series, Dr. Davidson’s series is infected with severe protocol irregularities. In support of the “syndrome”, the article reported that each of the 15 patients had reported sniffing up the gel. But discovery has revealed that in at least half of the patients the sniff was not reported in the patient’s medical records, and in one case it was contradicted by the medical records.⁴¹ When confronted with the discrepancy, Dr. Davidson first explained that in those cases where the records did not disclose sniffing his colleague and co-author, Dr. Alexander, had phoned the former patients to inquire whether they had sniffed. He later testified that this was incorrect; in fact, there had been a miscommunication between Drs. Alexander and Davidson: Dr. Alexander had assumed that all of the patients sniffed because this is what Dr. Davidson had told him. Dr. Davidson had assumed that Dr. Alexander had obtained

(..continued)
deposition in 2005. Exh. S (Davidson *Nelson Depo*) at 120.

⁴⁰ Exh. T (Alexander, Davidson Study).

⁴¹ Exh. X (Davidson *Bruno Trial Testimony*) at 115-118.

this information from the patients' medical records.⁴² Thus, a key assumption, and a key component of Dr. Davidson's "syndrome," was not supported by contemporaneous medical records in half of the small sample, and instead was based on an unverified anecdotal assumption.⁴³ Though he relied on the patients' own accounts of how they used the product and knew that *at least* half of the patients were represented by counsel and all had access to his public and litigation statements detailing what he needed to hear in a history to fit within his "syndrome," he did nothing to control or investigate the impact of litigation or information bias on their histories.⁴⁴

Dr. Davidson's theory that Zicam® causes smell loss is based on (1) temporal relationship, (2) unsupported extrapolation from studies involving high doses of a different compound (zinc sulfate), applied in a different manner, and mostly in different species; (3) the reports of a burning sensation in the nose following Zicam® use; and (4) case reports, including his own and Dr. Jafek's, describing anecdotal clinical observations of patients presenting with smell loss following Zicam® use. Virtually identical foundations proffered by Dr. Davidson and other experts (including the authors of all three case reports/series) have been found deficient under Rule 702 by all nine federal courts to consider the issue.⁴⁵

⁴² *Id.* at 118-120; Exh. J (Davidson *Bruno* Depo) at 78-81.

⁴³ Dr. Davidson's willingness to supply an assumption that the patient sniffed in the absence of evidence they did so, or in contradiction of evidence they did not, has been mirrored in his testimony in litigation. Exh. CC (Davidson *Seckman* Depo) at 30-32; Exh. V (Davidson *Gillespie* Depo) at 85, 97-98; Exh. J (Davidson *Bruno* Depo) at 11, 83-89; Exh. X (Davidson *Bruno* Trial Testimony) at 31, 40-41. Dr. Davidson makes the same unsupported assumption in this case, compounded by his unsupported assumption that Ms. Rose used the product in both nostrils.

⁴⁴ Exh. X (Davidson *Bruno* Trial Testimony) at 74-76; Exh. J (Davidson *Bruno* Depo) at 43-44, 72-73, 74-77.

⁴⁵ See *Benkwith v. Matrixx Initiatives, Inc.*, 467 F.Supp.2d 1316, 1328-1329 (M.D. Ala. 2006) (Dr. Jafek); *Hans v. Matrixx Initiatives, Inc.*, 2006 U.S. Dist. LEXIS 96779, *12-15 (W.D. Ky. Sept. 29, 2006) (copy attached) (Dr. Jafek); *O'Hanlon v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 65655, *9 (C.D. Cal. Sept. 29, 2006) (copy attached) (Drs. Jafek and Davidson and toxicologist Gerhard Schrauzer); *Sutherland v. Matrixx Initiatives, Inc.*, 2006 U.S. Dist. LEXIS 96652, *32-35 (N.D. Ala. Nov. 7, 2006) (copy attached) (Dr. Jafek); *Wyatt v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 67986, *13-15 (N.D. Ala. March 30, 2007) (copy attached) (Dr. Jafek and treating physician); *Lusch v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 72068, *12-13 (D. Or. Sept. 25, 2007) (copy attached)

(continued...)

Dr. Davidson has never done any scientific testing to determine if Zicam® actually does cause smell loss, or any of the other critical aspects of his opinion.⁴⁶ He has done no research at all on several of these issues – he just makes assumptions. Not only is there no scientific evidence supporting these assumptions/theories, there is data or literature contradicting them all, and Dr. Davidson has not reviewed it, nor has he attempted to replicate any of the relevant studies or perform any similar research on these central questions. In sum, he has done nothing to challenge his persistent but unverified hypothesis that Zicam® causes smell loss. It remains an unproven theory, without substantial and reliable scientific support.

III. **DISCUSSION AND APPLICATION OF RULE 702 TO DR. DAVIDSON'S OPINION** **TESTIMONY**

A. The Law Precludes Opinions Based On Junk Science

Rule 702 and *Daubert* require trial courts to police the foundations of expert causation opinions, principally so that juries are not burdened with junk science in sorting out complex scientific issues. “Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it.”⁴⁷ Rule 702 provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable

(..continued)

(Drs. Jafek and Seiden, Miriam Linschoten, and treating physician); *Salden v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 18552 (E.D. Mich. March 16, 2007) (copy attached) (Dr. Hirsch); *Hilton v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 73264 (N.D. Tex. Feb. 20, 2007) (copy attached) (Dr. Jafek); *Polski v. Quigley Co.*, 2007 U.S. Dist. LEXIS 66005 (D. Minn. Sept. 5, 2007) (copy attached) (Dr. Jafek). No expert has been permitted to testify under Rule 702 that Zicam® causes smell loss because opinions that it does so have been found to violate Rule 702 in every case.

⁴⁶ Exh. J (Davidson *Bruno* Depo) at 116, 143; Exh. CC (Davidson *Seckman* Depo) at 54, 76-77; Exh. S (Davidson *Nelson* Depo) at 42-43, 136; Exh. X (Davidson *Bruno* Trial Testimony) at 60-61.

⁴⁷ *Daubert v. Merrill Dow Pharms.*, 509 U.S. 579, 595 (1993). See also *Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244, 252 (6th Cir. 2001) (“close judicial analysis of expert testimony is necessary ‘because expert witnesses are not necessarily always unbiased scientists’”) (quoting *Turpin v. Merrell Dow Pharm., Inc.*, 959 F.2d 1349, 1352 (6th Cir. 1992)).

principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Rule 702 requires the court to ensure that any and all scientific testimony is not only relevant, but reliable.⁴⁸ To assure reliability the court must determine whether the expert's opinion qualifies as "scientific knowledge,"⁴⁹ i.e., whether it has a reasonable and reliable basis in the data and methodology, "and the court must exclude the opinion if it appears to be based on 'unsubstantiated generalizations, speculative hypotheses and subjective evaluation.'"⁵⁰ "Scientific" implies a grounding in the methods and procedures of science," and "knowledge" connotes more than subjective belief or unsupported speculation." Rather, "knowledge" is that which is "accepted as truth on good grounds."⁵¹ Accordingly, untested, unproven theories are inadmissible; to be admissible, an expert opinion must have a reliable basis in the knowledge and experience of the relevant discipline.⁵² The overall inquiry is designed to ensure that the expert has applied the same standards of scientific and intellectual rigor to his testimony in court as experts apply to their work in the relevant field.⁵³

Daubert set forth a non-exhaustive list of factors to be considered in evaluating whether scientific evidence is sufficiently reliable to be admitted: (1) whether the theory, technique, or hypothesis relied on by the expert has been or could be tested; (2) whether it has been subjected

⁴⁸ *Daubert*, 509 U.S. at 589.

⁴⁹ *Nelson*, 243 F.3d at 250-251. See also *Moore v. Ashland Chem. Co.*, 151 F.3d 269, 275, 278 (5th Cir. 1998) (*en banc*) (the court "must determine whether the evidence is genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist") (quoting *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316 (7th Cir. 1996), *cert. denied*, 526 U.S. 1064 (1999)).

⁵⁰ *Cacciola v. Selco Balers, Inc.*, 127 F.Supp.2d 175, 184 (E.D.N.Y. 2001). See also *In re Meridia Prods. Liab. Litig.*, 328 F.Supp.2d 791, 806 (N.D. Ohio 2004) ("the more subjective an expert's inquiry, the more likely the testimony should be excluded as unreliable"), *aff'd*, 447 F.3d 861 (6th Cir. 2006).

⁵¹ *Nelson*, 243 F.3d at 250 (quoting *Daubert*, 509 U.S. at 590).

⁵² *Id.* at 592.

⁵³ *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999); *Meridia*, 328 F.Supp.2d at 803. See also *Nelson*, 243 F.3d at 252.

to peer review and publication; (3) whether scientific standards and controls exist to govern the theory or technique's application or operation, and the known or potential error rate; and (4) whether the technique or theory has been generally accepted in the scientific community.⁵⁴

Additional reliability factors have been established: whether the expert relies on anecdotal evidence, such as case reports, on temporal proximity, or on unjustified extrapolations from data such as animal studies;⁵⁵ whether the expert is proposing to testify about matters growing directly out of independent research or whether the testimony was developed in the course of litigation; whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion; whether the expert has adequately accounted for obvious alternative explanations; whether the expert is being as careful as he would be in his regular work; and whether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion proffered.⁵⁶

The common thread: all these factors are designed to explore the expert's adherence to the scientific method. While the focus is on the principles and methods employed by the expert, rather than the conclusions they generate, conclusions and methodology are not entirely separable. Under Rule 702, the court should exclude opinions connected to existing data only by the *ipse dixit* of the expert, or where "there is simply too great an analytical gap between the data and the opinion proffered."⁵⁷

The determination of whether the opinion is undermined by an analytical gap applies not only to evaluating the reliability of the testimony, but also the second inquiry mandated by *Daubert* and Rule 702, whether the testimony "fits" the data and the case. Opinion testimony

⁵⁴ *Daubert*, 509 U.S. at 593-95; *Nelson*, 243 F.3d at 251 n.5.

⁵⁵ Advisory Committee Notes, FED. R. EVID. 702 (citations and internal quotations omitted). See also *In re Meridia*, 328 F.Supp.2d at 804; *In re Welding Fume Prods. Liab. Litig.*, 2005 WL 1868046, at *4 (N.D. Ohio Aug. 8, 2005). (copy attached).

⁵⁶ See Steven A. Saltzburg et al., FEDERAL RULES OF EVIDENCE MANUAL Sec. 702.02[7] (8th ed. 2002); see also *Downs v. Perstor Components, Inc.*, 126 F.Supp.2d 1090, 1125-27 (E.D. Tenn. 1999) (approving use of these "red flags"), *aff'd*, 2002 WL 22000 (6th Cir. Jan. 4, 2002).

⁵⁷ *General Elec. Co. v. Joiner*, 522 U.S. 129, 146 (1997).

does not “fit” and is not helpful to the trier of fact when it lacks a valid scientific connection to the matter at hand.⁵⁸ As we show below, Dr. Davidson’s reliance on assumptions which are unsupported by the record or the scientific literature create unbridgeable analytical gaps and deprive his opinions of fundamental reliability and any valid scientific connection to the question of the cause of Rose’s bilateral smell loss.

B. Dr. Davidson’s Specific Causation Opinion Is Not Supported By A Reliable Foundation And It Does Not “Fit” The Facts

In toxic tort cases involving disputed theories of causation, courts and scientists find it useful to bifurcate causation analysis into the questions of general causation and specific or individual causation. General causation asks whether the type of exposure alleged by the plaintiff is capable of causing the disease that plaintiff developed, i.e., whether the exposure can be “ruled in” as a potential cause of the plaintiff’s injury. Specific causation goes on to ask whether the ruled in exposure, compared to other potential causes in the plaintiff’s medical and factual profile, is the *most likely actual cause* of plaintiff’s injury.⁵⁹ We address specific causation first, because Dr. Davidson’s serial contradicted assumptions about Ms. Rose’s Zicam® use (use in both nostrils, vigorous bilateral sniffing) and lack of scientific evidence concerning the effect of a sniff on intranasal exposure so clearly rob his specific causation opinions of reliable basis and fit and render them inadmissible, even if Zicam® had been properly and reliably “ruled in” as a potential explanation for Rose’s smell loss.

1. There Is No Reliable Basis For Dr. Davidson’s Assumption That Rose Applied Zicam® In Both Nostrils And Then Sniffed In A Manner Capable Of Delivering Zicam® To Her Smell Tissue.

Dr. Davidson acknowledges that Zicam® must reach the smell tissue to have any toxic effect, and theorizes (without any scientific support) that a vigorous “sniff” of some type and magnitude can deliver it there. Further, given Rose’s bilateral smell loss, Zicam® could not be the cause of her loss unless she applied and sniffed the gel to her smell tissue in each nostril.

⁵⁸ *Daubert*, 509 U.S. at 591-592.

⁵⁹ *Meridia*, 328 F.Supp.2d at 798; *Sterling v. Velsicol Chem. Corp.*, 855 F.2d 188 (6th Cir. 1988).

Because none of these prerequisites to causation are supported by anything other than speculation, and in fact are contradicted by the available evidence, there are multiple analytical gaps in Dr. Davidson's chain of reasoning. Accordingly, he has no reasonable and reliable basis for his specific causation opinion and it lacks a valid scientific connection to the facts.

Rose testified, and told all her doctors (including Dr. Davidson) that she applied Zicam® only to her left nostril.⁶⁰ Nevertheless, Dr. Davidson chose not to believe this because it did not fit his causation theory, and instead tried to convince her that she must have used Zicam® in both nostrils.⁶¹ At his deposition, Dr. Davidson testified:

When she presented to me, she had expressed the opinion, both in deposition and to others, that she had only sprayed it in one or the other side. This made no physiological sense that one could spray a toxin into one side of the nose, absent a large septal perforation and have it destroy the olfactory receptors in both sides.

So I had a discussion with her, which I actually quite remember, in which I confronted her and said, "You obviously – you had to have sprayed it in both sides. And either from the trauma of the moment or whatever, you have forgotten that." And there was this sort of look of shock on her face as she comprehended this and realized that perhaps she had made a mistake.

Having found no other plausible cause for her to have had this acute smell loss and believing that it had to be an acute-toxin induced injury, whether she recalled it specifically or the trauma of the moment obscured her memory, it was my opinion that she sprayed it on both sides and she suffered, as a direct result of that, a bilateral zinc-induced anosmia.⁶²

Under these circumstances, it is neither reasonable nor reliable for Dr. Davidson to assume that Rose used Zicam® in both nostrils. He essentially assumes this solely to justify his

⁶⁰ Exh. A (Rose Depo) at 132, 138; Exh. B (Klug Depo) at 56; Exh. C (Klug Medical Records) at GRose-IN-DAK-00001-2; Exh. D (Davidson Medical Records) at GRose-TN-TD-0007; Exh. F (Duncavage IME Report); Exh. E (Davidson Rose Depo) at 11-14; Exh. L (Kern Report) at 2. Davidson did not review Rose's deposition testimony. Exh. E (Davidson Rose Depo) at 14.

⁶¹ Exh. E (Davidson Rose Depo) at 11-14; Exh. U (Davidson Rose Report) at Exh 1.

⁶² Exh. E (Davidson Rose Depo) at 12-13; *see also* Exh. U (Davidson Rose Report) at Exh. 1 ("Ms. Rose stated that the gel was only squirted into her left side. I questioned her about that and she realized that in the trauma and pain of the moment, she actually doesn't know whether she squirted it on one side or both sides of the nose.").

opinion.⁶³ In other words, to reach a conclusion at odds with the evidence, he relies on circular reasoning, assuming that which is necessary to his conclusion, and then justifying the conclusion based on the supplied assumption. The obvious lack of reliability and rigor where opinions are based on circular reasoning has been recognized in case law.⁶⁴

In any event, on this record it is crystal clear that Dr. Davidson's opinion is predicated on a key assumption which is nothing more than speculation. Indeed, given the consistent evidence to the contrary, it is less than speculation – it is fallacy. Opinions predicated on demonstrably false assumptions, or assumptions unsupported by substantial evidence, are unreliable and lack the requisite fit to be admitted.⁶⁵

A second and equally fatal analytical gap is presented by Dr. Davidson's assumption that Ms. Rose sniffed the gel in each nostril in a manner capable of drawing it to the smell tissue. First, there is no substantial evidence that she sniffed at all – she testified on January 10, 2008 that she did not remember sniffing and could not say that she did. Dr. Davidson claims she told him she sniffed a month later, because he wrote down the word “sniff” in his notes. None of Rose's contemporaneous medical records mention sniffing, and nothing in Dr. Cain's notes from the exam the day before Dr. Davidson's exam, or in Dr. Duncavage's exam two weeks later, indicate a sniff. This appears to be yet another instance of Dr. Davidson supplying a critical

⁶³ See Exh. U (Davidson *Rose* Report) at Exh. 1, p. 2 (“To make this diagnosis it is anatomically necessary for the individual to squirt the zinc nasal gel into both side [sic] of her nose and to sniff this gel into her olfactory clefts, where the zinc gluconate destroys the individual's olfactory epithelium. It is my opinion, again to a reasonable degree of medical and scientific certainty, that this occurred and the [sic] Ms. Rose has simply forgotten what transpired.”). See also Exh. E (Davidson *Rose* Depo) at 65.

⁶⁴ See *Nelson*, 243 F.3d at 254 (“the magistrate judge properly rejected the circular reasoning that the plaintiff must have been exposed to the PCB because PCBs were present in the environment and plaintiffs showed symptoms”); *Meridia*, 328 F.Supp.2d at 805. See also *Brown v. Syntex Labs., Inc.*, 755 F.2d 668, 673 (8th Cir. 1985); *O'Conner v. Commonwealth Edison Co.*, 807 F.Supp. 1376, 1396 (C.D. Ill. 1992), *aff'd*, 13 F.3d 1090 (7th Cir. 1994). See also Exh. G (Halmes Report) at 25-27.

⁶⁵ See *McLean v. 988011 Ontario Ltd.*, 224 F.3d 797, 800-801 (6th Cir. 2000); *United States v. L.E. Cooke Co.*, 991 F.2d 336, 342 (6th Cir. 1993). See also *Smelser v. Norfolk-Southern R. Co.*, 105 F.3d 299, 303 (6th Cir.) (opinion based on expert's subjective belief or unsupported speculation does not satisfy Rule 702), *cert. denied*, 522 U.S. 817 (1997); *Meridia*, 328 F.Supp.2d at 806 (“the more subjective an expert's inquiry, the more likely the testimony should be excluded as unreliable”).

assumption without any basis in the record. In any event, even if Ms. Rose did sniff after use in her left nostril, and did so in a manner sufficient to draw gel to the smell tissue on the left side, there remains no evidence that she did so in the right nostril, and hence, still no reliable basis for an inference that Zicam® caused her bilateral smell loss.

Moreover, Dr. Davidson's naked assumption that a sniff would have delivered gel to the smell tissue is itself scientifically and factually unsupported. Dr. Davidson can cite no scientific evidence which demonstrates that a sniff of *any* type or magnitude can draw a viscous gel to the sheltered smell tissue located in the very roof of the nose.⁶⁶ Again, the assumption is not only unsupported, it is *refuted* by the available scientific evidence (which Dr. Davidson has not studied).⁶⁷ But further, even if a sniff of some magnitude and type was demonstrated to be capable of drawing gel to the smell tissue, there is no basis for concluding that Ms. Rose's assumed sniff was of sufficient magnitude and type, because Dr. Davidson knows nothing about her supposed sniff.⁶⁸

In sum, Dr. Davidson's analysis of the predicate premise that Ms. Rose's smell tissue on both sides of her nose was exposed to Zicam® gel is undermined at every turn by a lack of scientific or factual evidence. It is speculation, or worse. These multiple critical analytical gaps render Dr. Davidson's causation testimony speculative, unreliable and irrelevant (in *Daubert* terms) at the threshold. As such it cannot assist the trier of fact. It must be excluded under Federal Rules of Evidence 702 and 403.

2. **There Is Insufficient Evidence To Adequately And Reliably Rule Out Alternative Causes Of Rose's Smell Loss And Select Zicam® As The Cause**

There are several common, well-established causes of smell loss in Rose's clinical

⁶⁶ Exh. J (Davidson *Bruno* Depo) at 116-118, 122; Exh E (Davidson *Rose* Depo) at 23-25, 92-95.

⁶⁷ Exh. H (Dalby Report) at 11; Exh. DD (Guo, Dalby Study); Exh. EE (Newman, Dalby Study); Exh. N (Herranz Study); Exh. O (Univ. Pittsburgh Study); Exh. CC (Davidson *Seckman* Depo) at 17-18; Exh. E (Davidson *Rose* Depo) at 23-25, 105-106.

⁶⁸ Dr. Davidson neither sought nor obtained any information about the nature and magnitude of the sniff. Exh. E (Davidson *Rose* Depo) at 21-22, 25-26, 28-30, 90-93.

picture, including URI, rhinitis, and sinusitis. Dr. Davidson ruled out URI because he dismissed the notion that she had a cold at the time she developed smell loss, relying on her supposed statement to him that she did not get a cold.⁶⁹ Rose's testimony tells a starkly different picture, as do her medical records from her treatment with Dr. Klug. Rose testified that she used Zicam® because she was experiencing cold symptoms.⁷⁰ During his examination a few days later, Dr. Klug found nasal congestion, swollen turbinates, and rhinitis.⁷¹ Dr. Davidson admits that congestion, swollen turbinates, and rhinitis are all consistent with Rose having a cold.⁷² He concedes that virus inoculation occurs more than 24 hours before any symptoms would appear.⁷³ He concedes that even a mild cold can cause chronic smell loss.⁷⁴ And he cannot rule out that Zicam did its job and prevented an existing cold from further developing.⁷⁵ Given that the cold is perhaps the most-common, well-established cause of bilateral smell loss, that Zicam® is not a cause generally accepted in the scientific community, and that Zicam® is not even a theoretical cause in the absence of use in both nostrils, Dr. Davidson's specific causation analysis discarding the cold in favor of Zicam® use is fundamentally unreliable.

Dr. Davidson also ruled out sinus disease, rhinitis and sinusitis, as a likely cause without any reliable factual and scientific basis. Dr. Klug diagnosed Rose with both rhinitis and sinusitis, both common causes of chronic or permanent smell loss. Dr. Davidson acknowledges that nasal sinus disease is a common and well-established cause of smell loss, and agrees that Rose

⁶⁹ Exh. E (Davidson *Rose* Depo) at 54-55, 65-66.

⁷⁰ Exh. A (Rose Depo) at 33.

⁷¹ Exh. C (Klug Medical Records) at GRose-IN-DAK-00003-12; Exh. F (Duncavage Report) at 2; Exh. E (Davidson *Rose* Depo) at 46.

⁷² Exh. E (Davidson *Rose* Depo) at 55-57.

⁷³ Exh. J (Davidson *Bruno* Depo) at 124; Exh. U (Davidson *Rose* Report) at 6.

⁷⁴ Exh. J (Davidson *Bruno* Depo) at 99.

⁷⁵ Exh. CC (Davidson *Seckman* Depo) at 28. Davidson also acknowledges that science has not determined when the damage to smell tissue occurs relative to introduction of the cold virus. *Id.* at 47-48.

suffered from ethmoid sinus disease.⁷⁶ He further acknowledges that sinusitis often develops after the onset of a cold.⁷⁷ He nevertheless ruled it out as a cause, and did not investigate whether it was present at the time of Rose's smell loss, simply because Rose did not respond to a course of steroids and antibiotics.⁷⁸

In sum, Dr. Davidson excluded common and well-established causes of smell loss solidly within Rose's clinical picture, based on incomplete data and unreliable assumptions. He ruled in and selected Zicam®, a controversial, hypothetical cause, without any reliable scientific evidence of the required binostril (or even single nostril) toxic exposure of the target organ. Dr. Davidson's subjective and standardless rejection of established alternative causes in favor of the proffered litigation cause, based primarily on temporality and *ipse dixit*, is precisely the type of subjective, unscientific speculation that violates Rule 702.⁷⁹ His specific causation testimony is not based on "sufficient facts or data", but on unsupported and unreliable assumptions; it is not "the product of reliable principles and methods ... [applied reliably] to the facts of the case", but subjective speculation, circular reasoning, leaps of faith, temporal fallacy, and discarding inconvenient facts in favor of rank speculation and assumption. His method of assuming his way to a conclusion without, and in spite of, evidence, is not generally accepted, has not been subject to peer review and publication, has never been tested, is entirely subjective and devoid of any objective controls or standards, and is clearly subject to a high, albeit uncalculated, rate of error.

⁷⁶ Exh. E (Davidson *Rose* Depo) at 50-51.

⁷⁷ Exh. E (Davidson *Rose* Depo) at 51.

⁷⁸ *Id.* at 51-53.

⁷⁹ See *Nelson*, 243 F.3d at 252-253, 254 (opinion on specific causation was unreliable where other possible explanations for the condition were not adequately considered before the expert ruled them out, and expert failed to establish (rather than assume) that plaintiffs had received a dose sufficient to cause the illness); *Downs*, 126 F.Supp.2d at 1126 (one red flag of inconsistency with the scientific method is "reaching a conclusion before the expert makes a reasonable attempt to eliminate some of the most obvious causes"); *Meridia*, 328 F.Supp.2d at 804 (one issue for reliability is whether the expert has adequately accounted for obvious alternative explanations); *Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 423-424 (5th Cir. 1987) (expert's subjective and standardless rejection of established alternative causes in favor of the proffered litigation cause, was unreliable and inadmissible).

It must be excluded under Rule 702.

C. Dr. Davidson's General Causation Opinions Also Lack A Reliable Foundation

Dr. Davidson's causation opinion fails for the further reason that there is no reliable evidence of *general causation*. Reliable evidence that the product *can* cause the harm experienced by plaintiff under the applicable circumstances of exposure is a prerequisite to any conclusion that the product actually *did* cause the harm.⁸⁰

1. There Is No Reliable Scientific Evidence That A Toxic Dose of Zicam® Reaches The Smell Tissue

The threshold reason that Dr. Davidson's general causation opinion is inadmissible is that there is no reliable scientific evidence that *any* Zicam® gel reaches the smell tissue when used as Rose did, much less a toxic dose.

Toxic exposure causation opinions are inherently speculative, unfounded and unreliable and fail to assist the trier of fact where they lack a predicate in (1) the dose of the particular substance (agent) required to cause the injuries (endpoint), i.e., the dose-response curve, and (2) the dose to which plaintiff was exposed. Evidence of the dose-response curve and that the dose of exposure meets or exceeds the level needed to produce the injury – a toxic exposure – are critical foundation to an admissible opinion on disease causation.⁸¹

⁸⁰ *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1238, 1253 (11th Cir. 2005); *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005); *Raynor v. Merrell Pharms.*, 104 F.3d 1371, 1376 (D.C. Cir. 1997).

⁸¹ *See, e.g., Nelson*, 243 F.3d at 252 (excluding causation opinion where expert "made no attempt to determine what amount of PCB exposure [plaintiffs] had received and simply assumed that it was sufficient to make them ill"); *Downs*, 126 F.Supp.2d at 1125 ("Dr. Kilburn has no idea of the dose of the chemical received by plaintiff, and he has no idea if the dose was of sufficient magnitude to cause a medical condition."); *Allen v. Pennsylvania Engineering Corp.*, 102 F.3d 194, 199 (5th Cir. 1996) (excluding causation opinion in part due to lack of scientific knowledge of (1) the level of exposure to the chemical which is considered harmful by the scientific community, and (2) and that the plaintiff was exposed to such quantities); *See also, e.g., Moore*, 151 F.3d at 278; *Wright v. Willamette Indus., Inc.*, 91 F.3d 1105, 1106 (8th Cir. 1996) ("a plaintiff in a toxic tort case must prove the levels of exposure that are hazardous to human beings generally as well as the plaintiff's actual level of exposure to the defendant's toxic substance before he or she may recover"); *id.* at 1107-1108 (expert testimony that the Plaintiffs' complaints were related to exposure should have been excluded as scientifically unreliable and "simply speculation" where it was not based on any knowledge about the amount of the agent which was toxic upon inhalation); *Mitchell v. Gencorp.*, 165 F.3d 778, 781 (10th Cir. 1999) (same).

Here, scientific research into nasal drug deposition and distribution patterns has shown that, even when that is the intent, it is extraordinarily difficult to deliver nasal spray formulations to the sheltered olfactory region. When the formulation is made up of large particles, like the viscous Zicam® gel, it is highly unlikely that any significant amount of the substance can reach the area of the smell tissue.⁸² Under the circumstances of use in this case, there is no basis for believing that a user gets any of the Zicam gel to the smell tissue, and certainly not in both nostrils.

Without exposure, there can, of course, be no toxic exposure. But even if Dr. Davidson had succeeded in reliably establishing that some of the Zicam® gel is capable of reaching the smell tissue, his general causation opinion further fails because he has no scientific evidence that a toxic dose reaches the smell tissue under ordinary conditions of use. Even if there were a reliable basis for assuming that Rose vigorously sniffed, Dr. Davidson's opinion that a sniff produces toxic exposure is pure speculation. Without knowing how much Zicam® must reach the smell tissue to cause the harm experienced by Rose, and without evidence that her manner of use is capable of delivering that toxic dose to the smell tissue, Dr. Davidson lacks a sufficient dose-response foundation. Dr. Davidson admits he does not know how much gel must reach the smell tissue in order to produce smell loss, nor how much gel reached Rose's smell tissue.⁸³ Under these circumstances, even if Rose were shown to have been exposed to some Zicam® gel, there is no reliable evidence that Rose received a toxic dose.⁸⁴

2. There Is No Reliable Scientific Evidence That Zicam® Use Can Cause Chronic Or Permanent Smell Loss

Dr. Davidson fails to support his opinion with reliable scientific evidence that a single dose of Zicam is capable of causing severe and chronic or permanent smell loss.

⁸² Exh. H (Dalby Report) at 5-10.

⁸³ Exh. E (Davidson *Rose* Depo) at 15-16, 21-33, 93-98, 106-108. *See also* Exh. J (Davidson *Bruno* Depo) at 12, 110, 112, 114, 116-118, 121-122, 134-135, 142-144.

⁸⁴ Exh. G (Halmes Report) at 26-29; cases cited footnote 81, *supra*.

a. It Is Not Scientifically Valid To Extrapolate From Experiments Involving Dissimilar Exposures To A Different Substance, Zinc Sulfate, To Reach Causation Conclusions Concerning Use of Zicam®

Dr. Davidson's assumptions regarding Zicam® toxicity rely on experiments involving dissimilar administrations of zinc sulfate, a different substance.⁸⁵ It is well-understood and generally accepted in the field of toxicology that even minor differences in chemical composition can produce very significant differences in biological effect, and compounds that are structurally related are not presumed to share the same toxicity profile or dose-response curve.⁸⁶ There are significant differences between zinc gluconate and zinc sulfate, including the level of zinc they contain and the proportion of their zinc that they release and make available to react with the smell tissue.⁸⁷ Administration of high doses of zinc sulfate directly to the olfactory epithelium bears little resemblance to the ordinary use of Zicam®, especially the single dose at issue. Without an adequate and scientifically reasonable explanation for why extrapolation from the high dose polio studies to Zicam® use is valid, reliance on such studies is scientifically invalid and unreliable. Dr. Davidson offers none.⁸⁸ *A fortiori*, without an adequate explanation of the additional influence of species differences, it is not reasonable to rely on animal studies involving direct application of high doses of zinc sulfate.⁸⁹ Again, Dr. Davidson offers none.⁹⁰

⁸⁵ Exh. E (Davidson *Rose Depo*) at 44, 108-109; Exh. U (Davidson *Rose Report*) at 9-17, 23-31.

⁸⁶ Exh. G (Halmes Report) at 29-33; Exh. E (Davidson *Rose Depo*) at 44-45, 110-11; Exh. J (Davidson *Bruno Depo*) at 126-129; *See also McClain*, 401 F.3d at 1246-1247 (improper and unreliable for expert to assume that analogy between toxicological characteristics of one compound applied to a structurally related compound without supporting scientific evidence).

⁸⁷ Exh. J (Davidson *Bruno Depo*) at 129-130, 135-136, 140; Exh. G (Halmes Report) at 29-33

⁸⁸ Exh. G (Halmes Report) at 29-33; Exh. E (Davidson *Rose Depo*) at 44, 108-109; Exh. U (Davidson *Rose Report*) at 9-17, 23-31.

⁸⁹ Exh. J (Davidson *Bruno Depo*) at 11-12.

⁹⁰ Exh. E (Davidson *Rose Depo*) at 44, 108-109; Exh. U (Davidson *Rose Report*) at 9-17, 23-31; Exh. J (Davidson *Bruno Depo*) at 11-12, 126-129, 134-136, 140; Exh. G (Halmes Report) at 29-33; *See also General Elec. Co v. Joiner*, 522 U.S. at 146; *In re Diet Drugs Prods. Liab. Litig.*, 2000 U.S. Dist. LEXIS 9661, at *36 (E.D. Pa. June 28, 2000) (copy attached) (extrapolation from animal studies is ordinarily unreliable due to differences in species, dosages, manner of administration, and metabolism); *id.* at *27-30, 36 (finding extrapolations from various human and animal studies unreasonable due to differences in chemicals, doses, and method of administration); *Moore*, 151 F.3d at 278 (expert's reliance (continued...))

Nine federal courts have found extrapolations from animal studies involving zinc sulfate to opine on the toxicity of Zicam® to humans to be unreliable and scientifically invalid.⁹¹ In order to provide *any* support for an inference of causality, the impact of the dissimilarities must be adequately and scientifically explained by the expert. Dr. Davidson has not supported his extrapolation from the zinc sulfate literature.

b. It Is Unreliable To Base Causation Opinions Primarily On Temporality And Case Reports

Dr. Davidson also relies on his clinical experience and published case series to support his opinion. But this begs the question. Dr. Davidson's clinical experience and the case series reflecting it are predicated largely on temporal proximity, his untested subjective belief that Zicam® can be sniffed up to the smell tissue, and that such sniffing can deliver a toxic dose capable of producing persistent smell loss, and his unsupported assumption that a burning sensation signifies damage to the smell tissue. There is no scientific support for any of these beliefs. Wrapping them in the mantle of "clinical experience" and publishing them as a case series does not transform them into scientific knowledge, or anything more than untested and unsupported theory.

Reliance on temporality is a necessity in the clinical setting, for the diagnosis and treatment of patients, but when it comes to scientific research on the toxicology of a substance, an exposure preceding the effect is certainly *necessary* to infer causation, but it is of little value in analyzing whether there is actually a relationship of cause-and-effect.⁹² Accordingly, courts have recognized that it violates the scientific method to attribute causation based primarily on the temporal connection between the exposure and the effect.

[P]roving a temporal relationship between taking Metabolife and

(..continued)

on study involving high dose exposure and on study involving a different chemical unreliable).

⁹¹ See footnote 45, *supra*.

⁹² Exh. G (Halmes Report) at 15-16; *Leathers v. Pfizer, Inc.*, 233 F.R.D. 687, 694-695 (N.D. Ga. 2006); *Siharath v. Sandoz Pharms. Corp.*, 131 F.Supp.2d 1347, 1372-1373 (N.D. Ga. 2001), *aff'd* 295 F.3d 1194 (11th Cir. 2002).

the onset of symptoms does not establish a causal relationship. In other words, simply because a person takes drugs and then suffers an injury does not show causation. Drawing such a conclusion from temporal relationships leads to the blunder of the *post hoc ergo propter hoc* fallacy. [¶] The *post hoc ergo propter hoc* fallacy assumes causality from temporal sequence. . . . It is called a fallacy because it makes an assumption based on the false inference that a temporal relationship proves a causal relationship.⁹³

Dr. Davidson's case series should not be confused with a scientific study; it is simply a description of his clinical observations with his opinion added. These types of reports have a role in the scientific method, but that role is to raise questions as to possible causal associations worth studying with scientific rigor. They are not substitutes for scientific testing and analysis, and are not, standing alone, proof of causation.⁹⁴ "Simply stated, case reports raise questions, they do not answer them."⁹⁵

Reliance on anecdotal data and temporal sequence to assume causation is especially problematic in this context. Zicam® is used to treat the cold, and is often used by individuals suffering from associated nasal or sinus disease. These are common, well-established causes of smell loss. When the relationship between the drug and the adverse effect is confounded by the condition the drug is used to treat, as here, it is particularly important that there be some

⁹³ *McClain*, 401 F.3d at 1243; *See also Moore*, 151 F.3d at 278 ("the temporal connection between exposure to chemicals and an onset of symptoms, standing alone, is entitled to little weight in determining causation").

⁹⁴ Exh. G (Halmes Report) at 15-16. The courts have frequently recognized the very limited value of anecdotal case reports in scientific assessment of causation. *See Casey v. Ohio Medical Products*, 877 F.Supp. 1380, 1385 (N.D. Cal. 1995) (case reports "are not reliable scientific evidence of causation, because they simply describe reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group . . . they do not isolate and exclude potentially alternative causes . . . and do not investigate or explain the mechanism of causation."); *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1199(11th Cir. 2002). In addition to these inherent limitations, as discussed above, Dr. Davidson's case series raises additional reliability issues. Discovery has revealed serious discrepancies between key data reported in the study and the actual data in the patients' underlying medical charts. Exh. E (Davidson *Rose* Depo) at 32-36, 40-41; Exh. J (Davidson *Bruno* Depo) at 77-81; Exh. W (Davidson *O'Hanlon* Depo) at 66-67; Exh. V (Davidson *Gillespie* Depo) at 29-33; Exh. X (Davidson *Bruno* Trial Testimony) at 115-121. There were also no controls in the case series for litigation and information bias, though they were clearly potential influences on the critical information taken from the patients. Exh. J (Davidson *Bruno* Depo) at 39, 43-44, 72-73, 75-76; Exh. E (Davidson *Rose* Depo) at 32-36, 40-41; Exh. X (Davidson *Bruno* Trial Testimony) at 115-121.

⁹⁵ *McClain*, 401 F.3d at 1243. *See also Nelson*, 92 F.Supp.2d at 969; Exh. G (Halmes Report) at 15-16.

evaluation of the background rate and evidence that the exposure is associated with an increased statistical risk of causing the adverse effect.⁹⁶ Dr. Davidson has not considered the background rate, and there is no evidence of an increased risk. Under these circumstances, reliance on anecdotal data is particularly unreliable and postulating that Zicam® use causes smell loss is inherently speculative.⁹⁷

Finally, Dr. Davidson suggests that causation can be inferred because his limited clinical population of “zinc-induced anosmia” patients typically described a severe burning sensation after administration of Zicam®. Dr. Davidson theorizes this is a sign of damage to the olfactory epithelium.⁹⁸ But this is simply more untested and unverified speculation. A stinging and burning sensation after administration of Zicam® is a fairly common side effect and occurs independently of claimed smell loss, and even independently of zinc.⁹⁹ Zinc gluconate is a salt with caustic properties, and tissues in the lower nasal cavity are rich with trigeminal nerve fibers which can be sensitive, especially when inflamed in response to a cold. Stinging and burning was often reported among the placebo group in the Zicam® clinical trials, as well as in the Zicam® group, and there were no reports of smell loss.¹⁰⁰ Thus, burning usually occurs without smell loss, smell loss usually occurs without burning, and occasionally, the same user experiences both. Under these circumstances, nothing about the presence of a report of burning justifies an inference of any interaction with or damage to the olfactory epithelium. Dr. Davidson cites no scientific evidence that burning is, in fact, some form of marker of damage to

⁹⁶ See *McClain*, 401 F.3d at 1243-1244. See also *Meridia*, 328 F.Supp.2d at 798-799 (in a similar causation scenario – the drug treated a condition (obesity) which was an established cause of the disease (cardiovascular disease) allegedly caused by the drug – plaintiff’s causation evidence, predicated on case reports rather than epidemiology, was unreliable).

⁹⁷ Exh. G (Halmes Report) at 15-16.

⁹⁸ Exh. E (Davidson *Rose Depo*) at 16-18, 35-39, 43-44, 96-101.

⁹⁹ Exh. G (Halmes Report) at 13-15.

¹⁰⁰ *Id.*; Exh. Y (Hensley Study); Exh. Z (Hirt Study); Exh. AA (Mossad Study); Exh. V (Davidson *Gillespie Depo*) at 66.

the olfactory epithelium.¹⁰¹ Like so many other elements of his analysis, this is simply his personal opinion, based on his own authority rather than any reliable scientific evidence.

3. Dr. Davidson's Violation Of Generally Accepted Scientific Methods And Principles

As shown, there are multiple analytical gaps, multiple leaps of faith, and multiple unsupported assumptions between links in Dr. Davidson's chain of analysis. Dr. Davidson deviates drastically from the generally accepted scientific methods and principles used by toxicologists to study cause and effect relationships between chemical exposures and medical conditions. The scientific method calls for generating a hypothesis for study, reviewing all of the relevant literature and evaluating it with scientific objectivity, and conducting controlled testing or experimentation designed to eliminate confounding variables and challenge the hypothesis, toward learning a scientific truth.¹⁰² At multiple links in his chain of reasoning, however, Dr. Davidson can cite no research or data to support his beliefs and simply expects the jury to trust him. There is no evidence that Zicam® can reach the olfactory epithelium, just Dr. Davidson's opinion that it does.¹⁰³ There is no evidence that sniffing draws gel to the smell tissue, or that a sniff by Rose did so, only Dr. Davidson's personal belief.¹⁰⁴ There is no evidence that a toxic dose reaches the olfactory epithelium, nor even evidence of what a toxic dose is, only Dr. Davidson's assurances that Rose and others have received a toxic dose.¹⁰⁵ There is no evidence that burning sensation in the nose signals destruction of smell tissue, only Dr. Davidson's

¹⁰¹ Exh. E (Davidson *Rose* Depo) at 98-101. Dr. Davidson concedes that a complaint of burning in the nose does not tell you anything about the specific source of the pain within the nose. Exh. S (Davidson *Nelson* Depo) at 36.

¹⁰² Exh. G (Halmes Report) at 7-9, 29-30. Dr. Davidson has conceded that his work has gone no further than the hypothesis stage when measured by the scientific method. Exh. X (Davidson *Bruno* Trial Testimony) at 60-63.

¹⁰³ Exh. G (Halmes Report) at 16-19, 25-39; Exh. H (Dalby Report) at 8-11.

¹⁰⁴ Exh. H (Dalby Report) at 9, 11; Exh. G (Halmes Report) at 26-27; Exh. J (Davidson *Bruno* Depo) at 110-112; Exh. E (Davidson *Rose* Depo) at 22-32, 64, 95-96.

¹⁰⁵ Exh. G (Halmes Report) at 15-19, 25-39.

assumption that this is what it means.¹⁰⁶ Dr. Davidson believes that a jury should be permitted to accompany him in these leaps of faith. Federal Rules of Evidence 702 and 403 preclude that journey.

D. Dr. Davidson's Opinions Were Developed In The Course Of Litigation

It is important to evaluating reliability whether the expert's analysis was developed in the course of litigation, or arose independently out of pure scientific research.¹⁰⁷ Dr. Davidson never studied the subject of zinc gluconate or Zicam® toxicity, nasal drug deposition and distribution, or zinc chemistry until he became involved in litigation against Matrixx. He coined the term "zinc-induced anosmia syndrome" to create a sound bite for a deposition; he prepared and published his retrospective case series in 2006, long after he began testifying and getting paid for preparing reports and consulting for litigation; to the limited extent he has reviewed it, he began reading the scientific literature on issues related to zinc toxicity, nasal air flow, and chemistry only after it became clear through depositions and a *Daubert* exclusion that he lacked an adequate foundation under Rule 702.¹⁰⁸ He first applied the Bradford-Hill causation criteria -- the generally accepted method of evaluating general causation -- in February 2008, long after he had formed and testified to his opinions, at the request of an attorney, for the purpose of trying to fulfill *Daubert* requirements.¹⁰⁹ Dr. Davidson reached a "clinical opinion" and then studied some of the scientific literature on subjects related to the opinion in response to questions he was asked on cross-examination or deposition in litigation.¹¹⁰ Under these circumstances, the red

¹⁰⁶ Exh. E (Davidson *Rose* Depo) at 16-18, 35-39, 43-44, 96-101; Exh. V (Davidson *Gillespie* Depo) at 66.

¹⁰⁷ *Sutherland*, 2006 U.S. Dist. LEXIS 96652, at *22 (copy attached); *Daubert v. Merrell Dow Pharms.*, 43 F.3d 1311, 1317 (9th Cir. 2005).

¹⁰⁸ Exh. E (Davidson *Rose* Depo) at 8-9; Exh. CC (Davidson *Seckman* Depo) at 7-9, 12-14, 17-20; Exh. J. (Davidson *Bruno* Depo) at 16-17, 44-48, 50.

¹⁰⁹ Exh. E (Davidson *Rose* Depo) at 71-72, 76; Exh. U (Davidson Report); Exh. G (Halmes Report).

¹¹⁰ Exh. E (Davidson *Rose* Depo) at 110-111.

flag for reliability that the expert's opinion was developed primarily for the courtroom rather than the laboratory is raised high, and further explains why Dr. Davidson takes the shortcuts and adopts the assumptions he does – and why the opinion testimony lacks reliability.

E. Dr. Davidson Has No Foundation For Opinions On Efficacy And Risk-Benefit

Finally, Dr. Davidson opines in his report that there is no scientific reason to believe Zicam® works, and thus it is an unreasonably unsafe medicine.¹¹¹ There is no foundation for this opinion. This is Dr. Davidson's personal opinion, not a scientific opinion. Dr. Davidson has done no research on efficacy, he has never conducted an efficacy study of intranasal zinc, and he has very limited familiarity with the Zicam® efficacy studies. He knows little about the potential mechanisms, or the virus receptors on which Zicam® is thought to act.¹¹² Dr. Davidson lacks the foundation under Rule 702 to offer opinions on the efficacy of Zicam®.

IV.
CONCLUSION

Dr. Davidson's opinions are speculative, lack basic reliability and adequate foundation, are not of assistance to the trier of fact, are prejudicial, and they must be excluded pursuant to Federal Rules of Evidence 702 and 403 and the case law designed to keep real science in the courtroom and junk science like this out.

¹¹¹ Exh. U (Davidson *Rose* Report) at "Zinc-Induced Anosmia", pp.31-33.

¹¹² Exh. V (Davidson *Gillespie* Depo) at 33-35, 37-39, 41; Exh. S (Davidson *Nelson* Depo) at 51-53.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and exact copy of the foregoing has been served via the court's electronic filing system and/or United States Mail, first class, postage pre-paid, to:

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