No. 21-55517

~~S273887~~

In the

United States Court of Appeals

for the

Ninth Circuit

MICHELLE HIMES; MARCIA BENJAMIN; and DANIEL BENJAMIN;

Plaintiffs-Appellants,

vs.

SOMATICS, LLC,

Defendant-Respondent.

Appeal from an Order of the United State District Court for the Central District of California, Case No. 2:17-cv-06686-RGK- JCx
Hon. R. Gary Klausner

APPELLANTS' REPLY BRIEF

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INTRODUCTION

Stripped to its core, Somatics' brief advocates for a legal landscape wherein the informed consent of patients is entirely irrelevant (i.e., "a red herring") and doctors are presumed to prescribe *and administer* electroshock therapy against their patients' will, *even though* such non-consensual administration would constitute tortious and criminal conduct and even though the doctors testified they would not have administered electroshock therapy had their patients (plaintiffs) refused consent.

Somatics' brief advances three primary arguments all of which are factually and/or legally flawed. *First*, Somatics posits there is now somehow an open debate as to whether it provided adequate warnings to plaintiffs' doctors, even though, in the district court, Somatics conceded it was "undisputed" that it did not provide warnings to plaintiffs' doctors concerning the risks at issue and, indeed, the district court likewise concluded that Somatics did not provide any such warnings. It is too late in the day for Somatics to take a factual position on appeal that is inconsistent with its admissions to the district court.

Second, Somatics misconstrues its burden under California's learned intermediary doctrine. California law is clear that, a manufacturer has a

continuing duty to warn consumers of known risks associated with its products and, given this is a prescription device, Somatics can *discharge* that duty by warning doctors as opposed to patients. Here, Somatics has admitted (and the district court has concluded) that Somatics did not provide warnings to doctors, and the doctors testified they were not aware of the risks of brain damage and permanent memory loss (and thus never passed on those warnings to plaintiffs). Accordingly, Somatics cannot seek shelter behind the learned intermediary doctrine under California Supreme Court precedent.

Third, Somatics contends that, under the learned intermediary doctrine, plaintiffs have not established proximate causation because their doctors purportedly testified that, even with stronger warnings, they would have, nevertheless, prescribed ECT to plaintiffs. Somatics attempts to paint plaintiffs in a dire light, priming the Court to buy into the notion that the doctors "knew best" and, under the learned intermediary doctrine, the only thing that matters is the doctors' prescribing decision. Simply put, Somatics seeks to take patient consent out of the causation equation, even though patient consent is an absolute necessity under established California Supreme Court precedent. As set forth in plaintiffs' opening

brief, even assuming the learned intermediary doctrine did apply, plaintiffs have established proximate causation because (a) the doctors testified that, had Somatics issued warnings about brain damage and permanent memory loss, it would have altered the doctors' conduct in that they would have relayed those warnings to plaintiffs and; (b) plaintiffs testified they would have refused treatment had they been so warned, accordingly, the doctors would not have and could not have legally administered ECT. Plaintiffs have more than met their causation burden. Had Somatics issued a proper warning, plaintiffs would not have been administered ECT and would not have suffered devastating permanent memory loss and brain damage caused by ECT.

ARGUMENT

I. Somatics Cannot for the First Time on Appeal Argue It Provided Adequate Warnings when, in its Summary Judgment Motion, it *Conceded* it Did Not Provide Warnings to Plaintiffs' Doctors and The District Court Made an Undisputed Finding of Fact That Somatics Did Not Provide Adequate Warnings

For the first time on appeal Somatics suggests it provided adequate warnings to plaintiffs' doctors and argues the district court never made a contrary finding. AB at 9-10 & 36-38. Somatics is wrong. In opposing

Somatics' motion for summary judgment, Plaintiffs' Separate Statement of Uncontroverted Facts No. 47 stated, in part, that "Somatics chose not to provide ***any warnings*** to plaintiffs' medical providers concerning ***any*** risks or adverse events associated with its ECT device." 2-ER-47–48 (emphasis added). Somatics responded to this factual contention as "**undisputed**." *Id.* (emphasis in original). Considering Somatics' concession, not surprisingly, the district court in the section of its order outlining the "undisputed facts" made the following findings of fact:

> Over the years, Somatics became aware, or should have been aware, of hundreds of complaints and reports of brain injury, permanent retrograde amnesia [and] cognitive impairment…associated with ECT. *Somatics never* investigated these complaints, nor did it submit adverse events to the FDA *or warn physicians and consumers of these risks*"

See 1-ER-4. After making the above-mentioned finding of fact, the district court in its discussion section of the Order went on to conclude that Somatics "did not provide any warnings to Dr. Frankel and Dr. Fidaleo concerning the risk of brain injury or permanent memory loss." 1-ER-9. Notwithstanding its admission and concession to the district court that it never provided adequate warnings to Plaintiffs' doctors (2-ER-47–48), Somatics in its Answering Brief appears to contend it somehow did

provide adequate warnings to the doctors. AB at 9-10 & 36-38. It is far too late in the day for Somatics to attempt to contest a fact it previously admitted was *undisputed* and which the district court correctly concluded was undisputed. 1-ER-4 & 2-ER-47–48. *Padgett v. Wright*, 587 F.3d 983, 986, n.2 (9th Cir. 2009) (refusing to consider arguments and issues that were not initially raised to the district court); *Coomes v. Edmonds School Dist. No. 15*, 816 F3d 1255, 1261, fn. 4 (9th Cir. 2016) (appellate courts will not consider evidentiary matters not presented or argued to the district court). Finally, it is well established that parties cannot contest on appeal matters to which they stipulated or that they otherwise conceded in the district court. *CDN Inc. v. Kapes*, 197 F3d 1256, 1259 (9th Cir. 1999) (stipulation limiting matters to be tried precluded raising on appeal matters not within scope of stipulation); *Baccei v. United States*, 632 F.3d 1140, 1149 (9th Cir. 2011).

Moreover, Somatics' representations are simply factually inaccurate. As way of example, in its Answering Brief, Somatics cites to the 16th Edition of its Manual, issued in **February 2013,** as proof it warned Dr. Fidaleo and Sharp Mesa Hospital of "neurological complications" associated with ECT. AB at 9, n.5 (citing to 2-ER-91). The problem is that Michelle Himes received her ECT treatment at Sharp Mesa Hospital between **April 2011**

and January 2012. Thus, the manual Somatics relies upon was issued more than a year ***after*** Himes had her treatment and has no relevance to the issue of whether Somatics provided adequate warnings to Sharp Mesa Hospital and Dr. Fidaleo prior to Himes' ECT procedures. The sole manual Somatics provided to Sharp Mesa Hospital at the time Himes received ECT was the 6th Edition (issued in 2001) and even Somatics' owner, Conrad Swartz, M.D. testified, this manual did not contain any warnings:

Q. Did Somatics provide any warnings concerning risk associated with its ECT devices to Sharp Hospital in 2002 when it sent over its manual, as well as the new ECT device?

A. No doubt Sharp received warnings in the form of the DGX[1] manual prior to 2002.

Q. My question was different. The manual that accompanied the ECT device for the Thymatron IV, did that manual contain any warning about the risks associated with the Thymatron IV device?

A. I believe it did not.

[1] DGX refers to a prior unrelated ECT device that Somatics sold and is not at issue in this case.

See 3-ER-387. During his deposition (3-ER-387–390), Dr. Swartz further elaborated that the 6th Edition of the Thymatron IV manual, which is the sole version that Sharp Hospital received prior to Himes' ECT procedures, *did not* contain any warnings:

> Q. …But version six, Doctor, if I asked you to point me to the page that contains the warnings and adverse events associated with the use of ECT, what page would I have to go to in this manual, Exhibit 3?
>
> A. There is no such page.

3-ER-390; see also 3-ER-510-564 (6th Edition Manual). Somatics' attempt to create a disputed fact on appeal that was unequivocally undisputed in the district court, and its attempt to muddy the waters even further by misrepresenting the record in trying to pass off the 16th Edition of the manual (published a year ***after*** Himes' ECT procedures) as somehow proof that it provided warnings to Sharp Mesa Hospital prior to Himes' procedures is troubling.[2]

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[2] As to the manual given to Northridge Hospital (the 5th Edition) (3-ER-566–610 & 4-ER-612–625), while there was some discussion of certain side effects, in the district court, Somatics agreed that it was "*undisputed*" that it

II. There is a Triable Issue of Fact as to the Issue of Proximate Causation Since Plaintiffs Have Demonstrated that, Had Somatics Provided Warnings Concerning Brain Injury and Permanent Memory Loss to Their Doctors, the Conduct of their Doctors in Securing Consent Would Have Altered and Plaintiff Would Not Have Been Administered ECT

It is clear from reading Somatics' brief that Somatics is under the *misconception* that plaintiffs are attempting to skirt their causation burden. Specifically, Somatics erroneously claims that plaintiffs are arguing that "they do not have to offer evidence that the inadequate warnings proximately caused their alleged injuries." AB at 19. Somatics clearly misapprehends plaintiffs' arguments and the applicable jurisprudence. Plaintiffs fully appreciate their causation burdens, which they have established irrespective of whether the learned intermediary doctrine applies.

Plaintiffs agree, California has adopted the learned intermediary doctrine, but disagree with the district court and Somatics' application of

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had not provided *any* warnings to plaintiffs' medical providers concerning any risks or adverse events associated with its ECT device. 2-ER-47–48. In addition, Somatics has not pointed to any evidence that it ever timely warned Northridge Hospital or Sharp Mesa Hospital of the risk of ***permanent* memory loss** and ***brain damage*** associated with its ECT device.

the doctrine. As outlined in the opening brief, California's learned intermediary doctrine provides that a medical device or drug manufacturer may "discharge" its duty to warn the consumer/patient by warning the patient's doctor. *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 994 (1971) ("the manufacturer of an ethical drug *discharges* its duty of warning if it adequately warns the doctor...") (emphasis added); *Love v. Wolf*, 226 Cal. App. 2d 378, 395 (1964) (same). Indeed, the Supreme Court has long held a drug manufacturer can seek shelter behind the learned intermediary doctrine only "***if*** adequate warning of potential dangers of a drug has been given to doctors." *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 65 (1973) (emphasis added). Subsequently, the Supreme Court clarified that the *only* "narrow exception" wherein the manufacturer is excused from providing warnings to an intermediary (i.e., doctor) and excused from warning the consumer is when the manufacturer knows that the intermediary is already aware or should be aware of the specific risk at issue and reasonably relies upon the intermediary to convey the warnings to the downstream user/patients. *Webb v. Special Elec. Co.*, 63 Cal. 4th 167, 187-188 (2016).

Here, Somatics conceded (and the district court made a finding of fact) that Somatics *never* provided any warnings to plaintiffs' doctors

concerning the risk of permanent memory loss and brain injury. Likewise, Somatics *never* presented any evidence (nor did it make any arguments) that the doctors at issue in this case were already aware of the risk of brain damage and permanent memory loss. To the contrary, the evidence established that the doctors were never informed or aware that ECT can cause brain damage or permanent memory loss, and both stated that, had they been so informed, they would have relayed such warnings to their patients (i.e., plaintiffs) as part of the informed consent process. 3-ER-337–340 & 344–345; 3-ER-363–364. Accordingly, Somatics failed to meet its burden to seek shelter behind the learned intermediary doctrine, i.e., it did not warn the doctors and did not present evidence that the -337doctors were independently aware of the risks of brain damage and permanent memory loss. Under these facts, the learned intermediary doctrine is inapplicable. *Hill v. Novartis Pharms. Corp.*, 944 F. Supp. 2d 943 (E.D. Cal. 2013) ("the doctrine, 'where it applies at all, applies only if a manufacturer provided adequate warnings to the intermediary.'"); *Stevens*, 9 Cal. 3d at 65 & 69.

Moreover, even if the learned intermediary doctrine did apply, plaintiffs have likewise established that Somatics' failure to warn their

doctors was a proximate cause of their ECT induced injuries. Specifically, both plaintiffs established that, had their doctors been adequately warned, both doctors *would have relayed the warnings to plaintiffs* and plaintiffs have testified they would not have consented to the ECT procedure had they been so warned, and thus would not have suffered the injuries induced by ECT. Under established California law as well as Circuit precedent cited *infra* and in the opening brief, this is more than sufficient to establish proximate causation.

Somatics, however (like the district court) seems to believe the only way plaintiffs can establish causation, is to show that the doctors would not have *prescribed* ECT. However, that is not the law. The injury here was not caused by the prescription of ECT, rather it was caused by the *administration* of ECT. Thus, if all that had occurred in this case was that the doctors prescribed ECT, but the plaintiffs decided not to consent to ECT and thus were not administered ECT, then no tort would have occurred, and no injury would have been caused by ECT. Accordingly, Somatics is incorrect to the extent it seeks to limit the inquiry to the issue of prescription only without any regard to the more important question of *administration*.

Rather than focusing exclusively on the prescription, circuit court precedent and California law have focused more broadly on whether the enhanced warning would have "altered the conduct" of the doctor (and the patient). *See Motus v. Pfizer Inc. (Roerig Div.)*, 358 F.3d 659, 661 (9th Cir. 2004) (holding the analysis in a *wrongful death* case is whether stronger warnings would have "*altered the conduct* of the prescribing physician") (emphasis added); *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1238 (9th Cir. 2017) ("In this case, viewing the evidence in the light most favorable to Plaintiffs, there is a genuine dispute of material fact as to whether Dr. Rich's *conduct* would have changed with warnings from Teva and GSK. Summary judgment was improper.") (emphasis added). *Changed conduct* would include the fact that, having received enhanced warnings, the doctor would have passed on those warnings to his patients (as both doctors testified they would have done in this case), and thus plaintiffs would have received stronger warnings and both plaintiffs have testified they would have refused to consent to the administration of ECT had they been so warned. This is more than sufficient to establish a triable issue of fact as to causation. *Georges v. Novartis Pharms. Corp.*, 988 F. Supp. 2d 1152, 1158 (C.D. Cal. 2013) (proximate causation established since doctor would have

passed on stronger warnings to patient and the patient testified with the enhanced warnings her use of the drug would have altered); *Hill v. Novartis Pharms. Corp.*, 2012 WL 6004161, at *4 (E.D. Cal. Nov. 30, 2012) ("*Hill I*"); (proximate causation burden met since, even though doctors testified they still would have prescribed the drug had they received enhanced warnings, they also testified they would have relayed those warnings to patients and plaintiff testified, had she been so warned, she would not have consented to drug's use); *Stanley v. Novartis Pharm. Corp.*, 11 F.Supp.3d 987, 1003 (C.D. Cal. 2014) (same); *Riera v. Somatics, LLC*, 2018 WL 6242154, at *11 (C.D. Cal. Sept. 14, 2018) (same).

For purposes of proximate causation, the following testimony given by the two doctors confirms that, had more detailed warnings concerning brain damage and/or permanent memory loss been provided to them by Somatics, their conduct would have changed:

A. Dr. Fidaleo (Himes' ECT Doctor)

Q. Doctor, you agree with me that the risk of brain injury is a serious risk?

A. I don't think it's a risk with the treatment, no.

Q. No. I'm asking -- I appreciate that. I'm asking a separate

question, Doctor. Assuming that a drug or a device causes brain injury, would you agree with me that is a serious risk.

A. *Well, if it causes brain injury then you would be reluctant to use it if we knew of it*.

See 3-ER-337 (emphasis added).

Q. And if a medication or a procedure had a risk of the patient losing the ability to formulate new memories, is that a risk that you would have alerted patients to?

A. Yeah. If you can't perform new memory, that would be a real problem. I mean, that means the person is functioning in a demented way. So that would not be a safe procedure. Okay.

* * *

Q. If Somatics had informed you that the use of their ECT device could potentially cause patients to lose the ability to formulate new memories, is that --

A. That would be significant. But I would have to see it also myself.

Q. But I'm asking you, Doctor, is that information you would have presented or at least informed your patients about?

A. *Yes, we would inform them*.

See 3-ER-338–340 (emphasis added).

Q. But you testified that had Somatics provided you warnings concerning either permanent memory loss, brain injury, or inability to formulate new memories that you would have relayed those warnings to your patients as a good doctor would?

A. *They would -- they would be in the informed consent*.

See 3-ER-344 (emphasis added).

Q. Absolutely. You agree with me that a patient who is present voluntarily in a hospital and is provided a medical option after being adequately informed, *that patient has the right to refuse treatment if they feel the risks outweigh the benefits*?

A. *Absolutely true*.

See 3-ER-345 (emphasis added). Notably, Himes (who was a voluntary patient) testified that, had she been so warned by her doctor concerning the risk of permanent memory loss and brain damage, she would not have consented to the ECT shock administrations. 5-ER-949.

The foregoing is more than sufficient to create a triable issue of fact as

to whether Somatics' failure to warn led to Himes consenting to being administered ECT and being injured by ECT. *First*, as outlined supra, Dr. Fidaleo testified that, had Somatics warned of brain injury, then he "*would be reluctant to use it if we knew of it*" (3-ER-337). This testimony alone is sufficient to create a triable issue of fact as to whether Dr. Fidaleo would have even prescribed, much less administered, ECT had Somatics issued an adequate warning. *Secondly*, and alternatively, even if Dr. Fidaleo had prescribed ECT, he testified he would provide enhanced warnings about brain damage and permanent memory loss had Somatics warned of these risks (3-ER-338–340 & 344); and confirmed that every fully informed patient has an absolute right to refuse treatment (3-ER-345). And, Himes has testified she would have refused the treatment had she been provided warnings about brain damage and permanent memory loss (5-ER-949 at ¶6). These facts are more than sufficient to create a triable issue of fact as to the issue of causation. At a minimum, these facts show an enhanced warning would have "altered the conduct" of Dr. Fidaleo in securing Himes' consent and, armed with the new warnings, Himes would not have consented to the administration of ECT and would have avoided its harms. *Georges*, 988 F. Supp. 2d at 1158; *Hill I,* 2012 WL 6004161, at *4; *Stanley*, 11

F.Supp.3d at 1003; *Riera,* 2018 WL 6242154, at *11; *see also Wendell*, 858 F.3d at 1238.

Somatics also makes an additional argument limited to Dr. Fidaleo (i.e., whether he relied or would have relied on Somatics' representations/warnings). See e.g., AB at 42, 44-46. This argument was *never* adjudicated by the district court, and thus is not appropriate for adjudication by this Honorable Court without the benefit of the district court's fact finding. *Wendell*, 858 F.3d at 1239 (refusing to adjudicate alternative issues advocated by the drug manufacturer appellee because the district court had not adjudicated those issues). Consistent with *Wendell*, this Honorable Court should not adjudicate in the first instance a fact intensive issue the district court has not ruled upon.

Even if this Honorable Court were to adjudicate this issue without the benefit of the district court's findings of fact, a review of the facts and the applicable jurisprudence confirms Somatics' alternative grounds for affirmance as to Himes are misplaced. Specifically, Somatics contends that, because Dr. Fidaleo testified he *does not recall* reading the manual, this must mean he never read the manual and that a stronger warning would not have altered his conduct. The facts, however, tell a different story. *First*,

Dr. Fidaleo *did n*ot testify that he did not read the manual, rather he merely testified he *did not recall* reading the manual and noted that the manual was made available to him by the hospital. *See* 3-ER-326. At this procedural juncture, where all inferences must be drawn in favor of the non-moving party, Himes, there is a triable issue of fact as to whether Dr. Fidaleo consulted the manual. *Mason v. SmithKline Beecham*, 2010 WL 2697173, *9 (C.D.Ill. July 7, 2010) (denying learned intermediary MSJ in a Paxil-suicide case and holding: "Nurse Schertz did not testify that she had never read the label; rather she '*did not recall*' whether she read it or not. At summary judgment stage all reasonable inferences are drawn in favor of non-moving party. Certainly it is reasonable to assume that Nurse Schertz did read the PDR and package insert at some point prior to prescribing it…") (emphasis added); *Grinnell v. Charles Pfizer & Co.*, 274 Cal. App. 2d 424, 441 (1969) (while no testimony was provided as to whether doctors had read the manufacturers label, the California Court of Appeal held that "*the jury could infer that the language of the insert was read by the doctors…and that they relied upon it*…") (emphasis added); *see also Toole v. Richardson-Merrell Inc.*, 251 Cal. App. 2d 689, 707–08 (1967) (even though doctor had not testified as to what specific statements or documents he had relied upon in

determining the safety of the drug (and had died by the time of trial), Court held that because the doctor at deposition testified he had been visited by sales representatives and that literature from the company had come to his attention, the jury *can infer* that the doctor had relied upon the drug manufacturers representations).

Second, Dr. Fidaleo testified the hospital nurse technician who conducts the ECT procedure read the Somatics manual, that the hospital nurse technician *was trained by Somatics sales representatives* on how to use Somatics' ECT machine and the hospital nurse technician then trained Dr. Fidaleo on its use. 3-ER-326; *see also* 3-ER-333 & 335. Thus, even if we were to assume that Dr. Fidaleo did not himself read the manual (which as discussed *supra* we cannot do at this procedural posture), the evidence is clear that the hospital nurse technician who administered the ECT and *who trained Dr. Fidaleo* did in fact read the manual, and because the manual had no discussions of risks and did not provide any warnings, no warnings were provided to the hospital or to Dr. Fidaleo. *Id*. Accordingly, at a minimum, Dr. Fidaleo relied upon the manual *indirectly* through his nurse technician who read the label, trained him and who administers the ECTs. *See American T. Co. v. California etc. Ins. Co.* 15 Cal.2d 42, 67 (1940) (reliance

can be established through evidence of *indirect* reliance); *Varwig v. Anderson-Behel Porsche/Audi, Inc.*, 74 Cal.App.3d 578, 581 (1977) (same); *see also Georges v. Novartis Pharms. Corp.*, 2013 WL 5217198, at *9 (C.D. Cal. Apr. 4, 2013) (noting under California law the manufacturers duty to warn runs not only to the prescribing physician but also to *other* medical providers who are in a position to reduce the risk of harm in accordance with instructions and warnings). The law in other jurisdictions is in accord. *See Holley v. Burroughs Wellcome Co.*, 74 N.C. App. 736, 746, 330 S.E.2d 228, 235 (1985) (collecting cases and holding that duty to warn extends to warning the *doctor's nurse* who had read and relied on the label); *Knipe v. SmithKline Beecham*, 583 F.Supp.2d 602, 621 (E.D.Pa. 2008) (denying summary judgment motion because, even though the prescribing physician had not been directly exposed to the drug manufacturer's promotional material, he relied upon "other sources," including other physicians, which "may have considered Paxil promotional material" and that any of these sources "could have resulted in him relying upon in some attenuated fashion, the substance of [drug manufacturer's] alleged misrepresentation regarding Paxil");

Third, contrary to Somatics' argument, the California Supreme Court

has held that the manual or label is not the sole, nor even the most effective, means that medical device companies communicate with physicians. *Stevens*, 9 Cal. 3d at 67 ("Many prescribing physicians would not come into contact with package inserts or warning labels attached to the drug when the pharmacist filed the prescription… It was within reason for the jury to find such warnings inadequate and to hold Parke, Davis liable for failing to reasonably warn of the drug's danger."). Moreover, device companies communicate with surgeons through a myriad of means, including, promotional literature, sales representatives, "Dear Doctor" letters, seminars, and medical journal articles. *Stevens*, 9 Cal.3d at 67-69 (sales representatives are "a highly effective means of promoting the use" and "to disseminate information as to the drug's hazard"). Thus, whether or not a doctor read a package insert does not serve as a litmus test for causation, rather, the key question is whether the doctor relies upon the device manufacturer's safety and risk representations, irrespective of the venue in which those representations occurred. *Stevens*, 9 Cal.3d at 67. Indeed, Dr. Fidaleo testified he receives "dear doctor" letters from device manufacturers updating and warning him of risks associated with their devices and that he relies upon these warning updates (3-ER-336); he

further testified if a device manufacturer had alerted him to new safety risks, he would relay those to his patients (3-ER-337–340); and also testified if Somatics had warned him about the risks of brain injury or permanent memory loss, he and the hospital would have included those risks in his inform consent forms to patients (3-ER-342–344). However, Somatics never timely issued any such safety updates and as Somatics testified, the first time it issued an amended and updated warning to its customers concerning risks of brain injury and permanent memory loss was in 2018 (years after the filing of this lawsuit). 3-ER-410–420; 4-ER-650–656 (copy of the 2018 enhanced warnings); 2-ER-48.

The foregoing facts confirm that, at a minimum, there is a triable issue of fact as to whether Dr. Fidaleo relied upon Somatics' representations and whether he would have relied upon enhanced warnings had Somatics issued any. *Wendell*, 858 F.3d at 1238 (reversing summary judgment because, even though the doctor testified that "it is not his 'regular practice to look at drug labeling[,]'" the doctor (like Dr. Fidaleo in this case) testified he does rely upon warnings, including Dear Doctor letters issued by drug manufacturers); *Grinnell*, 274 Cal. App. 2d at 441 ("the jury could infer that the language of the insert was read by the

doctors…and that they relied upon it…"); *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 99 (2008) (even though the doctor provided a declaration that he did not rely upon the drug label, the court reversed summary judgment because there was a triable issue of fact as to "the accuracy of [the doctor's] recollection" based on his prior testimony that he may have been exposed to and read the label during his residency).[3]

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[3] Somatics' reliance upon this Honorable Court's *Motus* decision is misplaced because, in that case, the doctor affirmatively testified that "he did not read the warning label" and indeed plaintiff *conceded* that the doctor had not read the label and did not rely upon information given by the drug company's sales representatives. *Motus,* 358 F.3d at 661. Unlike *Motus*, in our case, as discussed *supra*, Dr. Fidaleo never affirmatively testified that he did not read the label, rather he testified he did not recall if he read the label. Moreover, unlike *Motus*, Himes is not conceding that Dr. Fidaleo never read the label and indeed she has presented evidence that he at a minimum directly or indirectly relied upon the label through his nurse technician who read the label and trained him (and who in turn was trained by a Somatics sales representative); and most importantly, Dr. Fidaleo testified that he pays close attention to warnings and dear doctor letters that he receives from manufacturers and would relay any such warnings to patients. Thus, the facts of this case are more like *Wendell* (wherein this Court held that summary judgment was inappropriate) and not at all akin to *Motus*. *See Wendell*, 858 F.3d at 1238.

Somatics also relies upon *Ramirez v. Plough, Inc.*, 6 Cal. 4th 539 (1993), but *Ramirez* actually confirms that Dr. Fidaleo's second-hand reliance on the label sufficiently links the chain of causation. *Ramirez* dealt with an over-the-counter drug manufacturer that failed to issue warnings in Spanish. *Id*. at 555-56. The court determined causation was lacking because the minor-plaintiff's mother, who was literate only in Spanish, did

Somatics in passing also argues it had a "Patient Information Pamphlet" that Dr. Fidaleo purportedly never read. AB at 9-10. However, Somatics has not established it ever provided the Pamphlet to Dr. Fidaleo or to Sharp Hospital, nor did it even attach the Pamphlet as an exhibit to its MSJ, and it is not part of the appellate record. In fact, when plaintiffs subpoenaed Sharp Hospital for all documents it had received from Somatics, Sharp Hospital never identified or produced Somatics' Patient Information Pamphlet. *See* 3-ER-259 at ¶ 3. And most importantly, Somatics' owner testified that Somatics likely *never* sent the Patient Information Pamphlet to Dr. Fidaleo's hospital, Sharp Hospital. See 3-ER-384-385. Dr. Fidaleo cannot be expected to read something Somatics *never* provided to him or to his hospital, nor can the District Court or this Court be expected to speculate about the relevance of a document Somatics never bothered to include with its summary judgment motion and is not part of the appellate record.

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not read the label, and importantly, she did not have the English-language label translated to her. *Id.* Thus, implicit in the Court's analysis is that causation could have been established if the information in the label was relayed to her by someone else. Here, plaintiffs have presented evidence of this form of reliance, and more.

B. Dr. Frankel (Benjamin's ECT Doctor)

A review of the deposition of Dr. Frankel (like Dr. Fidaleo) confirms he was not adequately informed about the risks of brain injury and permanent memory loss and, had he been adequately warned by Somatics, he would have, at a minimum, altered his conduct and would have passed on stronger warnings to his patients (and as previously discussed, Benjamin has testified she would not have consented to the administration of ECT had she been so warned):

Q. And from time to time either doctors or sometimes the manufacturer will discuss these new risks either in the literature or at conferences or through labeling changes; correct?

A. Correct.

Q. And if you are alerted to new risks concerning a drug that you prescribe to patients or a device that you utilize, you would pay attention to that; correct, Doctor?

A. Correct.

Q. And if the manufacturer warned of a new serious risk, you would relay that risk to patients; correct?

A. Correct.

Q. You agree with me, Doctor, that if a drug or a device had a risk of brain injury, that that would be a serious risk?

A. Yes.

See 3-ER-363. Dr. Frankel further testified:

Q. Drawing your attention to Exhibit 9, does this appear to be the consent form that you utilized with patients?[4]

A. Yes, it is.

Q. In 2012?

A. Yes. Uh-huh.

* * *

Q. Now, does this consent form warn of permanent memory loss, Doctor?

A. I don't believe it does.

Q. And does this consent form warn of permanent brain damage, Doctor?

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[4] A copy of the consent form used with Ms. Benjamin is attached at 3-ER-490. A copy of the consent form used with Ms. Himes is attached at 3-ER-502. Neither consent document warns of permanent memory loss or brain damage.

A. Not that I'm aware of.

Q. If Somatics had informed you that ECT could be linked to permanent brain damage in some patients, is that information that you would have advised patients about, Doctor?

A. If it were the case I would definitely advise patients in terms of giving informed consent.

See 3-ER-364. Notably, Benjamin (who was also a voluntary patient) testified that, had she been so warned by Dr. Frankel concerning the risk of permanent memory loss and brain damage, she would not have consented to the ECT shock administrations. 5-ER-945 at ¶18; and 2-ER-293. For the same reasons articulated supra with respect to Dr. Fidaleo (and in plaintiffs' opening brief), the foregoing testimony is more than sufficient under California law to create a triable issue of fact as to whether Somatics' failure to adequately warn was a substantial factor in plaintiffs consenting to being administered (and injured) by ECT.

III. This Case Presents the Perfect Opportunity for this Honorable Court to Clarify the Discord in the District Courts and To Confirm that, Under California Law and Established Constitutional Principles, Even Under the Learned Intermediary Doctrine, the Consent of the Patient and How a Patient Would Have Responded to a Stronger Warning from their Doctor Remains Germane to the Issue of Proximate Causation

Plaintiffs pause to note the dichotomy that exists between some of the district court cases cited by Somatics and those cited by plaintiffs concerning the issue of proximate causation. Plaintiffs respectfully contend the cases that purport to rely on *Motus* for the proposition that the *only* way a plaintiff can establish proximate causation is to show that the doctor would not have prescribed ECT (or the drug), have been decided erroneously and misread *Motus*. In *Motus* as well as in *Wendell*, this Honorable Court simply held that, to establish proximate causation when the learned intermediary doctrine is at play, the plaintiff must show that the "conduct" of the doctor would have been "altered" or "changed" had he or she received stronger warnings from the manufacturer. *Motus*, 358 F.3d at 661 ("*altered the conduct*" of the doctor); *Wendell*, 858 F.3d at 1238 ("[doctor's] *conduct* would have changed"). Thus, while showing that a doctor would not have prescribed a drug is one path to establish causation, this is not the sole means by which one can show altered conduct as the district court decisions plaintiffs rely upon have recognized. Rather, altered conduct can include demonstrating that the doctor would have relayed enhanced warnings, and, armed with the enhanced warnings, the

patient/plaintiff would have refused consent to the treatment. As explained in plaintiff's opening brief, perhaps one of the reasons the district court decisions Somatics relies upon such as the district court decisions in *Motus*[5] and *Latiolais*[6] did not consider the testimony/consent of the patient is that they were "*wrongful death*" cases so the plaintiffs could not provide testimony as to what the deceased patient would have done had the doctor relayed enhanced warnings. Thus, the primary path by which a plaintiff in a wrongful death pharmaceutical products liability case can establish proximate causation is by establishing the doctor would not have prescribed the drug. Again, Benjamin and Himes are alive and have provided unrefuted testimony that they would not have consented to the administration of ECT had they been warned by their doctors regarding the risks of permanent memory loss and brain damage. They were able to provide the testimony that plaintiffs in wrongful death cases such as *Motus* and *Latiolais* were unable to provide.[7]

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[5] *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984 (C.D. Cal. 2001).
[6] *Latiolais v. Merck & Co.*, 2007 WL 5861354 (C.D. Cal. Feb. 6, 2007).
[7] In its Brief, Somatics complains that the testimony and declaration of Himes and Benjamin are self-serving and an affront to the learned intermediary doctrine. California routinely allows plaintiffs to provide

This case is perhaps the best example of the misinterpretation of *Motus* where the district court inferred (without basis) that, even if the two doctors had decided to prescribe ECT after receiving enhanced warnings, they would also have proceeded to *administer* ECT. Yet there is a crucial step from the *prescription* of ECT to the *administration* of ECT—that step is the *informed consent* of the patient. A step and process that is at the heart of our medical system, common law and indeed our statutory scheme.[8] The fact the district court completely ignored the necessity of plaintiff's informed consent in the administration of ECT for causation analysis and the fact that Somatics in its Answering Brief refers to patient consent as a "red herring" demonstrates how far we have come from one of the bedrocks of our free society. To see the destruction of such a core value

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"self-serving" testimony as to how they would have altered their conduct in failure to warn cases. *Colombo v. BRP US Inc.*, 230 Cal. App. 4th 1442, 1454 (2014) (collecting cases). And, the declarations do nothing to undermine the learned intermediary doctrine since plaintiffs have established that, had Somatics warned their doctors, their doctors in turn would have passed on the enhanced warnings to them, and armed with the enhanced warnings, they would not have consented to the ECT procedures. This is consistent with the learned intermediary doctrine as it maintains the doctor/intermediary within the causation and warning chain.

[8] CAL. WELF. & INS. CODE § 5326.85 (requiring informed consent of patient prior to ECT administration); *Cobbs v. Grant*, 8 Cal. 3d 229, 242 (1972).

one simply needs to juxtapose Somatics' argument that the ***consent of the patient is irrelevant*** as to whether she agrees to have electricity run through her brain at amperage that is one-fifth the amount used for the electric chair and that *only* the decision of the doctor to prescribe is relevant, compared to the following from the Fourth Circuit:

> Forcible medication with antipsychotic drugs implicates individual rights to freedom from physical invasion and freedom of thought as well as the right to privacy protected by the Constitution and the common law.
>
> The right to be free of undesired physical touching traces its origins to the English common law of the middle thirteenth century…and today is reflected in the tort of battery which protects the individual against even the slightest unconsented touching…The right to be free of unwanted physical contact and its ancient common law origins has been recognized by the Supreme Court:
>
> > No right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.
>
> The right to avoid unwanted touching of one's person forms the basis of the doctrine of informed consent. The doctrine of informed consent provides that a patient has a right to be informed of the value and possible consequences of a treatment and to refuse or consent to that treatment.

United States v. Charters, 829 F.2d 479, 490–92 (4th Cir. 1987) (internal

citations omitted). These constitutional principles concerning the importance of patient autonomy and informed consent have been echoed by California courts including *Riese v. St. Mary's Hosp. & Med. Ctr.*, 209 Cal. App. 3d 1303, 1317 (1987) and the Supreme Court in *Cobbs*, 8 Cal. 3d at 242–43 ("In many instances, to the physician, whose training and experience enable a self-satisfying evaluation, the particular treatment which should be undertaken may seem evident, but it is the prerogative of the patient, not the physician, to determine for himself the direction in which he believes his interests lie.")

The district court impermissibly ignored the fact that Himes and Benjamin had an absolute constitutional and statutory right to refuse the administration of ECT after being fully informed of its risks by their doctors. And now Somatics is asking this Honorable Court to affirm the district court's ruling and create a legal landscape in which the decision of whether an adult patient is to have mind altering and brain injury inducing electrical shock administered to their brain is placed exclusively in the hands of doctors, without regard to the ultimate consent of the patient.

CONCLUSION

Himes and Benjamin came to their respective doctors seeking hope and a remedy for their depression and anxiety. They consented to ECT after being assured by their doctors that it was safe and that any risks were transitory. Yet what Somatics knew and did not share with the doctors (and the doctors in turn could not share with Himes and Benjamin) is that its ECT machine is linked to risks of permanent injuries, including permanent memory loss and brain damage, injuries that continue to plague Himes and Benjamin to this day. It has robbed them of a most treasured asset, their memories and cognitive skills. Himes and Benjamin have presented sufficient evidence to allow a jury to adjudicate the issue of proximate causation. Let us not add salt to their wounds by telling them that irrespective of California's civil, criminal, statutory and common laws that protect and indoctrinate the right of patients to give free informed consent (especially in matters involving shock therapy) that somehow now under the tort system as Somatics and the district court interpreted it, the consent of Himes and Benjamin is irrelevant and immaterial to the issue of whether they would have been administered shock therapy. The district court's Order entered May 14, 2021, and resulting May 21, 2021, judgment

should be reversed and plaintiffs' Second, Third and Fifth Causes of Action should be reinstated.

Dated: November 17, 2021 Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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CERTIFICATE OF FILING AND SERVICE

Pursuant to Federal Rule of Appellate Procedure 25, I hereby certify that on November 17, I electronically filed the foregoing Appellants' Reply Brief via ECF, and service was accomplished on counsel of record by that means.

/s/ *Bijan Esfandiari*
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