**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF TEXAS**
**MARSHALL DIVISION**

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| RETRACTABLE TECHNOLOGIES, INC., et al. | § | |
| | § | |
| v. | § | Case No. 2:08-CV-16-MHS-RSP |
| | § | |
| BECTON, DICKINSON AND CO. | § | |

**MEMORANDUM ORDER**

Plaintiff Retractable Technologies, Inc. ("RTI") alleges violations of the Sherman and Clayton Acts, violations of the Texas Antitrust Act, false advertising in violation of the Lanham Act, product disparagement, tortious interference with prospective contract or business relations, and unfair competition by Defendant Becton, Dickinson and Company ("BD"). (Dkt. No. 73.)

Before the Court is BD's Motion to Preclude the Expert Testimony of Carol A. Scott, who has been retained as an expert witness by RTI. (Dkt. No. 157, filed January 6, 2012.) BD's motion seeks to exclude opinions and evidence concerning the brochure survey, the patient safe survey, and corrective advertising damages. Scott's report, which includes all the survey materials, is attached as an exhibit to BD's motion. (Scott Rep., Dkt. No. 157-3.) BD has taken a shotgun approach to objecting to Scott's report, raising numerous objections and citing 30 cases in support of its motion. The Court has considered every objection raised in BD's motion. However, more attention has necessarily been given to those objections that are more thoroughly briefed and appear to be more important to the parties. Having considered all of BD's objections individually and as whole, the Court finds that BD's objections do not warrant excluding Dr. Scott's report and testimony, and instead more properly go to the weight of the evidence. Accordingly, BD's Motion to Preclude the Expert Testimony of Carol A. Scott is **DENIED**.

## APPLICABLE LAW

### A. Expert Testimony

An expert witness may provide opinion testimony if "(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. A trial court is "charged with a 'gatekeeping role,' the objective of which is to ensure that expert testimony admitted into evidence is both reliable and relevant." *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1360 (Fed. Cir. 2008).

### B. Survey Evidence

In the Fifth Circuit, survey evidence may be admitted if it is "pertinent to the inquiry, upon a showing that the poll is reliable and was compiled in accordance with accepted survey methods." *C. A. May Marine Supply Co. v. Brunswick Corp.*, 649 F.2d 1049, 1054 (5th Cir. 1981). "In assessing the validity of a survey [courts] look to two factors: first, the manner of conducting the survey, including especially the adequacy of the universe; and second, the way in which participants are questioned." *Scott Fetzer Co. v. House of Vacuums Inc.*, 381 F.3d 477, 487 (5th Cir. 2004). However, usually, "methodological flaws in a survey bear on the weight the survey should receive, not the survey's admissibility." *Id.* at 488.

## DISCUSSION

### A. Brochure Survey

#### 1. Objection to Leading Questions

BD objects to Scott offering any opinion based upon questions 5 and 6 of the brochure survey on the grounds that they are improper closed, leading questions. (Mot. at 12-13, Dkt. No. 157.) Questions 4-6 are reproduced below:

> 4. What features or characteristics, if any, do you think that a needle or syringe must have in order to be advertised as a "Safe", "Safety", or "Safety-Engineered" Product?
>
> [TEXTAREA]
>
> * * *
>
> 5. Please check any of the following requirements that you think products must meet in order to be advertised as "Safe", "Safety", or "Safety-Engineered" :
>
> A "Safe", "Safety", or "Safety -Engineered" Syringe must:
> [Checkboxes – ROTATE LIST UP TO 'OTHER']
>
> a. _____ Be available in particular sizes
> b. _____ Be engineered to increase patient comfort.
> c. _____ Be no more expensive than conventional needle
> d. _____ Be engineered to reduce cost of the product
> e. _____ Be engineered to reduce accidental needlesticks to the lowest extent feasible in actual clinical settings
> f. _____ Have a mechanism for covering the needle when not being used for an injection
> g. _____ Have studies showing that they reduce needlesticks in actual clinical use
> h. _____ Be engineered to allow for one-handed activation of the safety mechanism
> i. _____ Be engineered to not increase any risk to the clinician
> j. _____ Other (Please specify)_____[textarea]
> k. _____ Don't Know / Not Sure
>
> * * *

6. If you purchase a needle or syringe advertised as a "Safe", "Safety", or "Safety-Engineered" Product rather than a conventional syringe, to what extent should it be able to reduce accidental needlesticks if used as directed in actual clinical settings?

   Please indicate the percentage reduction you expect "Safe", "Safety", or "Safety-Engineered" Products to provide if used as directed:

   If used as directed, I expect that "Safe", "Safety", or "Safety-Engineered" Syringes will reduce accidental needlesticks by ____ % [TEXT 3 chars]
   [CHECKBOX] Don't Know / Not Sure XX

(Scott Rep. Ex. 5 at 6-7, Dkt. No. 157-3.)

**a. Question 5**

With respect to question 5, BD argues that Scott should have provided a simpler choice for indicating reduction of accidental needlesticks—one that does not include the phrase "to the lowest extent feasible in actual clinical settings." RTI responds that question 5 is not a biased or leading because it is posed in the form of a "quasi-filter question" where "respondents could write in their own answer (Q5); [or] choose more than one option (Q5)." (Resp. at 9-10, Dkt. No. 217.)

The brochure survey was directed to medical professionals who are involved in the purchasing process for syringes used in institutional clinical settings. (*See* Scott Rep. Ex. 5 at 2-3, Dkt. No. 157-3.) In this context, the complained of answer choice does not appear to be unduly leading or biased. *See* Shari Seidman Diamond, *Reference Guide on Survey Research*, in Federal Judicial Center, *Reference Manual on Scientific Evidence*, 387-394 (3d ed.) (discussing principles and methods of formulating survey questions). Therefore, the Court finds that BD's objection to question 5 merely goes to the weight of the evidence.

**b. Question 6**

With respect to question 6, BD argues that it was improper to ask respondents to "'indicate the percentage reduction you expect "Safe", "Safety", or "Safety-Engineered" products to provide,' without first asking whether respondents had any such expectation." (Mot. at 12, Dkt. No. 157). RTI responds that the question is not improper because respondents could "choose any amount from zero to one hundred percent (Q6); or choose 'don't know / not sure' (Q5, Q6)." (Resp. at 10, Dkt. No. 217.)

BD concedes that the responses to other questions (presumably questions 4 and 5), "show that respondents did not have any such expectation" that safety products would reduce needlesticks by any given percentage reduction. (Mot. at 12, Dkt. No. 157.) This suggests that the brochure survey's design is sufficiently robust such that the alleged deficiency in question 6 does not render the survey as a whole unreliable, and that BD's objection is best addressed through cross-examination. Accordingly, the Court finds that BD's objection to question 6 only goes to the weight of the evidence and does not warrant exclusion.

**2. Objection to the Brochure Survey's Controls**

BD contends that the brochure survey must be excluded because Scott failed to use an experimental control group. BD argues that in conducting a false advertising survey, a control group should be shown a control advertisement (a control stimulus) that is similar to the allegedly false advertisement but does not contain the allegedly misleading message. The expert then compares the responses to the control advertisement and the responses to the allegedly false advertisement to determine the degree to which the allegedly false advertisement is deceptive or misleading. Without an adequate control, BD contends that Scott cannot separate the effects of the respondents' preexisting knowledge or beliefs from the effects of the allegedly false advertisement. (*See* Mot. at 7-9, Dkt. No. 157.)

RTI responds that the survey was designed to determine what messages are conveyed by BD's advertisement, and not to determine whether the advertisement caused deception. Because the survey was not testing causation, RTI contends that no control group was necessary. RTI maintains that a control group was nonetheless present because half of the respondents were asked general questions regarding their beliefs (questions 4-6 reproduced above) prior to being showing the advertisement (while the experimental group was asked the same questions after being shown the advertisement), which permits Scott to determine whether the advertisement alone created those beliefs. (*See* Resp. at 2-3, Dkt. No. 217.)

"[B]efore a court can determine the truth or falsity of an advertisement's message, it must first determine what message was actually conveyed to the viewing audience." *Johnson & Johnson * Merck Consumer Pharm. Co. v. SmithKline Beecham Corp.*, 960 F.2d 294, 298 (2d Cir. 1992). Surveys have generally been accepted as proof of the message conveyed by an advertisement. *Id.*; *see also Scotts Co. v. United Industries Corp.*, 315 F.3d 264, 280 (4th Cir. 2002) ("The purpose of consumer surveys in false advertising cases is to determine the message actually conveyed to consumers."). In the Fifth Circuit, survey evidence may be admitted if it is "pertinent to the inquiry, upon a showing that the poll is reliable and was compiled in accordance with accepted survey methods." *C. A. May Marine Supply Co. v. Brunswick Corp.*, 649 F.2d 1049, 1054 (5th Cir. 1981). *See generally, Scott Fetzer Co. v. House of Vacuums Inc.*, supra.

The Court finds that BD's criticism of the brochure survey's controls does not warrant excluding the survey, and but instead goes to the weight of the evidence. The Court is persuaded that questions 4-6, which were posed to a subset of respondents prior to being shown the stimulus, provide some basis to control for the respondents' preexisting beliefs.

The cases cited by BD do not compel a different result. In *Pharmacia Corp. v. GlaxoSmithKline Consumer Healthcare L.P.*, survey evidence was offered to prove that the comparative ad at issue contained an implied message that defendant's product was superior to plaintiff's product. 292 F. Supp. 2d 594, 600 (D.N.J. 2003). The court, which was acting as the finder of fact, determined that the survey should be given *no evidentiary weight* because it did "not adequately control for consumers' preexisting beliefs that comparative commercials imply some sort of superior efficacy." *Id.* at 604-605. In other words, because it was known that consumers generally imply a claim of superiority from comparative advertising, a survey should control for this preexisting belief when it seeks to prove that the advertisement's content itself implies a claim of superiority. BD has not shown that the advertising at issue in this case suffers from a similar well-known bias or flaw.

In *Proctor & Gamble Pharmaceuticals, Inc. v. Hoffmann-LaRoche, Inc.*, the consumer survey at issue was excluded because it suffered from several serious methodology flaws, and the court did not rely solely on the perceived inadequacy of the control stimulus. 2006 WL 2588002, at *22-25 (S.D.N.Y Sept. 6, 2006). The Court is not persuaded that Scott's brochure survey is similarly flawed.

**3. Objection to Using the Survey to Measure the Brochure's Conveyed Messages**

BD raises several related arguments that go to the relevance and proper use of the brochure survey evidence. (Mot. at 9-11, Dkt. No. 157.)

**a. Relating the Brochure Survey Results to the Meaning of BD's Safety Claims**

First, BD argues that it would be improper to permit RTI to argue that Scott's results "relate to the meaning of 'safety' in reference to BD's safety-engineered products . . . " because

survey research has never been used to "set the standard to which objectively verifiable claims must be held." (*Id.* at 10.)

The two principal cases upon which BD relies do not appear to apply to the facts in this case. In *Mead Johnson & Co. v. Abbott Laboratories*, the appellate court found that the trial court erred by relying on flawed consumer survey evidence to find that the phrase "'1st Choice of Doctors' conveyed to consumers the message that at least a majority of physicians prefer [the product] on grounds of qualitative superiority" as opposed to the phrase's objectively determinable meaning that "more physicians prefer this product than any of its rivals." 201 F.3d 883, 883-85 (7th Cir. 2000). Similarly, in *American Italian Pasta Co. v. New World Pasta Co.*, the appellate court found that the phrase "America's Favorite Pasta," both standing alone and in the context of the relevant advertising, was not a specific measurable claim that is actionable under the Lanham Act. 371 F.3d 387, 391-93 (8th Cir. 2004). Thus, the trial court erred in relying on consumer survey evidence to find that "America's Favorite Pasta" conveyed to consumers a claim that the product at issue was the number one brand. *Id.* at 393. As explained by the *American Italian Pasta* court, both cases involved the use of survey evidence to establish a claim benchmark that was unsupported by the plain language of the advertisement:

> To allow a consumer survey to determine a claim's benchmark would subject any advertisement or promotional statement to numerous variables, often unpredictable, and would introduce even more uncertainty into the market place. A manufacturer or advertiser who expended significant resources to substantiate a statement or forge a puffing statement could be blind-sided by a consumer survey that defines the advertising statement differently, subjecting the advertiser or manufacturer to unintended liability for a wholly unanticipated claim the advertisement's plain language would not support. The resulting unpredictability could chill commercial speech, eliminating useful claims from packaging and advertisements. As the Seventh Circuit noted, the Lanham Act protects against misleading and false statements of fact, not misunderstood statements.

*Id.* at 393-394 (citing *Mead Johnson*, 201 F.3d at 886).

The same concern is not presented in this case. Unlike *Mead Johnson* and *American Italian Pasta*, no party contends that the "safety" claims at issue here are mere puffery or that the plain and ordinary meaning of the claims should apply. BD itself argues that the appropriate benchmark is set by FDA and OSHA regulations. (*See* Mot. at 11, Dkt. No. 157.) Given that a fact dispute exists with respect to the meaning of the advertising claims in this case, and that BD has not offered evidence that forecloses the consideration of survey evidence that bears on this issue, the Court is persuaded that the survey evidence is relevant and should not be excluded.

**b. Asking Respondents About Their Beliefs Instead of the Message Conveyed by the Stimulus**

BD next argues that brochure survey should be excluded because courts exclude surveys where respondents are asked what their beliefs are as opposed to what message is conveyed by the advertisement. (Mot. at 10-11, Dkt. No. 157.) The Court finds that this objection does not warrant exclusion of the brochure survey.

Questions 2 and 3 are clearly directed to determining the messages conveyed by the BD brochure:

> 2. What is the main message(s) being communicated by these pages?
> [Textarea]
>
> * * *
>
> 3. According to this brochure, these three products have some features or characteristics in common (that is, they are the same or alike), and have some features or characteristics that are different.
>
> [ROTATE WORDING OF "same" AND "different"]
> For each of the following, please indicate whether you believe the brochure describes the three products as being the same, or believe the brochure describes the three products to be different.
> [ROTATE COLUMNS FOR "…same" AND "…different"]
> Claim to be the same  Claim to be different  Don't Know/Not Sure

(Scott Rep. Ex. 5 at 5-6, Dkt. No. 157-3.) Moreover, BD itself has argued that a proper survey controls for respondents' preexisting beliefs. (Mot. at 7-8, Dkt. No. 157.) The Court finds that it makes little sense to require Scott to consider the effects of respondents' preexisting beliefs on the survey's findings, but not permit Scott to explain that portion of the brochure survey's methodology and findings to the jury. BD's objection on this ground is overruled.

**c. Brochure Survey Findings Conflict with FDA and OSHA Definitions**

Finally, BD argues that the brochure survey cannot be used to set the standard for assessing BD's safety claims because the brochure survey's findings conflict with definitions set by regulations promulgated by the FDA and OSHA. (*Id*. at 11.)

The Court finds that BD has not adequately substantiated its contention that any FDA or OSHA regulation governs determining whether BD's advertising claims in this case are false or misleading. The *Sandoz* case cited by BD explains that there are key differences between the statutes enforced by the FDA and OSHA, and the Lanham Act:

> [The Lanham Act] provides a private remedy to a commercial plaintiff who meets the burden of proving that its commercial interests have been harmed by a competitor's false advertising. The [Food, Drug, and Cosmetic Act] in contrast, is not focused on the truth or falsity of advertising claims. It requires the FDA to protect the public interest by "pass[ing] on the safety and efficacy of all new drugs and . . . promulgat[ing] regulations concerning the conditions under which various categories of OTC drugs . . . are safe, effective and not misbranded."

*Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3d Cir. 1990).

The issue presented in *Sandoz* was "whether a Lanham Act false labeling claim exists against a manufacturer who lists an ingredient as 'inactive' when FDA standards seem to require that such an ingredient be labeled as 'active.'" *Id.* In other words, the gravamen of the plaintiff's claim was that that the label was false because FDA labeling standards for drugs seemed to require that the ingredient be labeled as "active." Because the FDA had not decided

whether the type of ingredient at issue must be labeled "active," the appellate court found that the trial court erred in applying the FDA regulations on its own, and deciding that it should have been so labeled. *Id.* at 230-31. However, *Sandoz* does not stand for the proposition that any definition provided by a regulation necessarily governs determining whether a statement is actionable under the Lanham Act.

Here, BD merely provides a string of citations to definitions given in regulations, without (1) any analysis or explanation of how those definitions apply to the advertising claims at issue in this case, or (2) any analysis of why the regulation at issue should control over the Lanham Act. Accordingly, BD's objection is overruled.

**B. Patient Safe Survey**

BD argues the patient safe survey should be excluded because (1) "it was preordained that respondents would express interest in a product that they were told to assume would benefit their patients;" and (2) that the survey "is an unreliable measure of whether real potential customers would purchase the product and at what price" because respondents were told "to assume the truth of clinical claims that their healthcare facilities usually systematically test." (Mot. at 13-14, Dkt. No. 157.) RTI provides a comprehensive defense of the survey in its response. (Resp. at 11-13, Dkt. No. 217.) The Court finds that these objections go to the weight of the evidence, and do not warrant exclusion of the patient safe survey.

BD also objects, in conclusory fashion, that the survey lacks proper controls and uses leading questions. The Court has reviewed the questions associated with the patient safe survey, and finds that the record does not reveal reliability or methodology concerns that warrant exclusion of the survey. (*See* questions 18-22, Scott Rep. Ex. 5 at 13-14, Dkt. No. 157-3.) BD's objections to the patient safe survey are overruled.

### C. Corrective Advertising Damages Opinion

BD objects to Scott's "estimate of corrective advertising damages that is based on unsupported assumptions rather than reliable analysis." (Mot. at 14, Dkt. No. 157.) The focus of BD's less than one page of argument dedicated to the corrective advertising damages opinion is that key assumptions in Scott's analysis have no factual support. On this record, the Court finds that these criticisms more properly go to the weight of the evidence, and do not warrant exclusion. Accordingly, BD's objections to the corrective advertising opinion are overruled.

## CONCLUSION

Having considered and overruled all of BD's objections to Dr. Scott's opinions and anticipated testimony, BD's Motion to Preclude the Expert Testimony of Carol A. Scott is hereby **DENIED**.

**SIGNED this 27th day of February, 2013.**

ROY S. PAYNE
UNITED STATES MAGISTRATE JUDGE