NO. 18-A-_____

IN THE SUPREME COURT
OF THE UNITED STATES

ISAAC OWENS
Applicant

VS.

AUXILIUM PHARMACEUTICALS, INC.
Respondent

Exhibit A

District Court Decision

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

In re: Testosterone Replacement	**)**	
Therapy Products Liability Litigation	**)**	**Case No. 14 C 1748**
Coordinated Pretrial Proceedings	**)**	**MDL No. 2545**
	)	
(This document applies to all cases)	**)**	

CASE MANAGEMENT ORDER NO. 76
(Rulings on Auxilium's motions to exclude expert testimony and for summary judgment – dkt. 34, 38, & 39 in *Holtsclaw v. Auxilium*, Case No. 15 C 3941, and dkt. 29, 33, & 34 in *Owens v. Auxilium*, Case No. 14 C 5180)

MATTHEW F. KENNELLY, District Judge:

Plaintiffs in this multidistrict litigation (MDL) proceeding allege that they suffered either arterial cardiovascular injuries or injuries related to blood clots in the veins (venous thromboembolisms, or VTEs) as a result of taking prescription testosterone replacement therapy (TRT) drugs. Defendants Auxilium Pharmaceuticals, LLC (formerly known as Auxilium Pharmaceuticals, Inc.) and Endo Pharmaceuticals Inc. (collectively, Auxilium) manufacture and sell Testim,[1] one of the TRT drugs at issue in this litigation. Two cases in which Auxilium is a defendant have been selected for "bellwether" trials. In each of those cases, Auxilium has moved to exclude the testimony of a number of plaintiffs' expert witnesses under Federal Rules of Evidence 702 and 403 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and for summary judgment. This Court has already ruled on motions raising similar issues in cases brought against AbbVie, another of the defendants in this proceeding, concerning its TRT drug Androgel. *See In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings* ("*In re: TRT*"), No. 14 C 1748, 2017 WL

[1] Endo acquired Auxilium in January 2015.

1833173, at *1 (N.D. Ill. May 8, 2017) (ruling on motions to exclude expert testimony and for summary judgment on issue of causation); *In re: TRT*, No. 14 C 1748, 2017 WL 1836435, at *1 (N.D. Ill. May 8, 2017) (ruling on motion for summary judgment on failure-to-warn claims); *In re: TRT*, No. 14 C 1748, 2017 WL 1836443, at *1 (N.D. Ill. May 8, 2017) (ruling on motions to exclude expert testimony and for summary judgment on claims concerning "off-label" marketing). In this opinion, the Court assumes familiarity with those rulings.

Isaac Owens and Steve Holtsclaw are the plaintiffs in the two bellwether cases against Auxilium. Owens alleges that his use of Testim caused him to suffer a deep vein thrombosis (DVT)[2] in July 2013. Holtsclaw alleges that his Testim use caused him to suffer a heart attack in July 2014. Both plaintiffs contend that Auxilium marketed Testim "off label"—that is, for uses other than that for which the Food and Drug Administration (FDA) approved the drug—and that Auxilium misrepresented the safety and efficacy of Testim for off-label use. They also contend that Auxilium failed to adequately warn that Testim could cause users to suffer DVTs and heart attacks. Owens has brought claims against Auxilium under the state laws of Kentucky. Holtsclaw has sued Auxilium and Endo,[3] asserting claims under Tennessee law.

Auxilium seeks to exclude the testimony of a number of plaintiffs' expert witnesses. According to Auxilium, the opinions of Drs. Peggy Pence, Steven Woloshin,

[2] As the Court has discussed in prior opinions, a DVT occurs when a blood clot (thrombus) forms in a deep vein, usually in the legs. A DVT often causes pain and swelling and may result in the blockage of blood flow in the lungs (pulmonary embolism) if a clot breaks loose and travels through the bloodstream to the lungs.

[3] Initially, Holtsclaw also brought suit against GlaxoSmithKline LLC (GSK), a company that does not manufacture or sell Testim but was involved in the marketing and promotion of the drug from May 2012 through August 2013. Holtsclaw has since dismissed his claims against GSK by stipulation.

and David Handelsman, concerning Auxilium's alleged off-label marketing of Testim, are inadmissible because they are based on speculation about Auxilium's intent or are otherwise irrelevant. Auxilium also moves to exclude testimony from plaintiffs' experts concerning whether Testim caused the plaintiffs' injuries. Auxilium maintains that Dr. Hossein Ardehali has no reasonable basis for concluding that Testim, as opposed another potential risk factor, caused Holtsclaw's heart attack. Similarly, Auxilium argues that Dr. Jihad Abbas has no reasonable basis to conclude that Testim caused Owens's heart attack; Auxilium also contends that Dr. Abbas' opinion is based on inaccurate assumptions about Owens's use of Testim. Finally, Auxilium contends that the opinions of Owens's treating physicians, Drs. Ardel Cagata and Martin Ozor, that Testim is capable of causing DVTs are not based on any reliable methodology and are therefore inadmissible.

In addition to seeking exclusion of expert testimony, Auxilium has moved for summary judgment against both plaintiffs, contending, among other things, that their failure-to-warn and design-defect claims are preempted by federal law and that plaintiffs otherwise lack sufficient evidence to support their claims that Auxilium's marketing and inadequate warning labels caused them to take Testim or that Testim caused their injuries. Endo has also moved for summary judgment on all of Holtsclaw's claims because it did not acquire Auxilium until after Holtsclaw suffered his heart attack. For the following reasons, the Court grants Auxilium's motion to exclude the opinions of Drs. Abbas and Cagata and its motion for summary judgment in Owens's case. The Court also grants Endo's motion for summary judgment in Holtsclaw's. The Court otherwise denies Auxilium's motions, except with respect to certain expert testimony as discussed

below. This leaves for trial Holtsclaw's claims against Auxilium.

Background

As with the other TRT products in this litigation, the FDA has approved Testim for the treatment of male hypogonadism. The term "hypogonadism" refers generally to a disorder characterized by abnormally low levels of testosterone in the blood and associated signs and symptoms including reduced libido, fatigue, infertility, depressed mood, and reduced muscle mass. Plaintiffs maintain that Testim has been proven safe and effective only for the treatment of so-called "classical" or "pathological" hypogonadism—that is, hypogonadism that results from certain recognized medical conditions, such as Klinefelter syndrome or injury to the testicles. According to plaintiffs, Auxilium and other TRT manufacturers have inappropriately marketed TRT products beyond the use for which they were approved by targeting users who suffer from symptoms associated with the normal male aging process. Plaintiffs assert that "age-related hypogonadism," also referred to as "andropause" or "Low T," is a fictitious condition, created by Auxilium and other manufacturers of TRT and for which TRT use has never been proven safe or effective. According to plaintiffs, Testim and other TRT drugs do not appreciably improve the symptoms of aging but do increase the risk that users will suffer cardiovascular injuries (namely, heart attacks and strokes) or VTE injuries (DVTs and pulmonary embolisms).

The Court need not elaborate on the purported mechanisms by which TRT allegedly causes cardiovascular and VTE injuries, having already discussed those mechanisms in prior rulings. In general, plaintiffs and their experts posit that TRT increases the risks of cardiovascular and VTE injuries because of its pro-thrombotic

nature—that is, because of its tendency to increase the risk of clotting in the blood. According to plaintiffs and their experts, TRT is pro-thrombotic because of its tendency to increase (1) estradiol, a metabolite of testosterone and a form of estrogen, which has been connected to increased risk of clot formation; (2) thromboxane A2 receptors, which can promote abnormal platelet function and an increased risk of clotting; and (3) hematocrit (the ratio of the volume of red blood cells to the total volume of blood), which can increase blood viscosity, leading to a higher incidence of clotting.

The FDA has, at various times, considered requiring TRT manufacturers and sellers, including Auxilium, to warn about the risk of cardiovascular and VTE injuries that might accompany TRT use. The Court focuses here on the regulatory history regarding warnings for cardiovascular injuries because that history is more relevant for the issues discussed below. In January 2010, the FDA received notice that a clinical trial studying the effects of TRT on elderly men (the TOM—testosterone in older men—trial) had been stopped prematurely because of an increase in adverse cardiovascular events among study participants treated with testosterone compared to placebo. In response to the discontinued study, the FDA undertook a qualitative review of available information regarding adverse events associated with testosterone therapy in men. After reviewing the results of the TOM trial and other published studies on the topic, the FDA noted the limitations of the TOM trial and, in January 2011, ultimately concluded that the evidence from that trial and other studies available at the time did not support an association between TRT and increased risk of cardiovascular events in men. The FDA noted that larger safety trials designed to evaluate cardiovascular outcomes were necessary to provide a more conclusive answer on the relationship between TRT and adverse

cardiovascular events.

In January 2014, after new published articles suggested a possible increase in adverse cardiovascular events among TRT users, the FDA announced that it was investigating the risk of stroke, heart attack, and death in men taking TRT but had not concluded that TRT drugs increases the risk of those outcomes. Later that year, the FDA requested that the label for Testim and other TRT drugs be updated to warn that TRT use may increase the risk of venous thromboembolic events. Auxilium responded to that request by proposing to include a warning with the more general phrase "embolism and thrombosis" instead of "venous thromboembolic events." Dkt. no. 45-8, Case No. 15 C 3941, at 2. In June 2013, the FDA rejected Auxilium's proposal to use the more general phrase, noting that its "requested labeling changes were based on [its] review of cases of **venous** thromboembolism (DVT,PE), and not arterial thromboembolism (strokes, heart attacks)" and that the more specific phrase was therefore more accurate "clinically and scientifically, to describe the said warning." Dkt. no. 41-1, Case No. 15 C 3941, at 2 (emphasis in original). Auxilium views the FDA's response to its proposal as a clear indication that the FDA would have rejected an attempt by Auxilium at that time to strengthen the Testim warning label with respect to cardiovascular risk.

After the FDA announced that it was investigating the risk of stroke, heart attack, and death in men taking TRT, the group Public Citizen submitted a citizen petition asking the FDA to (1) add a "black box" warning to the labels for all drugs containing testosterone highlighting the increased risks of cardiovascular dangers, (2) send "Dear Doctor" letters to warn physicians of the possibility of cardiovascular effects, and (3)

require the medication guide for all testosterone products to be updated to reflect this risk. The FDA denied the requests in July 2014, concluding that there was not sufficient evidence of a causal link between TRT and adverse cardiovascular link to support the actions requested in the citizen petition. The agency noted, however, that the studies included in the petition warranted further exploration of a possible safety signal regarding TRT and cardiovascular risk. In September 2014, the FDA convened an advisory committee to consider the issue, and the committee ultimately agreed that a weak signal of cardiovascular risk had emerged from the results of recent epidemiological studies. In May 2015, the FDA required Auxilium to add the following warning to the Testim label:

> **5.5 Cardiovascular Risk**
> Long term clinical safety trials have not been conducted to assess the cardiovascular outcomes of testosterone replacement therapy in men. To date, epidemiological studies and randomized controlled trials have been inconclusive for determining the risk of major adverse cardiovascular events (MACE), such as non-fatal myocardial infarction, non-fatal stroke, and cardiovascular death, with the use of testosterone compared to non-use. Some studies, but not all, have reported an increased risk of MACE in association with use of testosterone replacement therapy in men. Patients should be informed of this possible risk when deciding whether to use or to continue to use Testim.

Dkt. no. 46-5, Case No. 15 C 3941, at 7.

As the Court noted above, plaintiffs emphasize Auxilium's promotion of Testim for the treatment of aging men who do not have classical hypogonadism. It is undisputed that neither Owens nor Holtsclaw recalls viewing any advertisement or other promotional material for Testim or any other TRT drug before each began using Testim. There is also no evidence in the record that either plaintiff independently asked his doctor about TRT because of promotional material he had seen. Plaintiffs contend,

however, that evidence in the record tends to show that plaintiffs' prescribing physicians received false and misleading marketing materials and communications from Auxilium and relied on that misleading information when deciding to prescribe Testim for Owens and Holtsclaw. In response to this contention, Auxilium points out that both Dr. Dennis Smith, Owens's prescribing physician, and Dr. Dean McLaughlin, Holtsclaw's prescribing physician, testified that they never received any information from Auxilium that they believed was false or inaccurate.

Plaintiffs maintain that the record supports an inference that the physicians relied on Auxilium's misrepresentations. With respect to Dr. McLaughlin, plaintiffs emphasize the frequency with which he interacted with Testim sales representatives. Plaintiffs note that in addition to providing Dr. McLaughlin with promotional materials and brochures, Testim sales representatives called his office at least 95 times and provided him with a meal during a sales presentation at least ten times. During his deposition, Dr. McLaughlin testified that he relied on Auxilium to provide him with accurate information about Testim's risks and benefits. McLaughlin also stated his belief that TRT is effective for treating men with low testosterone who suffer from common symptoms of aging, including fatigue, decreased energy, lack of libido, and muscle loss, and that the benefits of TRT outweigh the risks for those patients, regardless of whether an underlying condition was causing the patient's symptoms or low levels of testosterone in the blood. Plaintiffs maintain that the lack of scientific support for Dr. McLaughlin's beliefs, combined with his frequent communications with Testim sales representatives and willingness to rely on their representations, supports the inference that Auxilium's representations were the source of his belief that TRT can safely and effectively treat

age-related hypogonadism.

With respect to Dr. Smith, plaintiffs also emphasize his belief that TRT is safe and effective for treating many common symptoms of aging, a belief they contend is not supported by the scientific literature. Though Dr. Smith did testify that he relied on the accuracy of information from Auxilium sales representatives, the evidence of Dr. Smith's contact with representatives from Auxilium is less extensive than in Dr. McLaughlin's case. Instead plaintiffs emphasize that Auxilium provided Dr. Smith with the so-called "ADAM" questionnaire, a TRT promotional device designed to assist in diagnosing age-related hypogonadism. Plaintiffs maintain that the device contains misleading information and that Owens's use of the device to diagnose patients with hypogonadism indicates that he relied on Auxilium's alleged misrepresentations.

During a December 2013 visit, Dr. McLaughlin diagnosed Holtsclaw with hypogonadism based on his complaints of chronic fatigue and laboratory work that revealed a low testosterone level in his blood. Dr. McLaughlin prescribed Testim to treat Holtsclaw's symptoms. Within a month of using the drug, Holtsclaw's testosterone level had returned to the normal range, and he testified during his deposition that he believed that using Testim increased his energy level. In July 2014, roughly seven months after he began taking Testim, Holtsclaw suffered a heart attack at the age of 59. Dr. Ardehali reviewed Holtsclaw's records for this case and noted that his risk factors for atherosclerotic cardiovascular disease prior to the heart attack included dyslipidemia (abnormal amount of lipids in the blood), diabetes, and obesity. According to Dr. Ardehali, the films from the cardiac catheterization performed on Holtsclaw indicate that he experienced a thrombotic event in his coronary arterial system. Based on those

films, the preexisting cardiovascular risk factors, and the fact that Holtsclaw suffered his heart attack within a few months of beginning to use Testim, Dr. Ardehali opines that Testim caused Holtsclaw to suffer an acute clotting event that resulted in his July 2014 heart attack.

Dr. Smith diagnosed Owens with hypogonadism in July 2011 based on complaints of low energy, decreased libido, erectile dysfunction, and a blood test that revealed a below-normal testosterone level. It is undisputed that Owens used Testim sporadically between July 2011 and July 2013, refilling his prescription only three times during that period. There is some dispute about whether the refills were for 30-day or 150-day supplies of the drug, but in either case, Owens would have not have had enough of the drug to take a full dose daily over that time period. Testim, like AndroGel, is a gel that is applied to the skin and enters the blood transdermally. Though the medication guide that accompanies the drug instructs users to apply Testim only to the shoulders and upper arms and not to the abdomen, Owens testified that he would apply the drug to his thighs and stomach. Owens also testified that he did not use the recommended daily dose of Testim. The medication guide instructs users to use daily an entire tube, which contains five grams of gel and fifty milligrams of testosterone. Owens says, however, that when he applied the gel, he used an amount equal to only one-third to one-half of a tube. During a July 2013 appointment, Dr. Smith noted that Owens had "not been using the Testim as diligently as he should" and had "noticed a decrease in his energy level because of this." Dkt. no. 37-7 at 4. Dr. Smith noted that Owens would "get back on the Testim 5g daily" and provided him with a new prescription for a one-month supply with five refills. *Id.* Nine days after his appointment

with Dr. Smith, Owens visited an immediate care center because of pain in his left leg, which had begun two to four days earlier. Doctors at the immediate care center recommended that Owens go to the emergency room, where an ultrasound revealed a DVT in his left leg.

Owens was 62 years old when he suffered the DVT in July 2013. That DVT was the second that Owens has experienced; his first DVT was in 2005, prior to any TRT use. Owens has also previously suffered a stroke, which left him paralyzed on the left side of his body. Dr. Abbas, who reviewed Owens's medical history and records, acknowledged that Owens's preexisting risk factors for DVT include his prior DVT, paralysis, age, and obesity. Nevertheless, Dr. Abbas opines that Testim was a substantial factor in causing Owens's second DVT. Dr. Abbas testified during his deposition that his opinion that Testim caused Owens's second DVT is based on the assumption that Owens was using the full prescribed dose. With respect to whether Testim use at a less-than-regular dose could cause Owens's injury, Dr. Abbas testified that he does not have an opinion and "would have to investigate it." Dkt. no. 46-4 at 165:5–7. Dr. Smith, for his part, says that Owens never told him that he was taking less than the recommended dose. And Owens, when asked whether it is possible that he would have started using a full tube of Testim after Dr. Smith instructed him to be more diligent about using Testim, said he "do[es]n't recall whether [he] would have or not." Dkt. no. 60-4 at 289:15–20.

Dr. Cagata, who treated Owens in the hospital for his second DVT, also opines that Testim was a cause of the DVT. This opinion is based on Dr. Cagata's knowledge from medical school that hormone therapy could increase DVT risk and his belief that

having multiple risk factors for an injury increases one's risk for that injury.

Discussion

Summary judgment is appropriate if the moving party "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). When ruling on a motion for summary judgment, a court "views the record in the light most favorable to the nonmoving party and draws all reasonable inferences in that party's favor." *Zerante v. DeLuca*, 555 F.3d 582, 584 (7th Cir. 2009). Yet a court's "favor toward the nonmoving party does not extend to drawing inferences that are supported by only speculation or conjecture." *Singer v. Raemisch*, 593 F.3d 529, 533 (7th Cir. 2010) (internal quotation marks and emendations omitted). Where an element of a plaintiff's claim must be established by expert testimony, a court may properly grant summary judgment if it determines that the only expert testimony offered to prove that element is inadmissible. *See Lewis v. CITGO Petroleum Corp.*, 561 F.3d 698, 700 (7th Cir. 2009).

A. Expert testimony

Rule 702 and the principles set forth in *Daubert* govern the admissibility of expert testimony. The framework provided by Rule 702 and the *Daubert* principles is essentially a three-step analysis: for an expert's testimony to be admissible, (1) he or she must be qualified; (2) the reasoning or methodology underlying the testimony must be reliable; (3) and the testimony must be relevant—that is, likely to assist the trier of fact to understand the evidence or to determine a fact in issue. *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir. 2007). A primary objective of *Daubert*'s "gatekeeping" requirement is "to make certain that an expert . . . employs in the

courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). In general, a court's focus must be on the expert's "principles and methodology, not on the conclusions that they generate," *Daubert*, 509 U.S. at 595, or the "factual underpinnings" of those conclusions. *Walker v. Soo Line R. Co.*, 208 F.3d 581, 586 (7th Cir. 2000). Nevertheless, an opinion must be connected to the existing data by more than "the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). An expert's opinions may be inadmissible because "there is simply too great an analytical gap between the data and the opinion offered." *Id.* Expert testimony must also be relevant: in other words, it "must fit the issue to which the expert is testifying and be tied to the facts of the case." *Hartman v. EBSCO Indus., Inc.*, 758 F.3d 810, 819 (7th Cir. 2014) (internal quotation marks and emendations omitted).

1. Drs. Abbas and Cagata

Owens has enlisted two physicians, Drs. Abbas and Cagata, to testify regarding specific causation—that is, the proposition that Testim caused his DVT. Auxilium contends that Dr. Abbas's specific causation opinion does not fit the facts of Owens's case and that neither expert's opinion is based on a reliable methodology. None of Owens's claims can survive summary judgment, Auxilium argues, without admissible expert testimony that his Testim use caused his injury. Owens, for his part, does not dispute that expert testimony is required to establish specific causation or that causation is an element of each of his claims. *See Adams v. Cooper Indus., Inc.*, No. CIV.A. 03-476-JBC, 2012 WL 2339741, at *1–2 (E.D. Ky. June 19, 2012) (noting that specific causation requires "scientific assessments that must be established through expert

testimony" and determining that plaintiff's tort claims failed under Kentucky law because her experts' testimony was insufficient to establish specific causation). Owens contends, however, that both experts' opinions are admissible because they reached their conclusions by employing the reliable methods they use in their daily medical practice. According to Owens, any disputes concerning the factual assumptions underlying those opinions should be resolved by the jury. Auxilium also challenges the experts' general causation theories (that TRT, in general, causes DVTs), but the Court need not address that challenge. The Court concludes that neither expert's specific causation is admissible, a conclusion that requires the Court to grant summary judgment against Owens on all of his claims regardless of whether Testim is capable of causing DVTs in general.

Owens maintains that both Dr. Abbas and Dr. Cagata performed "differential etiologies" to reach their respective conclusions that Testim caused, or was a substantial factor in causing, Owens's DVT. This Court has previously ruled that a differential etiology, if performed properly, is a reliable methodology for determining specific causation. *See In re: TRT*, 2017 WL 1833173, at *17. A doctor performing a differential etiology "rules in all the potential causes of a patient's ailment and then by systematically ruling out causes that would not apply to the patient, the physician arrives at what is the likely cause of the ailment." *Myers v. Illinois Cent. R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010). Whether a differential etiology is reliable is determined "on a case-by-case basis," with the focus on "which potential causes should be 'ruled in' and which should be 'ruled out.'" *Id.* Though an expert who reaches a causation opinion based on a differential etiology is not required to rule out every alternative cause, the expert's

analysis should "show why a particular alternative explanation is not, in the expert's view, the *sole* cause of the [injury]." *Id.* (emphasis in original).

Auxilium argues that Dr. Abbas's causation opinion is inadmissible because it is based solely on the fact that Owens suffered his DVT soon after resuming use of Testim. *See Ervin*, 492 F.3d at 904–05 ("The mere existence of a temporal relationship between taking a medication and the onset of symptoms does not show a sufficient causal relationship."). Auxilium may be correct that Dr. Abbas lacks a reliable basis for his specific causation opinion. But the opinion is inadmissible for an independent reason: his proposed testimony does not fit the facts of Owens's case. *See Hartman*, 758 at 819. Dr. Abbas testified unequivocally that his specific causation opinion is based on the premise that Owens applied Testim as prescribed and used the full, therapeutic dose. He conceded that he does not know, and does not have an opinion on, whether Testim could cause an injury like Owens's when the drug is misapplied or when users consistently apply less than the full dose. The evidence is clear, however, that Owens did not apply Testim as instructed and did not use the full dose. Dr. Abbas's opinion is therefore irrelevant to Owens's case.

Owens contends that whether he used the full dose of Testim is an issue that should be resolved by the jury and that the Court should not assess the accuracy of Dr. Abbas's factual assumptions. It is true that physicians "reasonably may be expected to rely on self-reported patient histories" and that "district courts usually should allow [purported] inaccuracies in [a self-reported] history to be explored through cross-examination." *Walker*, 208 F.3d at 586. But Dr. Abbas did not rely on Owens's self-reported history; rather, he assumed that Owens had been taking the full dose because

his physician had prescribed that dose. In addition, although it is usually the province of the jury to assess the accuracy of an expert opinion's "factual underpinnings," *id.*, no reasonable jury could conclude that Dr. Abbas' assumption about Owens's Testim use was accurate. Owens argues that Dr. Smith's note indicated that he had not been using Testim diligently and that the jury could infer that he would resume using five grams of Testim daily. But that note does not support the inference that Dr. Smith told Owens to start using the full dose of Testim or that Owens did so. Rather, Dr. Smith testified that he does not recall Owens ever reporting that he used less than the full dose, and he has no note in his records of such a conversation. And when asked whether he began using a full dose of the medication after Dr. Smith told him to resume Testim use, Owens replied only that he does not recall whether he would have or not. In theory, an expert could offer an opinion that the amount of Testim Owens did use and the way in which he used it was sufficient to cause his DVT. Dr. Abbas, however, has not offered such an opinion in this case, and his testimony is therefore irrelevant and inadmissible.

Owens maintains that even if Dr. Abbas's opinion is excluded, he can survive summary judgment by relying on the specific causation opinion of Dr. Cagata. Dr. Cagata's opinion, however, is not based on any reliable methodology and is therefore inadmissible as well. Dr. Cagata did not prepare an expert report in this case, though he did offer opinions on scientific matters during the course of his deposition, including his opinion that Owens's Testim use was a cause of his DVT. Owens contends that Dr. Cagata's causation opinion is based on a differential etiology, a methodology that he applies regularly in his medical practice when attempting to determine the cause of patients' ailments. From his deposition testimony, it is unclear whether Dr. Cagata

actually did conduct a differential etiology. But to the extent his opinion is based on that method, he has not applied the method with the "level of intellectual rigor that characterizes the practice of an expert." *Kumho Tire Co.*, 526 U.S. at 152. First, Dr. Cagata "failed to reliably 'rule in'" Testim as a potential cause of Owens's injury. *Brown v. Burlington N. Santa Fe Ry. Co.*, 765 F.3d 765, 774 (7th Cir. 2014). Dr. Cagata included Testim among the potential causes of Owens's DVT because his training in medical school provided him with "a general knowledge that any of these hormones" could increase the risk of a DVT. Dkt. no. 46-10 at 65:6–8, 16. Not only is this explanation conclusory; it is purportedly based on what Dr. Cagata learned in medical school, from which he graduated in 1993. As the Court has discussed in its prior rulings, the significant epidemiological studies concerning the relationship between TRT and VTEs have all been published in the past half-decade. *See In re: TRT*, 2017 WL 1833173, at *3. Second, Dr. Cagata did not account for the possibility that Owens's other preexisting risk factors were the sole cause of his DVT. Indeed, he conceded that Owens's other risk factors alone would be sufficient to have caused his DVT. He also testified expressly that he was not able to determine which of Owens's potential risk factors (including, presumably, Testim) was the cause of his DVT. And for a patient, like Owens, whose risk factors included obesity, a prior DVT, and paralysis, Dr. Cagata justified his conclusion that Testim could be another "factor in the cause of a DVT," *id.* at 67:10, based solely on his understanding that "[m]ultiple risk factors can increase your risk of something," *id.* at 67:23–24. Dr. Cagata's assertion regarding causation is conclusory and does not result from a proper application of differential etiology and thus is "not the stuff of science." *C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 837 (7th

Cir. 2015). Rather, his conclusion amounts to little more than "*ipse dixit*" and is therefore inadmissible.

Without expert testimony to support his assertion that Testim caused his injury, Owens cannot succeed on any of his claims. The Court therefore grants summary judgment in defendants' favor and, in the remainder of this opinion, will not address the other issues Auxilium raises with respect to his claims.

2. Dr. Ardehali

Auxilium contends that Dr. Ardehali lacks a reliable basis for his conclusion that Testim was a substantial factor in causing Holtsclaw's heart attack. Specifically, Auxilium argues that Dr. Ardehali has not reliably explained why Holtsclaw's preexisting medical conditions—including diabetes, high cholesterol, obesity, and obstructive sleep apnea—were not the sole cause of the heart attack. In response, Holtsclaw cites Dr. Ardehali's explanation that Holtsclaw's medical records and history fit with Dr. Ardehali's general causation opinion, which the Court has discussed in previous rulings, regarding the circumstances under which TRT might cause heart attacks. According to Dr. Ardehali, TRT has a particular tendency to increase coagulation (the blood's tendency to clot) in an individual who has systemic chronic inflammatory disease, and that increased coagulation can lead to blood clots that result in particular types of heart attacks. In the case of Holtsclaw, Dr. Ardehali determined that his other risk factors indicated chronic inflammatory disease, and the cardiac catheterization showed evidence of clotting. Dr. Ardehali concluded, therefore, that Testim likely contributed to his heart attack, and though the other potential risk factors contributed to his systemic inflammatory disease, they were likely not the sole cause of his injury. Unlike the

opinion of Dr. Setaro, which the Court excluded in one of the cases against AbbVie, Dr. Ardehali's opinion bridges the "analytical gap between the data and the opinion offered." *Joiner*, 522 U.S. at 146.

Auxilium argues that the unreliability of Dr. Ardehali's method is apparent from his response to a hypothetical question during his deposition. Dr. Ardehali was asked about a hypothetical "twin brother" of Holtsclaw who had all of Holtsclaw's preexisting risk factors and who suffered the same heart attack but had not been using TRT. When asked what was the likely cause of the twin brother's heart attack, Dr. Ardehali rejected the premise of the question, citing his experience that each patient has a unique history. He ultimately answered, however, that he would tell the patient that the multiple risk factors for coronary disease were the cause of his heart attack. Auxilium contends that because Dr. Ardehali concedes that the other risk factors could be the sole cause of the hypothetical twin brother's heart attack, he has not reliably explained why those risk factors were not the sole cause of the heart attack of the patient who took Testim—that is, Holtsclaw. Setting aside the fact that a physician's response to a hypothetical question that recalls the first year of law school is a not a viable basis for excluding expert testimony, Dr. Ardehali's answer to the question does not establish that his method is unreliable. It is entirely consistent for Dr. Ardehali to say, on the one hand, that a particular combination of risk factors could theoretically be a sole cause of a heart attack, while simultaneously concluding, on the other hand, that those some risk factors were unlikely to be the sole cause in a patient who was taking Testim and whose records and history are consistent with a TRT-induced heart attack. The Court denies Auxilium's motion to exclude Dr. Ardehali's testimony.

3. Drs. Pence and Woloshin

Auxilium has moved to exclude certain testimony from Drs. Pence and Woloshin, each of whom intends to offer testimony regarding Auxilium's marketing and promotion of Testim. The Court has already ruled on motions to exclude testimony from both witnesses in cases against AbbVie. *See In re: TRT*, 2017 WL 1836443, at *16–*18. In that ruling, the Court excluded certain testimony from each expert, and that testimony will also be inadmissible here. Dr. Pence, for example, is prohibited from speculating about why the FDA acted or failed to act, and Dr. Woloshin is prohibited from using the term "disease mongering," which carries an inappropriately pejorative connation. *Id.* at *16–*17. Auxilium contends that the Court's ruling regarding Dr. Woloshin should be extended to cover the term "mass, uncontrolled experiment." The Court disagrees that the phrase is so inflammatory or prejudicial to warrant exclusion.

The Court does agree with Auxilium that certain advertising and promotional material that Drs. Pence and Woloshin discuss is likely to be inadmissible. Auxilium argues that plaintiffs' experts should not be permitted to testify about marketing and promotional materials that were not viewed or relied upon by plaintiffs or their prescribing physicians. As the Court discusses below, there is sufficient evidence to support the inference that Dr. McLaughlin relied on promotional material concerning Testim. Auxilium's marketing material—at least the material that predates Holtsclaw's use of Testim—therefore is, in general, relevant to the jury's determination of the content of the material that Dr. McLaughlin likely viewed and also to provide context for understanding Auxilium's motive and intent with respect to its marketing and promotion of Testim.

For two categories of marketing, however, the danger of unfair prejudice indicates a need to limit the extent of marketing evidence admitted at trial. It is undisputed, for example, that Holtsclaw does not recall viewing any advertisements for Testim prior to taking the drug. Thus, although evidence about Auxilium's direct-to-consumer marketing is relevant as just described, the probative value of that evidence is more limited than the evidence that was aimed at physicians or that physicians saw. Similarly, although plaintiffs contend that Auxilium tried to capitalize on, and complement, the marketing campaigns of other companies such as AbbVie, at some point testimony and evidence about other companies' advertisements would carry with it a significant risk of unfair prejudice to Auxilium. On these two categories, the Court will need to strike the appropriate balance between providing the necessary context for Auxilium's more relevant marketing activities and minimizing the risk of unfair prejudice. The Court can determine the appropriate place to draw that line at trial or in dealing with the parties' motions *in limine*.

The remainder of Auxilium's motion to exclude the testimony of Drs. Pence and Woloshin largely repeats arguments that the Court has rejected previously, and Auxilium has not provided a basis for the Court to reconsider those prior rulings. Auxilium contends, for example, that Dr. Pence should be precluded from testifying about Auxilium's knowledge about the accuracy of Testim label and its intent to market the drug off label. According to Auxilium, those opinions are based on documentary evidence that the jury can review for itself and use to reach its own conclusion about what Auxilium knew. But as the Court has already ruled, testimony of the kind Dr. Pence and Dr. Woloshin intend to offer "will assist the jury in determining its ultimate

conclusions" and is appropriately admitted as a summary of voluminous material "under Federal Rule of Evidence 1006 as well as Rule 702 in the sense that [they] are identifying what [they], given [their] background and expertise, consider[] to be the most salient aspects of those voluminous materials." *In re: TRT*, 2017 WL 1836443, at *15. For this same reason, Dr. Pence may properly testify about concerns GSK expressed to Auxilium during the period in which the companies were parties to a co-promotion agreement. That testimony, too, will provide a helpful summary of voluminous materials, informed by Dr. Pence's background and expertise. In a similar vein, though Auxilium argues for the exclusion of Dr. Pence's opinion regarding the "intended use" of Testim and Auxilium's purported "misbranding" of the drug, the Court has already ruled that testimony of the sort Dr. Pence intends to offer provides a "framework by which the jury can assess what [Auxilium] intended via its marketing." *Id.* At the same time, the Court cautions Dr. Pence that she may "walk up to [the] line," but may not cross it and offer a conclusion about what Auxilium intended. *Id.*

4. Dr. Handelsman

Auxilium has also moved to exclude the testimony of Dr. Handelsman concerning Auxilium's marketing of Testim. Plaintiffs respond that they do not intend to offer any opinion from Dr. Handelsman pertaining to marketing, advertising, or over-promotion. The parties, therefore, no longer have a dispute on the issue, and testimony from Dr. Handelsman on those matters will not be admissible at trial.

B. Preemption

1. Failure to warn

Auxilium contends that Holtsclaw's failure-to-warn claim is preempted by federal

law. A state-law failure-to-warn claim is preempted by federal law if it would be impossible under federal law to add the warning label that a plaintiff alleges is required under state law. In the context of failure-to-warn claims concerning prescription drugs, the Supreme Court has held that the state-law claims are preempted only where there is "clear evidence" that the FDA would have rejected an attempt by the manufacturer to make the change to the drug's label that a plaintiff contends was necessary. *Wyeth v. Levine*, 555 U.S. 555, 571–72 (2009). In a previous ruling, the Court determined that there was no "clear evidence" that the FDA would have rejected efforts by AbbVie to add warnings about cardiovascular risk to the AndroGel warning labels. *See In re: TRT*, 2017 WL 1836435, at *7–*11. The regulatory history for Testim is similar to that of AbbVie, and Auxilium has not offered any new facts or cited any changes in the law that would warrant reconsideration of the Court's previous ruling.

Auxilium argues that the Court's prior ruling with respect to AndroGel should not apply in the case of Testim because of certain distinct aspects of Testim's regulatory history. The Court disagrees, however, that these purported distinctions provide "clear evidence" that the FDA would have rejected Auxilium's attempts to add warnings about Testim's cardiovascular risk. First, Auxilium notes that Testim was the drug administered in the TOM trial and that the FDA's conclusion that the trial did not support an association between TRT use cardiovascular risk is clear evidence that the FDA would have rejected a strengthened cardiovascular warning label for Testim in particular. The Court previously ruled, however, that the FDA's response to the TOM trial is not clear evidence that FDA would have rejected attempts to add a cardiovascular warning. *See id.* at *9. That conclusion was based not on the particular

TRT drug administered in the trial but rather on the fact that the FDA's failure to find a conclusive causal link between TRT and adverse cardiovascular outcomes would "not necessarily preclude AbbVie from adding the warning on its own." *Id.* The same reasoning applies with respect to Auxilium.

Auxilium also points to the fact that the FDA rejected the request for a warning in the 2014 Public Citizen petition a mere thirteen days after Holtsclaw's injury. This lack of a temporal gap between the injury and the FDA's action, according to Auxilium, provides a clear indication of how the FDA would have responded to efforts to alter the warning label at or before the time of Holtsclaw's injury. But this distinction is also not relevant with respect to the Court's prior reasoning. The Court ruled previously that the FDA's rejection of the citizen petition is not clear evidence that the FDA would have rejected any attempt to add a cardiovascular warning. This is because the FDA did not state definitively that TRT is not causally associated with cardiovascular risk (and indeed, indicated that it wanted to complete its own evaluation on the matter) and because there were indications that the FDA was responding to the *specific* labeling changes requested by the petition and not to all possible labeling changes regarding cardiovascular risk. *See id.* at *10–*11. The timing of Holtsclaw's injury with respect to the FDA's rejection of the citizen petition is irrelevant, because the rejection itself does not provide clear evidence that the FDA would have rejected attempts from Auxilium to add a warning about cardiovascular risk to the Testim label.

Finally, Auxilium points to the fact that the FDA actually rejected Auxilium's attempt to add a warning regarding cardiovascular risk. But when viewed in the proper context, FDA's response to Auxilium's proposed warning does not provide clear

evidence that the FDA would have rejected the label changes Holtsclaw contends are necessary. After the FDA asked Auxilium to update the Testim label to warn about the risk of venous thromboembolic events, Auxilium responded by proposing that the more general phrase "embolism and thrombosis" be substituted for the phrase "venous thromboembolic events" on the new label. The FDA rejected that proposal because its requested change was based on its review of VTE case reports, not on embolisms and thromboses occurring in the cardiovascular context. The FDA's response to an attempt by Auxilium to alter a proposed label from the FDA in the VTE context does not provide clear evidence of what the FDA would have done had Auxilium independently attempted to add a warning about cardiovascular risk to its label. The FDA did not say, for example, that any warning about cardiovascular risk would be inappropriate. Rather, it was attempting to add a label about VTE risk based on VTE cases it had reviewed and therefore rejected a more general warning about the possibility of "embolism and thrombosis" that would not accurately describe the risk it was seeking to address *at that time*. There is no clear evidence, for example, that the FDA would have rejected a proposal from Auxilium for a more specific warning addressing cardiovascular risk as opposed to a vague and general warning about the possibility of "embolism and thrombosis."

Because Auxilium has not presented clear evidence that the FDA would have rejected its attempts to add a warning about cardiovascular risk to the Testim label, there is no conflict between federal law and Holtsclaw's failure-to-warn claim.

2. Design defect

Auxilium also maintains that Holtsclaw's claim for design defect is preempted

because once the FDA approved Testim's design, Auxilium was prohibited from altering that design on its own. *See Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2475, 186 L. Ed. 2d 607 (2013) (design-defect claim against manufacturer of generic drug preempted because legally impossible for manufacturer to redesign drug or change warning label); *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 298 (6th Cir. 2015) ("post-approval design defect claim [against manufacturer of brand-name drug] is clearly preempted by federal law"). As the Court also discusses below, however, Holtsclaw's response to Auxilium's argument makes clear that he is not asserting a true "design defect" claim. That is, he is not contending that Testim's design alone renders it a dangerous product. Rather, he maintains that Testim is "defectively designed *for use in men with age-related declines in their testosterone*," Pls.' Mem. of Law in Opp'n, dkt. no. 55, at 17 (emphasis added), or where it is not accompanied by a proper warning label. Holtsclaw's "design defect" claim may be more accurately characterized as a failure-to-warn or a misrepresentation claim. But in any event, because Holtsclaw does not seek to alter Testim's design, his claim is not precluded under *Bartlett* or *Yates*.

C. Negligent misrepresentation, fraud, and breach of express warranty

Auxilium argues that the Court should grant summary judgment on Holtsclaw's negligent misrepresentation and fraud claims because he has failed to satisfy his burden to show that Dr. McLaughlin received and relied upon a misrepresentation made by Auxilium. It is true that Holtsclaw has not identified any direct evidence that Dr. McLaughlin relied upon any *particular* misrepresentation from Auxilium when deciding to prescribe Testim to Holtsclaw. But viewing the evidence in the light most favorable to Holtsclaw—evidence that includes Dr. McLaughlin's frequent contacts with Testim sales

representatives and Dr. McLaughlin's admission that he relies upon Auxilium for accurate information about Testim's risks and benefits—the Court concludes that a reasonable jury could infer that Dr. McLaughlin relied on Auxilium's representations to form his belief that Testim was safe and effective for the treatment of age-related hypogonadism and that Dr. McLaughlin prescribed Testim on the basis of that belief.

Auxilium also contends that Holtsclaw cannot maintain his claim for breach of express warranty because he has not identified any affirmation of fact on Testim's warning label that was false, as distinct from merely inadequate, at the time of his injury. *See Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 395 (6th Cir. 2013). Holtsclaw's breach of express warranty claim, however, is based not on a purported inaccuracy in the warning label, but rather on the same alleged misrepresentations in Auxilium's marketing and promotion discussed above. Because the Court concludes that there is enough evidence in the record to support an inference that Dr. McLaughlin relied on those alleged affirmative misrepresentations, Holtsclaw's breach of express warranty claim survives along with his fraud and negligent misrepresentation claims.

D. Design defect

Auxilium has also moved for summary judgment on Holtsclaw's claim for strict liability design defect. Holtsclaw points to the fact that this Court previously denied AbbVie's motion for summary judgment motion on a claim for strict liability design defect under Tennessee law, and he argues that that ruling should control here. *See In re: TRT*, 2017 WL 1836435, at *19. Auxilium responds that its motion for summary judgment is based on a different argument than the one the Court rejected in the case against AbbVie. In that ruling, the Court determined that comment (k) to section 402A

of the Restatement (Second) of Torts did not confer immunity on AbbVie for strict liability design defect claims. The Court noted that comment (k) provides immunity for manufacturers of prescription medications only where a proper warning accompanies the drug, and the Court concluded there was a genuine dispute about whether AbbVie provided adequate warnings. *Id.* Auxilium argues that the Court should grant summary judgment on Holtsclaw's design-defect claim, not because of comment (k), but because Holtsclaw has failed to identify any defect in Testim's design.

Auxilium is correct that Holtsclaw has not identified any defect that is attributable solely to Testim's design. Rather, according to Holtsclaw, Testim is dangerous because it is marketed for treatment of the wrong conditions and is not accompanied by adequate warnings of the drug's risks. Under Tennessee law, a manufacturer of a product may be held liable for an injury caused by the product if that product was "unreasonably dangerous" at the time it left the manufacturer's control. Tenn. Code Ann. § 29-28-105(a). One definition of "unreasonably dangerous" under Tennessee law is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it." *Id.* § 29-28-102(8). Even without evidence of a specific defect in Testim's *design*, therefore, the evidence regarding Auxilium's marketing of Testim and its warning (or lack thereof) regarding the drug's risks would allow a jury to find Testim to be dangerous to an extent beyond that which an ordinary consumer would expect. Thus although "design defect" may be a misnomer for Holtsclaw's claim, there is sufficient evidence in the record to support a strict products liability claim

against Auxilium under Tennessee law, regardless of how the claim is labeled.[4]

E. Tennessee Consumer Protection Act

The Tennessee Consumer Protection Act (TCPA) allows a consumer to bring an action where a TCPA violation has resulted in "an ascertainable loss of money or property . . . ." Tenn. Code Ann. § 47-18-109(a)(1). The TCPA does not, however, provide a remedy for personal injuries. *See, e.g.*, *Birdsong v. Eli Lilly & Co.*, No. 3:10-01182, 2011 WL 1259650, at *3 (M.D. Tenn. Mar. 31, 2011). Auxilium contends that Holtsclaw cannot recover under the TCPA for any economic damages he allegedly suffered because those "asserted damages . . . do not exist independently of the personal injuries that he suffered." *Fleming v. Janssen Pharm., Inc.*, 186 F. Supp. 3d 826, 834 (W.D. Tenn. 2016) (internal quotation marks and emendations omitted). In the cases against AbbVie, however, this Court interpreted a similar consumer protection statute to allow a consumer to recover economic losses, including the costs of purchasing AndroGel. *See In re: TRT*, 2017 WL 1836443, at *10. Holtsclaw alleges that he would not have purchased Testim but for Auxilium's misrepresentations about the drug's safety and efficacy. The cost of purchasing Testim is an "ascertainable" economic loss that is distinct from the damages resulting from his heart attack and therefore appears to be recoverable under the TCPA.

The district court in *Fleming* rejected the plaintiff's argument that he could recover damages under the TCPA based on the purchase price of the drug at issue, but it did so because "nothing in the record . . . indicate[d] Plaintiff's expenditures from purchasing [the drug]," *Fleming*, 186 F. Supp. 3d at 834, not because those

[4] In the bellwether case brought against AbbVie under Tennessee law, for example, the Court instructed the jury on a claim for "strict liability," without specifying a "design defect" or "failure to warn" theory.

expenditures resulted from the plaintiff's personal injury. Auxilium has not argued that there is inadequate support in the record of Holtsclaw's expenditures on Testim. The Court therefore concludes that Holtsclaw may pursue recovery of damages based on those expenditures under the TCPA.

F. Claims against Endo

Endo has moved for summary judgment on all claims brought against it. In its initial brief, Endo argued that summary judgment was warranted under Tennessee law, which generally prohibits product liability actions against "any seller, other than the manufacturer." Tenn. Code Ann. § 29-28-106. It is undisputed that Endo did not acquire Auxilium until after Holtsclaw suffered his heart attack and stopped using Testim, and Holtsclaw concedes that his claims against Endo are precluded if Tennessee law applies. But on this issue of successor liability, Holtsclaw contends that the applicable law is either the law of Pennsylvania, where Auxilium and Endo are incorporated, or Delaware law, which governs the agreement by which Endo acquired Auxilium. According to Holtsclaw, Pennsylvania and Delaware have adopted the so-called "product line" exception to the general rule that a successor company is not liable for the pre-acquisition conduct of its predecessor.[5] Under that exception, the successor may be strictly liable for injuries caused by defects in the product line of its predecessor if "[t]he successor undertakes to conduct the same manufacturing operation of the

[5] Holtsclaw maintains that it is unclear whether even the general rule applies in Delaware, but Delaware does appear to recognize the rule. *See In re Asbestos Litig. Estate of Franco v. CSX Transp., Inc.*, No. CV N13C-08-317 (ASB), 2015 WL 4399960, at *2 (Del. Super. Ct. July 13, 2015) (applying Delaware law and noting that "where one company sells or otherwise transfers all of its assets to another company, the latter is not liable for the debts and liabilities of the transferor, including those arising out of the former's tort[i]ous conduct.") (internal quotation marks omitted).

transferor's product lines in essentially an unchanged manner." *Childers v. Power Line Equip. Rentals, Inc.*, 452 Pa. Super. 94, 116, 681 A.2d 201, 212 (1996).

Endo contends that the product-line exception does not apply in this case, regardless of which state's law applies. The Court agrees and thus foregoes a choice-of-law analysis. *See Townsend v. Sears, Roebuck & Co.*, 227 Ill. 2d 147, 155, 879 N.E.2d 893, 898 (2007) ("A choice-of-law determination is required only when a difference in law will make a difference in the outcome."). The purpose of the product-line exception is to allow recovery for plaintiffs who would otherwise be "left remediless against a defunct corporation." *Brotherton v. Celotex Corp.*, 202 N.J. Super. 148, 159, 493 A.2d 1337, 1342 (Law. Div. 1985). It is therefore "an essential condition precedent to imposition of liability on a successor manufacturer under the product line exception that the successor have eliminated an effective remedy against the predecessor, as when a successor has purchased the predecessor's assets under an agreement requiring dissolution of the predecessor." Am. L. Prod. Liab. 3d § 7:28 (Aug. 2017 update); *see also S. Bend Lathe, Inc. v. Amsted Indus., Inc.*, 925 F.2d 1043, 1047 (7th Cir. 1991) ("The continuation of the predecessor corporation bars recovery from the successor under the product line rule in every decision we have found that considers the issue."). There is no dispute that Auxilium still exists as an operating company and no contention that Holtsclaw would be unable to seek recovery against Auxilium. Holtsclaw has pointed to no case in which a court applied the "product line" exception where a remedy was still available against the predecessor. The Court therefore grants summary judgment for Endo under the general rule that a successor is not liable for an injury allegedly caused by a product its predecessor manufactured.

Conclusion

For the reasons stated above, the Court grants Auxilium's motion to exclude the testimony of Drs. Jihad Abbas and Ardel Cagata [dkt. no. 34 in Case No. 14 C 5180] and its motion for summary judgment against plaintiff Isaac Owens [dkt. no. 29 in Case No. 14 C 5180]. The Clerk is directed to enter judgment dismissing with prejudice the Owens case, Case No. 14 C 5180. The Court also grants Endo's motion for summary judgment against plaintiff Steve Holtsclaw [dkt no. 34 in Case No. 15 C 3941] but otherwise denies defendants' motions [dkt nos. 34, 38, & 39 in Case No. 15 C 3941], except with respect to various items of expert testimony as discussed in the body of this opinion. The Holtsclaw case will proceed to trial as scheduled on November 6, 2017. The parties are directed to be prepared to advise the Court at the final pretrial conference on November 2, 2017 how the Court should select a replacement case or cases for the April 2018 trial slot for Auxilium/Endo.

Date: October 23, 2017

MATTHEW F. KENNELLY
United States District Judge