UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

EXELTIS USA INC.,

Plaintiff,

v.

FIRST DATABANK, INC.,

Defendant.

Case No. 17-cv-04810-HSG

ORDER DENYING THE MOTIONS TO EXCLUDE THE EXPERT TESTIMONY OF J. KEVIN GOROSPE AND NORMAN SMITH AND GRANTING IN PART THE MOTION TO EXCLUDE THE EXPERT TESTIMONY OF KATHRYN M. REXRODE

Re: Dkt. Nos. 169, 170, 190

Pending before the Court are Defendant First Databank, Inc.'s motions to exclude the expert reports and anticipated testimony of three of Plaintiff Exeltis USA Inc.'s experts. Dkt. Nos. 169, 170, 190. The Court heard argument on these motions on December 18, 2019. As detailed below, the Court **DENIES** the motions to exclude the testimony of Dr. J. Kevin Gorospe and Norman Smith, Dkt. Nos. 169, 170, and **GRANTS IN PART** the motion to exclude the testimony of Dr. Kathryn M. Rexrode.

I. BACKGROUND

The parties are familiar with the facts of this case, and the Court only briefly summarizes them here as context for the pending motions to exclude. In this action, Plaintiff, a prenatal vitamin manufacturer, challenges the new coding system that Defendant, a publisher of a pharmaceutical database called "MedKnowledge," is using for Plaintiff's products. See Dkt. No. 160 ("FAC"). According to Plaintiff, Defendant's database is used by Medicaid and private insurance providers to determine whether products are covered by public and private insurance plans. See id. at ¶¶ 1, 16, 53–58, 62–64. Historically, the "class value" field in the database indicated whether manufacturers identified their products as prescription-only. See id. at ¶¶ 1, 64,

98. Code "F" identified product labels that indicated prescription or physician supervision was required, including prescription prenatal vitamins, and "O" identified when the product label did not contain any dispensing limitations. See id. at ¶¶ 1, 8, 66–68. Beginning in 2017, Defendant proposed adjusting the class value field to identify whether federal law requires a prescription. Id. at ¶¶ 2, 73–77. Under this revamped field, code "O" would signify "[p]roducts with no federal legal prescription requirement." Id. at ¶¶ 89, 91. Then in September 2018, Defendant announced a new plan: the creation of a new class value, "Q," which would include all prenatal vitamins (both prescription and over-the-counter). See id. at ¶ 82; see also Dkt. No. 180-12, Ex. 38, at Ex. A at 3–4. Class values "O" and "F" would be limited to drug and device products:

> F – Prescription drugs or medical devices as defined in the Food Drug and Cosmetic Act (FDCA), including bulk drug ingredients
> O – Non-prescription drugs or medical devices
> Q – Products that are neither drugs nor devices, such as dietary supplements (including prenatal and other vitamins), medical foods, herbal preparations, and bulk flavorings or colorants.

See id. at 4.

Plaintiff alleges that the coding changes would falsely characterize its prenatal vitamins as over-the-counter and mislead users of the database. See FAC at ¶¶ 93–109. Plaintiff further urges that Defendant's new coding "will cause patients to lose coverage for prescription prenatal vitamins," which are critical to preventing birth defects. Id. at ¶¶ 111–16. At issue in these motions are the expert reports and anticipated testimony of three experts that Plaintiff proffers regarding (1) how Defendant's database is used in claims processing; (2) the anticipated effects of the change in class value definitions in claims processing; and (3) the anticipated effects of the change in class value on women's health. See Dkt. Nos. 169. 170, 190.

II. LEGAL STANDARD

Federal Rule of Evidence 702 allows a qualified expert to testify "in the form of an opinion or otherwise" where:

> (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.

Fed. R. Evid. 702. Expert testimony is admissible under Rule 702 if the expert is qualified and if the testimony is both relevant and reliable. See Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 597 (1993); see also Hangarter v. Provident Life & Acc. Ins. Co., 373 F.3d 998, 1015 (9th Cir. 2004). Rule 702 "contemplates a broad conception of expert qualifications." Hangarter, 373 F.3d at 1018 (emphasis in original).

Courts consider a purported expert's knowledge, skill, experience, training, and education in the subject matter of his asserted expertise. United States v. Hankey, 203 F.3d 1160, 1168 (9th Cir. 2000); see also Fed. R. Evid. 702. Relevance, in turn "means that the evidence will assist the trier of fact to understand or determine a fact in issue." Cooper v. Brown, 510 F.3d 870, 942 (9th Cir. 2007); see also Primiano v. Cook, 598 F.3d 558, 564 (9th Cir. 2010) ("The requirement that the opinion testimony assist the trier of fact goes primarily to relevance.") (quotation omitted). Under the reliability requirement, the expert testimony must "ha[ve] a reliable basis in the knowledge and experience of the relevant discipline." Primiano, 598 F.3d at 565. To ensure reliability, the Court "assess[es] the [expert's] reasoning or methodology, using as appropriate such criteria as testability, publication in peer reviewed literature, and general acceptance." Id. at 564.

III. DISCUSSION

Defendant challenges the expert reports and the anticipated testimony of three of Plaintiff's experts: Dr. J. Kevin Gorospe; Norman Smith; and Dr. Kathryn M. Rexrode. See Dkt. Nos. 169, 170, 190.[1]

A. Dr. J. Kevin Gorospe

Defendant first moves to exclude the expert report, expert declaration, and testimony of Dr. J. Kevin Gorospe. See Dkt. No. 169. Dr. Gorospe proffers several different opinions in his report and declaration: (1) Defendant's database is responsible "for most prescription drug transactions"

[1] Defendant refiled two of the motions as fully unredacted following the Court's order on the motions to seal. See Dkt. Nos. 210, 211.

in the United States; (2) the "class value field is a payment screen for drug claims adjudication"; (3) coding prescription prenatal vitamins as either "O" or "Q" is false and misleading; and (4) coding prescriptions prenatal vitamins as either "O" or "Q" will cause women to be denied coverage for prescription prenatal vitamins. See generally Dkt. No. 171-43, Ex. QQ ("Gorospe Report"); Dkt. No. 171-51 ("Gorospe Decl."). Defendant appears to challenge both Dr. Gorospe's qualifications as an expert to offer these opinions, and his factual support for these conclusions. See Dkt. No. 169.

i. Rule 26

As an initial matter, Defendant argues that Plaintiff failed to comply with Federal Rule of Civil Procedure 26, meaning that Dr. Gorospe's testimony should be excluded on this basis. See Dkt. No. 169 at 14–15. Defendant contends that in preparing his report, Dr. Gorospe relied on documents that Plaintiff failed to disclose, including news articles and sales figures about medical foods. See id. at 15. During his deposition, Dr. Gorospe explained that he had done some factual research to prepare his report. See Dkt. No. 171-8, Ex. H ("Gorospe Depo.") at 17:25–18:20. Counsel had also provided him with a binder of materials. See id. at 45:15–46:15. When asked whether he received any documents that were not cited in his report, he stated "I believe I may have, but I don't recall." See id. at 46:12–15. Dr. Gorospe also stated that he "Googled on the Internet" after looking at documents provided to him by counsel concerning sales figures for medical foods after Defendant changed the class value for medical foods from F to O "to try to understand th[em] more." See id. at 250:5–251:10.

An expert witness must prepare a written report that contains "a complete statement of all opinions the witness will express and the basis and reasons for them," as well as "the facts or data considered by the witness in forming them." Fed. R. Civ. P. 26(a)(2)(b)(i)–(ii). The Ninth Circuit has explained that the disclosure obligation is broad, and "extends to any facts or data 'considered' by the expert in forming the opinions to be expressed, not only those relied upon by the expert." See Republic of Ecuador v. Mackay, 742 F.3d 860, 869–70 (9th Cir. 2014) (citing Fed. R. Civ. P. 26 advisory committee notes (2010 amendments)). Moreover, under Rule 26(e), a party has a duty to supplement a Rule 26(a) expert report "if the party learns that in some material respect the

disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties . . . ." Fed. R. Civ. P. 26(e). Rule 37(c)(1) "gives teeth" to Rule 26's disclosure requirements. See Yeti by Molly, Ltd. v. Deckers Outdoor Corp., 259 F.3d 1101, 1106 (9th Cir. 2001).

Under Rule 37, "[i]f a party fails to provide information or identify a witness as required by Rule 26(a)," then the party may not use that information or witness at trial, "unless the failure was substantially justified or is harmless." See Fed. R. Civ. P. 37(c)(1)(A)–(C). The Ninth Circuit has enumerated several factors to guide district courts in determining whether the failure was substantially justified or harmless, including: "(1) prejudice or surprise to the party against whom the evidence is offered; (2) the ability of that party to cure the prejudice; (3) the likelihood of disruption of the trial; and (4) bad faith or willfulness involved in not timely disclosing the evidence." See Lanard Toys Ltd. v. Novelty, Inc., 375 Fed. App'x 705, 713 (9th Cir. 2010). The Court has "particularly wide latitude . . . to issue sanctions under Rule 37(c)(1)." Yeti by Molly, 259 F.3d at 1106.

Plaintiff responds in conclusory fashion that "Dr. Gorospe did disclose in his report all documents and data he considered in formulating his opinion in this case." See Dkt. No. 177 at 16. Plaintiff further notes that to the extent Dr. Gorospe may have seen other information on websites, "he did not cite or rely on it," and Plaintiff confirms that it does not intend to introduce any of these documents at trial. See id. Plaintiff's response misses the mark. As noted above, Rule 26 requires disclosure of "the facts or data considered" by Dr. Gorospe in forming his opinions, and not just those that he actually relied on and cited in his report. See Fed R. Civ. P. 26(a)(2)(b) (emphasis added); see also Republic of Ecuador, 742 F.3d at 869–70.

Nevertheless, the Court finds that the failure to disclose this information was harmless, and declines to exercise its discretion to exclude Dr. Gorospe's testimony on this basis. When questioned during his deposition about the documents that he considered when preparing his report and declaration, Dr. Gorospe stated that he identified in his report the "e-mails and documents that confirmed [his] understanding . . . of the situation." See Gorospe Depo. at 47:6–20. He also explained that he did not cite any news articles from his online research in his report

because "[t]hey were just confirmatory from some other information I looked at." See id. at 251:2–10. Dr. Gorospe therefore confirmed that any documents omitted from his report did not help him form his opinions in the first instance, but merely confirmed the opinions that he had already formed. See id. Plaintiff's counsel also explained that they believed that all of the documents Dr. Gorospe considered or reviewed in formulating the opinions contained in his report and declaration had been produced to or were already in Defendant's possession. See id. at 46:16–47:2. Moreover, Defendant was made aware of the existence of such documents and news articles during his deposition on June 5, 2019. It had the opportunity to question Dr. Gorospe about them at that time and to request or seek identification of any such documents before the close of expert discovery.

ii. Expert Qualifications

Defendant next suggests that Dr. Gorospe lacks the requisite qualifications to offer expert opinions about Defendant's database or how third parties such as Medicaid and private insurance providers use the database. See Dkt. No. 169 at 5–11. Defendant argues, for example, that Dr. Gorospe has no experience with payor systems that use the class value field, and has no knowledge base from which to conclude how payors will implement the new "Q" value. See id.; see also Dkt. No. 188 at 2–5. Defendant points out that during his deposition, Dr. Gorospe stated that he is not familiar with how specific private payor systems may actually use the class value in Defendant's database when making coverage determinations or how they intend to adapt to the new "Q" value. See Dkt. No. 169 at 5–6 (citing Gorospe Depo. at 68:9–69:8; 70:3–14; 72:2–15; 78:8–19; 79:22–80:12; 229:8–230:8; 234:14–18).

The Ninth Circuit has emphasized that Rule 702 "contemplates a broad conception of expert qualifications." See Hangarter, 373 F.3d at 1015 (emphasis in original). As such, only a "minimal foundation of knowledge, skill, and experience" is required. See id. at 1016 (emphasis omitted). The Court is "a gatekeeper, not a fact finder," Primiano, 598 F.3d at 564, and the lack of particularized expertise merely "goes to the weight" of the testimony, "not to the admissibility of h[is] opinion as an expert," see United States v. Garcia, 7 F.3d 885, 890 (9th Cir. 1993).

Here, Dr. Gorospe is a licensed pharmacist and is a Principal of Gorospe Solutions LLC, a

healthcare consulting firm. See, e.g., Gorospe Report, Ex. A. In his consulting role, he advises clients—who include health plans, pharmacy benefit managers, pharmacy providers, and government agencies—regarding policies related to state and federal law, especially as they relate to drug coverage and expenditures, and in benefit plan design. See id.; see also Gorospe Decl. at ¶ 7. He worked for the California Department of Health Care Services from 2000 to 2010 as the Chief of the Medi-Cal Policy Branch in the Pharmacy Benefits Division. See Gorospe Decl. at ¶¶ 1–2; see also Gorospe Depo. at 11:25–13:5. In that role, he was responsible for, inter alia, setting the Medi-Cal reimbursement policy, and he would utilize information from Defendant's database to make changes to the claims processing system. See Gorospe Depo. at 23:9–30:20; see also id. at 96:23–100:3; 288:2–290:6. Through this work, Dr. Gorospe also became familiar with the claims adjudication systems for other entities such as CalPERS, Medco, Caremark, Involve Health, Express Scripts, and MedImpact. See id. at 13:6–15:4.

The Court acknowledges Defendant's concerns that Dr. Gorospe does not appear to have worked directly with the claims adjudication systems outside Medi-Cal, and that his knowledge is instead limited to reviewing entities' "technical data and their technical responses to [requests for proposals]." See id. Dr. Gorospe also acknowledged that he didn't "specifically recall" seeing documentation about the use of the class value for these entities. See id. at 68:24–69:8. And Medi-Cal stopped using the class value field in the early 2000s. See id. at 70:15–71:9. But the Court finds that Dr. Gorospe has established the "minimal foundation of knowledge, skill, and experience" necessary to testify as an expert on claims processing systems, including how they utilize Defendant's database. See Hangarter, 373 F.3d at 1016. Defendant is free to explore the limitations of Dr. Gorospe's experience, and thus his opinions, during cross examination. And the jury may decide what, if any, weight to give his conclusions at that time.

iii. Reliability of Expert Opinions

Defendant's other arguments are directed at the basis for Dr. Gorospe's conclusions and whether they are adequately supported by reliable principles and methods.

First, Defendant repeatedly urges that Dr. Gorospe simply relies on emails and other hearsay documents in reaching his conclusions, making him an improper mouthpiece for hearsay

evidence. See Dkt. No. 169 at 4–5. As the Supreme Court has explained, "[u]nlike an ordinary witness . . . an expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation." Daubert, 509 U.S. at 592. "[T]his relaxation of the usual requirement of firsthand knowledge . . . is premised on an assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline." Id. Rule 702 only permits expert opinions where "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." Fed. R. Evid. 702. Accordingly, expert testimony that "merely summarizes the record evidence and gratuitously interprets it" is improper. See Lord Abbett Mun. Income Fund, Inc. v. Asami, No. C-12-03694 DMR, 2014 WL 3417941, at *13, n.8 (N.D. Cal. July 11, 2014), aff'd, 653 F. App'x 553 (9th Cir. 2016).

Here, Dr. Gorospe explains that his opinions are premised on his expertise, formed from his decades of experience in the healthcare industry. Dr. Gorospe states, for example, that "[i]n [his] experience" Defendant's database is "crucial for the sale, dispensing, and coverage for drugs in the United States." See Gorospe Report at ¶ 20. He also details the complicated healthcare system and how Defendant's database fits into it. He explains, for example, how the database "act[s] as a gatekeeper at three points in the drug transaction process: (1) formulary design/management; (2) e-prescribing; (3) claims adjudication." See e.g., id. at ¶¶ 23–31, 37, 41, 48–56, 60, 72. He also describes how a class value of "O" would be misleading given the historical understanding of that term, and how this could lead to payors improperly denying coverage or doctors not prescribing Plaintiff's products. See, e.g., id. at ¶¶ 111, 121–23.

Still, the Court shares Defendant's reservations that throughout Dr. Gorospe's report he appears to cite straightforward facts about Defendant's database and marketing practices that do not require any specific expertise to understand. See, e.g., id. at ¶¶ 21, 23, 44–47, 57–59. He also cites correspondence within First Databank and with Defendant's customers, despite acknowledging that he did not speak with the people in the emails and did not have any additional information regarding the emails' context. See, e.g., id. at ¶¶ 48:23–9; 62–68, 70–71. He does not reference his expertise in explaining this information. At one point Mr. Gorospe even stated that

"what is in the e-mails is, you know, what is in the e-mails, whatever the face value of the e-mail is." See id. at 49:7–9.

Dr. Gorospe's report may not serve as a compendium of otherwise straightforward background information, nor may Plaintiff use Dr. Gorospe at trial to introduce otherwise inadmissible evidence that does not require his specialized knowledge to understand. See Fed. R. Evid. 702; Fed. R. Evid. 703. Plaintiff's own cases make clear that an expert's ability to offer commentary on any document or exhibit in evidence "is limited to explaining the regulatory context in which the document or exhibit was created, defining any complex or specialized terminology therein, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge." See, e.g., Hines v. Wyeth, No. CIV.A. 2:04-0690, 2011 WL 2730908, at *2 (S.D.W. Va. July 13, 2011).

Dr. Gorospe later clarified in his deposition that his use of documents in his report was solely to underscore or confirm his opinions. See, e.g., Gorospe Depo. at 47:6–20; 251:2–10. Although Dr. Gorospe's expert report presents a close call, the Court is satisfied that the report is based on his own expertise and is not simply a summary of documents in the record. The Court cautions Plaintiff to ensure that Dr. Gorospe's testimony is similarly based in his own experience in the healthcare industry, and the Court will consider any such objections as they arise at trial.

Second, Defendant argues that Dr. Gorospe cannot opine on the market role that Defendant plays in prescription drug transactions because he did not "independently verify or analyze the total number of prescription drug transactions in the United States, nor how First Databank's data is used in such transactions." See Dkt. No. 188 at 2. Yet Dr. Gorospe's opinions are based on his experience, not on some independent study or survey. And as already noted above, he explained in his expert report that "[i]n my experience, First Databank's solutions are crucial for the sale, dispensing, and coverage for drugs in the United States," and its "solutions are directly integrated into its customers systems." See Gorospe Report at ¶¶ 20, 23. To the extent Defendant believes that Dr. Gorospe lacks direct knowledge about specific customers' practices or the scale of Defendant's business, Defendant may cross examine him on those topics.

Third, and relatedly, Defendant contends that Dr. Gorospe cannot opine on whether the

class value field is used by payors as a payment screening method for claims adjudication; whether the proposed coding change would be false or misleading; or what the effects may be from any coding change because Dr. Gorospe does not know how payors actually use Defendant's database. See Dkt. No. 169 at 5–13. Yet again, Defendant seems to ignore Dr. Gorospe's cited industry experience and his explanation that "many plans cover[] prescription drugs but do not cover drug products and [] non-drugs." See Gorospe Report at ¶¶ 60, 72. During his deposition, Dr. Gorospe said that he could not "identify the specific coding of any specific PBM," see Gorospe Depo. at 104:22–25, and certainly the effects of the new class value "Q" are unfolding in real time. Yet "[l]ack of certainty is not, for a qualified expert, the same thing as guesswork." Primiano, 598 F.3d at 565. Rather, expert opinion testimony "is reliable if the knowledge underlying it has a reliable basis in the knowledge and experience of the relevant discipline." Id. As described above, the Court finds that Dr. Gorospe is sufficiently qualified as an expert and Defendant may challenge Dr. Gorospe's conclusions through vigorous cross-exanimation at trial. See Daubert, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."). It is not, however, the Court's role to try to predict how persuasive Dr. Gorospe's testimony ultimately will be given the scope of his industry knowledge.

Lastly, Defendant argues that Dr. Gorospe may not opine on whether Defendant's proposed changes to the database would be false or misleading. See Dkt. No. 169 at 14. As Plaintiff concedes, Dr. Gorospe is not proffered as a legal expert and he will not be tasked with stating what the law is. See Dkt. No. 177 at 15. The Court will instruct the jury on the correct legal standards. See Hangarter, 373 F.3d at 1016 ("[I]nstructing the jury as to the applicable law is the distinct and exclusive province of the court.") (quotation omitted).

As to Defendant's concern that Dr. Gorospe is providing improper legal conclusions, the Ninth Circuit has held that "an expert witness cannot give an opinion as to [his] legal conclusion, i.e., an opinion on an ultimate issue of law." See Mukhtar v. California State Univ., Hayward, 299 F.3d 1053, 1066 n.10 (9th Cir. 2002); see also Nationwide Transp. Fin. v. Cass Info. Sys., 523

F.3d 1051, 1058 (9th Cir. 2008). Thus, although an expert witness may give opinion testimony that embraces an ultimate issue to be decided by the jury, that expert may not express a legal opinion as to the ultimate legal issue. Id.; see also Fed. R. Evid. 704(a) ("An opinion is not objectionable just because it embraces an ultimate issue."). No expert will be permitted to testify to legal conclusions, and here, the jury must ultimately determine whether Defendant's new coding system is false or misleading. Nevertheless, there is still a place for Dr. Gorospe, and the experts in this case in general, to discuss how Defendant's proposed changes may be received by the relevant industry players. The Court finds no reason to fashion an order precluding legal opinions based on—and limited to—the anticipated testimony of Dr. Gorospe. At trial, the Court will have the opportunity to evaluate any such objections in context.

* * *

Accordingly, the Court **DENIES** Defendant's motion to exclude the expert report and testimony of Dr. Gorospe. Dkt. No. 169.

B. Norman Smith

Defendant next moves to exclude the expert report and testimony of Plaintiff's expert Norman Smith. Dkt. No. 170. In addition to his "experience and expertise," Mr. Smith designed an "empirical survey" of twelve "pharmacy directors at major health plans that use First Databank for formulary management or claims processing" regarding the likely confusion caused by Defendant's proposed changes to the database. See Dkt. No. 171-44, Ex. RR ("Smith Report"). Defendant appears to challenge both Mr. Smith's qualifications as an expert, and the methodology he used in arriving at his conclusions.

i. Rule 26

Defendant contends that Plaintiff violated Rule 26 by failing to disclose the identities of the pharmacists that Mr. Smith contacted as part of his survey, as well as certain other related documents. See Fed. R. Civ. P. 26(a)(2)(b)(i)–(ii). For this reason, Defendant requests that the Court strike Mr. Smith's report and testimony under Rule 37. See Fed. R. Civ. P. 37(c)(1)(A)–(C). Defendant previously filed a discovery motion to compel production of this information, see Dkt. No. 161, which Magistrate Judge Sallie Kim denied, see Dkt. No. 164. Defendant then moved for

relief from Judge Kim's pretrial order. Dkt. No. 173. The Court denied the motion for relief and affirmed Judge Kim's order. See Dkt. No. 176. Yet again, Defendant urges the Court to reconsider Judge Kim's well-reasoned order. See Dkt. No. 170 at 21–25. Defendant raises the same arguments again here: (1) Mr. Smith did not conduct a true "survey," so he has no confidentiality obligations to the people he contacted; and (2) during his deposition, Mr. Smith revealed that he had original notes and transcripts of his interviews that Plaintiff had not produced. Compare Dkt. No. 173 with Dkt. No. 170 at 21–25.

Again, the Court is not persuaded. As Judge Kim aptly explained:

> [S]everal factors weigh in favor of protecting the identities of the survey participants from disclosure. First, the participants were promised that their identities would be confidential, and an order protecting them would prevent annoyance to them. The participants in the survey are not parties to this action and deserve a heightened level of protection. Second, Defendant has access to the same information that Plaintiff has, since the survey participants are Defendant's customers.

See Dkt. No. 164 at 4. Moreover, regardless of whether Mr. Smith conducted a quantitative or qualitative survey, "[i]f courts routinely allowed disclosure of the identities of [a] survey's participants, it is unlikely that people would agree to participate in surveys." Id. at 5. Mr. Smith echoed these concerns himself, explaining that he has worked with these participants over the course of twenty years and they participate, at least in part, because Mr. Smith assures their confidentiality. See Dkt. No. 171-9, Ex. I ("Smith Depo.") at 159:14–24.

Defendant's suggestion that Plaintiff has failed to provide material information from Mr. Smith's survey is similarly unavailing. Defendant suggests that Plaintiff did not provide an accurate accounting of his interviews with participants because he "cleaned up" the document that was ultimately produced. See Dkt. No. 170 at 24. But Mr. Smith's deposition testimony makes clear that this process was not substantive. While interviewing the participants he "put in the substantive response," and then later he "took out some of the abbreviations" and ensured that the responses "were not missing words." See Smith Depo. at 202:13–19, 203:20–204:7. Mr. Smith further explained that he was "just making sure you c[ould] understand what the thought was at the time and the answers to question[s]." See id. at 205:20–25. He said "I can mistype as well as

the next guy and so I went back and cleaned it up. There were typos, as there usually are." See id. at 205:25–206:4. Defendant's suggestion that this reveals that Mr. Smith somehow changed the nature or substance of the responses is unsupported. The evidence before the Court indicates that Defendant received a copy of the responses from the survey participants, and any variation between the draft and final versions was non-substantive, and therefore harmless.

Plaintiff's counsel further indicates that following Mr. Smith's deposition, Mr. Smith searched his records for other documents relevant to the expert report that he testified may exist. See Dkt. No. 178-1 at ¶ 2. Mr. Smith identified two additional documents, which Plaintiff produced to Defendant. See id. at ¶ 3. The first was a slide that contained definitions of the "F," "O," and "Q" class values, shown to participants. See Dkt. No. 178-2, Ex. A. This tracks verbatim the definitions that Defendant announced it would use. Compare id. with Dkt. No. 180-12, Ex. 38, at Ex. A at 4. The second was the initial email sent to the participants soliciting their involvement in the survey. See Dkt. No. 178-3, Ex. B. Defendant already had access to the nearly identical confirmation emails that Plaintiff sent to the twelve pharmacists participating in the survey. See Dkt. No. 171-50, Ex. XX. Like the initial email, the confirmation email indicated that the market research study would take between fifteen and twenty minutes; responses would be confidential; and participants would receive a $250 honorarium. See id. Defendant has not identified any meaningful difference between the documents. The Court finds that these late disclosures are also harmless. The Court further directs Defendant not to continue to file serial motions in the hope that the Court will eventually reverse itself and rule that the identities of the survey participants should be revealed.

ii. Expert Qualifications

Defendant's argument that Mr. Smith lacks the qualifications to testify as an expert in this case is based on the idea that he is being proffered as a quantitative survey expert, and that he lacks the requisite experience or education. See Dkt. No. 170 at 7–8. The Court finds that Defendant takes too narrow a view of Mr. Smith's proffered testimony and qualifications. As noted above, the Court looks to Mr. Smith's knowledge, skill, experience, training, and education in the subject matter of his asserted expertise. See Hankey, 203 F.3d at 1168. Here, Mr. Smith

was tasked with determining whether:

- [A] significant number of commercial and public payers use First Databank for formulary design and management and drug claims processing.
- [A] significant number of commercial and public payers were aware of First Databank's decision to recode prescription prenatal vitamins and the corresponding change in definitions of the class value field.
- [A] significant number of commercial and public payers are likely to be confused by First Databank's proposed coding of prescription prenatal vitamins (as O or Q).

See Smith Report at 5. In addition to surveying twelve pharmacists, Mr. Smith also relied on his "years of experience and expertise in the managed care and payer fields" and "a review of public documents and internal documents produced by First Databank." See id. at 6.

In support of his qualifications to address these issues, Mr. Smith identifies considerable industry experience. He currently teaches "Marketing to Managed Care" at St Joseph's University Haub School's pharmaceutical MBA program, and has lectured on pharmaceutical marketing at Columbia University's Healthcare Strategies course. See Smith Report at 2. He founded a consulting company, Viewpoint Consulting, Inc., which focused on market research among managed markets decisionmakers to pharmaceutical and biotech companies, and also worked at Research America, Inc., where he conducted hundreds of market research studies for pharmaceutical and biotech companies. Id. He has worked in both Merck and Genentech's managed care divisions. Id. During his deposition, he explained that through his work he developed expertise in "reimbursement, formulary access, pricing, and contracting" in the managed care sector. See Smith Depo. at 17:5–9. He also has experience designing and administering "[q]ualitative surveys . . . with managed care customers." See id. at 27:2–6.

Defendant cites to deposition testimony in which Mr. Smith said he is not "an expert in surveys," see Dkt. No. 170 at 1–2, 7–8 (citing Smith Depo. at 26:17–27:1, 39:22–25, 43:21–23, 46:1–3), but as Plaintiff notes, Mr. Smith did not purport to design a quantitative survey, see Dkt. No. 178 at 4–5. That Mr. Smith disclaims authority to conduct such quantitative surveys is thus neither surprising nor significant. During his deposition, Mr. Smith did confirm, however, that he

is an expert in designing qualitative surveys, or "qualitative market research," with managed care customers, as he did in this case. See, e.g., Smith Depo. at 27:3–6, 40:19–21, 41:5–8. As the Court noted when discussing Dr. Gorospe's qualifications, only a "minimal foundation of knowledge, skill, and experience" is required see Hangarter, 373 F.3d at 1016 (emphasis omitted), and Plaintiff has met its burden of establishing Mr. Smith's qualifications. To the extent Defendant continues to have concerns about the nature of Mr. Smith's background and his familiarity with conducting the kind of qualitative survey he designed in this case, Defendant may raise them at trial during cross examination. Such concerns go to the weight, but not the admissibility, of Mr. Smith's opinions.

iii. Reliability of Expert Opinions

Relatedly, Defendant appears to take umbrage with Plaintiff and Mr. Smith's characterization of Mr. Smith's work in this case as a "survey." During his deposition, Mr. Smith explained that he conducted a "study" or "qualitative market research." See Smith Depo. at 41:17–22. Defendant urges the Court to treat the qualitative research that Mr. Smith conducted as a quantitative survey, and then lists the myriad ways in which Mr. Smith's work did not meet the requirements for quantitative surveys. See Dkt. No. 170 at 8–15. The Court understands Defendant's concerns that the scale of Mr. Smith's survey is small, and that because he hand-selected the individuals with which he spoke, their responses may not be representative for purposes of drawing useful inferences for this case See id. Mr. Smith only interviewed twelve Directors of Pharmacy by telephone for fifteen minutes, and asked whether they knew about the change to the database and solicited their understanding of the F, O, and Q categories. See Smith Report at 6–8. Several were unaware of Defendant's proposed changes, and Mr. Smith therefore did not follow up by asking how they understood the database change. See Smith Report, Ex. C at 5–6. Still, the Court finds that Mr. Smith is an expert in qualitative market research and designed a reasonable approach to solicit feedback from Defendant's customers about the role of the database and their understanding of the proposed changes to the class value. Mr. Smith indicated that his "survey exceeded generally accepted practices in the field of survey design for payer research." See Smith Report at 6–7. And Mr. Smith explained why he designed the survey as he

did, including why he solicited responses from certain entities and not others, and what level of knowledge the participants had about the case. See, e.g., Smith Depo. at 54:10–57:7; 133:14–134:10; 137:7–18; 141:19–143:10. The significance of Mr. Smith's qualitative work is for the jury to decide. See Keith v. Volpe, 858 F.2d 467, 480 (9th Cir. 1988) ("Technical inadequacies in the survey, including the format of the questions or the manner in which it was taken, bear on the weight of the evidence, not its admissibility.").

Defendant's authorities are not to the contrary. In *Sirko v. Int'l Bus. Machines Corp.*, No. CV 13-03192 DMG SSX, 2014 WL 4452699, at *4 (C.D. Cal. Sept. 3, 2014), for example, plaintiff's counsel sent a survey to putative class members to support a pending motion for class certification. In excluding the results, the court reasoned that the survey "lacked the essential hallmarks of reliability" because it was not conducted by experts and the respondents were aware that they could potentially benefit from the litigation. Id. (citation omitted). Similarly, in M2 Software, Inc. v. Madacy Entm't, 421 F.3d 1073, 1087 (9th Cir. 2005), the Ninth Circuit affirmed the exclusion of a survey where the survey creator did not qualify as an expert in designing or analyzing the type of survey at issue in that case. Id.; accord Casey v. Home Depot, No. EDCV142069JGBSPX, 2016 WL 7479347, at *21 (C.D. Cal. Sept. 15, 2016). Defendant is of course free to cross examine Mr. Smith as to the nature of his research and its limitations.

iv. Hearsay

Defendant also urges that even if Mr. Smith's testimony is not excluded, Plaintiff should not be permitted to introduce the actual survey responses. See Dkt. No. 170 at 19–20. Defendant contends that they are "inadmissible and utterly unreliable hearsay . . . ." See id. at 19. In support, Defendant again challenges Mr. Smith's survey, including the manner in which he recorded responses. Id. at 19–20. Defendant's argument, therefore, is a reiteration of its challenge to the survey methodology discussed in Section III.B.iii above. During his deposition, Mr. Smith explained that he may not have included "word for word" what participants said, but he " put in the substantive response." See Smith Depo. at 203:20–204:7. To the extent Defendant believes that Mr. Smith failed to faithfully record the responses, it may cross examine Mr. Smith and highlight such concerns for the jury. However, "[a]n expert is permitted wide latitude to offer

opinions, including those that are not based on firsthand knowledge or observation." Daubert, 509 U.S. at 592. "Rule 703 . . . permits such hearsay, or other inadmissible evidence, upon which an expert properly relies, to be admitted to explain the basis of the expert's opinion." See Paddack v. Dave Christensen, Inc., 745 F.2d 1254, 1261–62 (9th Cir. 1984). If Plaintiff seeks to introduce any of the responses as evidence at trial, Defendant may raise specific objections to them at that time. The Court declines to speculate as to how Plaintiff may attempt to use the responses in future.

* * *

Accordingly, the Court **DENIES** Defendant's motion to exclude the expert report and testimony of Norman Smith. Dkt. No. 170.

C. Dr. Kathryn M. Rexrode

Defendant also moves to exclude the expert report and testimony of Dr. Kathryn M. Rexrode. Dkt. No. 190. Dr. Rexrode is the Chief of the Division of Women's Health at Brigham and Women's Hospital, and is an Associate Professor of Medicine at Harvard Medical School. See Dkt. No. 190-2 ("Rexrode Decl.") at ¶¶ 4–6. Her report is intended "to assess the impact on public health and women's health in the United States," assuming the proposed changes to Defendant's database "would result in Medicaid plans and commercial insurers denying coverage for prescription prenatal vitamins." See id. at 1. Dr. Rexrode concluded that "[i]f women are unable to obtain Medicaid coverage for prescription prenatal vitamins, fewer women will take the prenatal vitamins they were prescribed" which, in turn, "will have serious and wide-spread negative public health consequences in this country." Id. at ¶ 3. Plaintiff further provides a bulleted list of Dr. Rexrode's anticipated testimony regarding the importance of prenatal vitamins:

- Prenatal vitamins are vital to the health of expecting mothers and their babies, because they provide numerous benefits including prevention of preterm delivery, low birth weight babies, neural tube defects, vitamin deficiencies, and improved nutrition;
- Medical organizations recommend women take prenatal vitamins;
- Prescription prenatal vitamins in particular provide unique treatment benefits;
- Research shows that too few women take prenatal vitamins of any kind;

- Medicaid coverage of prenatal vitamins helps ensure poor women have access to essential prenatal care; and
- Women across the country will suffer if they do not have Medicaid coverage for prescription prenatal vitamins.

See Dkt. No. 195 at 3–4.

Defendant explains that the importance of prenatal vitamins and the possible effects of the coding change on third parties is simply not at issue in this case. See Dkt. No. 190 at 10–16. According to Defendant, Dr. Rexrode does not provides opinions about how the class value field in Defendant's database is used in the claims adjudication process; how the change in the class value fields would be misleading; or how such changes would affect Plaintiff or Plaintiff's damages. See id. In response, Plaintiff urges that Dr. Rexrode provides important "background information" for the case, and her testimony is also relevant to Plaintiff's causes of action.

i. "Background" Testimony

Plaintiff cites two non-binding out-of-circuit cases to support its contention that Dr. Rexrode's opinions provide proper background for this case. See Dkt. No. 195 at 4–5 (citing United States v. Mulder, 273 F.3d 91, 102 (2d Cir. 2001); CDX Liquidating Tr. ex rel. CDX Liquidating Trustee v. Venrock Assocs., 411 B.R. 571, 588 (N.D. Ill. 2009)). The Court acknowledges that experts may provide background information, but such background must still be relevant to the factual or legal questions at issue in the case. As Rule 702 details, an expert may testify "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue." See Fed. R. Evid. 702 (emphasis added). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." Daubert, 509 U.S. at 591.

Much of Plaintiff's proffered background, however, is not relevant to the issues in this case. What prenatal vitamins are, and the fact that there are both prescription and over-the-counter prenatal vitamins is certainly relevant to determining whether Defendant's coding of these products is false or misleading. See Rexrode Decl. at ¶¶ 11, 35–40. But "why physicians and health organizations universally recommend prenatal vitamins as the standard of care for women who are or may become pregnant"; "the benefits of prescription prenatal vitamins"; "how, when,

and why a patient may be prescribed a prenatal vitamin"; and "the rate of vitamin deficiency in pregnant women and the importance of vitamin supplementation in reaching proper levels" are not. See Dkt. No. 195 at 4. As explained in the Court's preliminary injunction order, the Court understands that "there may be a public interest in the database and in women's access to prenatal vitamins," but this "does not alter the fact that this is a private dispute between private parties." See Dkt. No. 57 at 9–10, n.5. Plaintiff, the manufacturer of prenatal vitamins—and not the women taking them—has brought this case against Defendant.

ii. Relevancy of Expert Testimony

In this case, Plaintiff asserts causes of action against Defendant for: (1) violating 15 U.S.C. § 1125(a)(1) of the Lanham Act; (2) violating California's Unfair Competition Law ("UCL") as "unlawful, unfair, [and] fraudulent" conduct; (3) false advertising under Cal. Bus. & Prof. Code §§ 17500 et seq.; (4) intentional interference with prospective economic advantage; and (5) trade libel. See FAC at ¶¶ 117–160. Defendant urges that Dr. Rexrode's testimony is irrelevant to all five causes of action. See Dkt. No. 190 at 10–16. Plaintiff appears to acknowledge that Dr. Rexrode's testimony is not relevant to Plaintiff's state law claims for false advertising or intentional interference with prospective economic advantage. See Dkt. No. 195 at 10–11.

As to Plaintiff's Lanham Act claim, the elements are:

> (1) a false statement of fact by the defendant in a commercial advertisement about its own or another's product; (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience; (3) the deception is material, in that it is likely to influence the purchasing decision; (4) the defendant caused its false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to defendant or by a lessening of the goodwill associated with its products.

Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1139 (9th Cir. 1997). Plaintiff urges that Dr. Rexrode's testimony is relevant to "purchasing decisions" because Dr. Rexrode will testify regarding "how physicians are more likely to prescribe prenatal vitamins (and other medications) when the product is covered by a patient's insurance than they are a product that is not." See

Rexrode Decl. at ¶¶ 39, 43, 48–49. This, in turn, can explain how Defendant's actions may affect patients' purchasing decisions and Plaintiff's sales. See id. at ¶¶ 48–49, 52–54. The Court understands Defendant's concerns that such evidence will not establish Plaintiff's specific lost profits damages and that such in-depth analysis would likely require an economic analysis outside Dr. Rexrode's expertise. See Dkt. No. 197 at 5–6. But the Court nevertheless finds that Plaintiff has established that Dr. Rexrode's testimony about prescribing decisions for prenatal vitamins is still sufficiently relevant to explaining the possible impact of Defendant's database changes to prescribers and patients.

Plaintiff next suggests that Dr. Rexrode's testimony regarding "the clinical and therapeutic benefits of prescription prenatal vitamins" over "other types of prenatal vitamins" is relevant to Plaintiff's trade libel claim. See Dkt. No. 195 at 7–8 (citing Rexrode Decl. at ¶¶ 35–40). "Trade libel is defined as an intentional disparagement of the quality of property, which results in pecuniary damage." See Aetna Cas. & Sur. Co. v. Centennial Ins. Co., 838 F.2d 346, 351 (9th Cir. 1988). In the FAC, Plaintiff identifies the purported "intentional disparagement" as the "coding change" that will categorize "Exeltis's prescription prenatal vitamins [as] 'Non-Rx' and over-the-counter." See FAC at ¶ 157. Plaintiff concludes, without detail, that Dr. Rexrode's testimony "is relevant to showing how First Databank's misstatement that Exeltis's products are 'not drugs' and not prescription, is a 'disparagement' of the 'quality' of Exeltis's products." See Dkt. No. 195 at 8. In other words, Plaintiff argues that there is a difference in "quality" between prescription prenatal vitamins and over-the-counter prenatal vitamins. Although Defendant is correct that part of the trade libel analysis will include the accuracy of Defendant's proposed coding changes, see Dkt. No. 197 at 5, Dr. Rexrode's testimony as to the differences between prescription and over-the-counter prenatal vitamins is still relevant.

Lastly, Plaintiff urges that Dr. Rexrode's testimony is relevant to Plaintiff's UCL claim. See Dkt. No. 195 at 7. "Unfair competition" under the UCL is broadly defined as "any unlawful, unfair or fraudulent business act." See Cal. Bus. & Prof. Code § 17200; see also McDonald v. Coldwell Banker, 543 F.3d 498, 506 (9th Cir. 2008) ("An unfair business practice is one that either 'offends an established public policy' or is 'immoral, unethical, oppressive, unscrupulous or

substantially injurious to consumers.'" (quoting People v. Casa Blanca Convalescent Homes, Inc., 159 Cal. App. 3d 509, 530 (1984))). In the FAC, Plaintiff alleges that Defendant's conduct is unfair "because its statements are false and misleading." See FAC at ¶ 132. But in opposition to Defendant's motion, Plaintiff takes this argument still further, and suggests that Defendant's proposed changes "will cause substantial harm [to women] without any countervailing benefit." See id. On the basis of this third-party harm, Plaintiff suggests Dr. Rexrode's testimony about the possible impact on women's health is relevant to this claim.

But critically, there is a disconnect between Plaintiff's UCL claim and Dr. Rexrode's testimony about women's health. Plaintiff's basis for bringing a UCL claim is its own economic injury. As the California Supreme Court has noted, to have standing to bring a UCL claim, "a party must now (1) establish a loss or deprivation of money or property sufficient to qualify as injury in fact, i.e., economic injury, and (2) show that that economic injury was the result of, i.e., caused by, the unfair business practice or false advertising that is the gravamen of the claim." Kwikset Corp. v. Superior Court, 51 Cal. 4th 310, 322 (Cal. 2011) (emphasis in original). Plaintiff may have standing to assert economic injury based on its lost profits from Defendant's alleged false or misleading statements. However, to the extent that Plaintiff now suggests that Defendant's business practices are also unfair to lower income women who may be denied coverage for their prescription prenatal vitamins, this is unrelated to Plaintiff's own economic injury.

* * *

The Court therefore finds that some of Dr. Rexrode's expert testimony is admissible, but she may not testify regarding "why physicians and health organizations universally recommend prenatal vitamins as the standard of care for women who are or may become pregnant"; "the benefits of prescription prenatal vitamins," except to explain the differences between prescription and over-the-counter prenatal vitamins; "how, when, and why a patient may be prescribed a prenatal vitamin"; "the rate of vitamin deficiency in pregnant women and the importance of vitamin supplementation in reaching proper levels"; or "the harm to patients and the public health that will be caused by coverage denials." See Dkt. No. 195 at 4, 7. The Court therefore **GRANTS**

IN PART and **DENIES IN PART** Defendant's motion to exclude Dr. Rexrode's expert report and testimony. Dkt. No. 190. To the extent this case proceeds to trial, Dr. Rexrode's testimony will be limited to only those topics relevant to Plaintiff's claims in this case.

IV. CONCLUSION

Accordingly, the Court **DENIES** the motions to exclude the reports and testimony of Dr. Gorospe and Mr. Smith and **GRANTS IN PART** and **DENIES IN PART** the motion to exclude the report and testimony of Dr. Rexrode. This order also terminates Dkt. Nos. 210, 211.

IT IS SO ORDERED.

Dated: November 30, 2020

Haywood S. Gilliam, Jr.

HAYWOOD S. GILLIAM, JR.
United States District Judge