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No. S273887

# IN THE SUPREME COURT

*OF THE*

# STATE OF CALIFORNIA

MICHELLE HIMES

*Plaintiff-Appellant*

v.

SOMATICS, LLC

*Defendant-Respondent*

Question Certified by Request of the United States Court of Appeals

for the Ninth Circuit, Case No. 21-55517

## APPLICATION BY CALIFORNIA LIFE SCIENCES TO FILE AN AMICUS CURIAE BRIEF IN SUPPORT OF SOMATICS, LLC

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Pursuant to California Rules of Court, rule 8.520(f), California Life Sciences[1] ("CLS"), respectfully seeks leave to file the accompanying amicus curiae brief. CLS and its counsel certifies that no party or party's counsel authored this brief in whole or in part, no party or party's counsel made a monetary contribution intended to fund the preparation or submission of this brief, and no person or entity other than amicus curiae, its members, or its counsel made such a monetary contribution.

CLS is the state's largest life sciences membership organization, advocating for the sector and its innovation pipeline. For more than 30 years, CLS has served the community by supporting companies of all sizes, from early-stage innovators and startups to established industry leaders in the fields of biotechnology, pharmaceuticals, and medical device technology.[2] CLS works to shape public policy, improve access to breakthrough technologies, educate lawmakers, and advance equity within our ecosystem by championing innovative solutions for the most pressing medical challenges of our times.

This case presents a question of critical importance to CLS. Therefore, CLS requests permission to file an amicus curiae brief regarding the key legal question in this

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[1] California Life Sciences ("CLS") and their counsel certifies that they are trade association with no parent corporations and that no entity or person has a 10% or greater ownership interest in CLS, and they do not know of any person or entity, other than the parties themselves, that has a financial or other interest in the outcome of the proceeding that the Justices should consider in determining whether to disqualify themselves. A list of CLS's members can be found at https://www.califesciences.org/member-directory.

[2] In 2015, BayBio and the California Healthcare Institute, also known as CHI, merged to form the California Life Sciences Association, or CLSA. In 2021, CLSA dropped "Association" from its name and became CLS. All references to CLS, and its history of advocacy and service, in this document include that of its predecessor organizations. (See *BayBio and CHI Merge Making California Life Sciences Association the Largest Life Sciences Advocacy Group in US*, BioSpace, May 14, 2015 https://www.biospace.com/article/baybio-and-chi-merge-making-california-life-sciences-association-the-largest-life-sciences-advocacy-group-in-u-s-/ (last visited November 7, 2022, 1:33 PM).)

case, which revolves around the causation element in a failure-to warn case against a manufacturer involving a medical device prescribed by a learned intermediary. The Ninth Circuit found that there is no controlling state precedent to guide them on this issue adding "the question implicates important policy concerns." (*Himes v. Somatics, LLC*, 29 F.4th 1125, 1127 (9th Cir. 2022)) CLS, which represents numerous medical device manufacturers, is concerned that the plaintiff-appellant is attempting to broaden the causation element in a failure-to warn case to such a degree that it would substantially weaken the learned intermediary doctrine. Since the learned intermediary doctrine applies to both prescription medical devices and prescription pharmaceuticals, this case has the potential to negatively impact CLS's diverse biopharmaceutical and medical device manufacturing membership. In its decades of public policy advocacy, CLS has successfully fought legislative attempts to substantially weaken the learned intermediary doctrine in the California Legislature and, therefore, believes it can provide useful information to the Court regarding this important public policy issue. CLS, therefore, respectfully requests that the Court accept the accompanying brief for consideration in this case.

Respectfully submitted,

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DATED: November 17, 2022

## CERTIFICATE OF SERVICE

I certify that:

- I am a resident of the State of California and over the age of eighteen years, and not a party to the within action.

  -And-

- My business address is 1215 K Street, Suite 1100, Sacramento, CA, 95814.

  -And-

- On November 17, 2022, I served the following document(s) described as:

**APPLICATION BY CALIFORNIA LIFE SCIENCES TO FILE AN AMICUS CURIAE BRIEF IN SUPPORT OF SOMATICS, LLC,**

on the interested parties in this action, as follows, by filing and serving the foregoing through:

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**(X) BY FIRST-CLASS MAIL**: I enclosed said document(s) in a sealed envelope or package to each addressee set forth below. I am readily familiar with the firm's practice of collection and processing correspondence for mailing. Under that practice it would be deposited with the U.S. postal service on that same day with postage thereon fully prepaid at Sacramento, California in the ordinary course of business.

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I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct and that this proof of service is executed at Sacramento, California on November 17, 2022.

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No. S273887

# IN THE SUPREME COURT

*OF THE*

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MICHELLE HIMES

*Plaintiff-Appellant*

v.

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**BRIEF OF CALIFORNIA LIFE SCIENCES**
**AS AMICUS CURIAE**

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## CERTIFICATE OF INTERESTED ENTITIES OR PERSONS

California Life Sciences (CLS") and their counsel certifies that no party or party's counsel authored this brief in whole or in part, no party or party's counsel made a monetary contribution intended to fund the preparation or submission of this brief, and no person or entity other than amicus curiae, its members, or its counsel made such a monetary contribution. Further, CLS and their counsel certifies that they are trade association with no parent corporations and that no entity or person has a 10% or greater ownership interest in CLS, and they do not know of any person or entity, other than the parties themselves, that has a financial or other interest in the outcome of the proceeding that the Justices should consider in determining whether to disqualify themselves. A list of CLS's members can be found at https://www.califesciences.org/member-directory.

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DATED: November 17, 2022

## CERTIFIED QUESTION

> "Under California law, in a claim against a manufacturer of a medical product for a failure to warn of a risk, is the plaintiff required to show that a stronger risk warning would have altered the physician's decision to prescribe the product? Or may the plaintiff establish causation by showing that the physician would have communicated the stronger risk warnings to the plaintiff, either in their patient consent disclosures or otherwise, and a prudent person in the patient's position would have declined the treatment after receiving the stronger risk warning?" (*Himes v. Somatics, LLC*, 29 F.4th 1125, 1127 (9th Cir. 2022).)

## INTEREST OF AMICUS CURIAE

California Life Sciences ("CLS") is the state's largest life sciences membership organization, advocating for the sector and its innovation pipeline.[3] For more than 30 years, CLS has served the community by supporting companies of all sizes, from early-stage innovators and startups to established industry leaders in the fields of biotechnology, pharmaceuticals, and medical device technology.[4] In addition, CLS

[3] California Life Sciences ("CLS") certifies that no party or party's counsel authored this brief in whole or in part, no party or party's counsel made a monetary contribution intended to fund the preparation or submission of this brief, and no person or entity other than amicus curiae, its members, or its counsel made such a monetary contribution. Further, CLS certifies that they are trade association with no parent corporations and that no entity or person has a 10% or greater ownership interest in CLS, and they do not know of any person or entity, other than the parties themselves, that has a financial or other interest in the outcome of the proceeding that the Justices should consider in determining whether to disqualify themselves. A list of CLS's members can be found at https://www.califesciences.org/member-directory.

[4]In 2015, BayBio and the California Healthcare Institute, also known as CHI, merged to form the California Life Sciences Association, or CLSA. In 2021, CLSA dropped

works closely with universities, academic and research institutions, the investment community, and other critical partners that promote this vibrant sector. CLS works to shape public policy, improve access to breakthrough technologies, educate lawmakers, and advance equity within our ecosystem by championing innovative solutions for the most pressing medical challenges of our times.

This case presents a question of critical importance to CLS. The key legal question in this case revolves around the causation element in a failure-to warn case against a manufacturer involving a medical device prescribed by a learned intermediary. The Ninth Circuit found that there is no controlling state precedent to guide them on this issue adding "the question implicates important policy concerns." (*Himes v. Somatics, LLC* at 1127.) CLS, which represents numerous medical device manufacturers, is concerned that the plaintiff-appellant is attempting to broaden the causation element in a failure-to warn case to such a degree that it would substantially weaken the learned intermediary doctrine. Furthermore, since the learned intermediary doctrine applies to both prescription medical devices and prescription pharmaceuticals, this case has the potential to substantially impact CLS's membership. In its decades of public policy advocacy, CLS has successfully fought legislative attempts to substantially weaken the learned intermediary defense in the California Legislature and, therefore, believes it can provide useful information to the Court regarding this important public policy issue.

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"Association" from its name and became CLS. All references to CLS, and its history of advocacy and service, in this document include that of its predecessor organizations. See *BayBio and CHI Merge Making California Life Sciences Association the Largest Life Sciences Advocacy Group in US*, BioSpace, May 14, 2015 https://www.biospace.com/article/baybio-and-chi-merge-making-california-life-sciences-association-the-largest-life-sciences-advocacy-group-in-u-s-/ (last visited November 1, 2022).

## INTRODUCTION AND SUMMARY OF ARGUMENT

This case is an attempt by the plaintiff-appellant to weaken the learned intermediary doctrine in the courts and we urge the Court to reject this attempt, just as the California Legislature rejected legislative attempts to substantially weaken the learned intermediary doctrine via legislation introduced in the California State Assembly in 2008. The district court applied the correct common law causation standard when it granted summary judgment in favor of Somatics after concluding that the plaintiff-appellant failed to establish causation due to an absence of evidence that stronger warnings would have affected their physician's decision to prescribe electroconvulsive therapy ("ECT") to the plaintiff-appellant. On appeal, plaintiff-appellant contends that they established causation through testimony of the prescribing physicians that, had Somatics given them stronger warnings, they would have communicated those warnings to the appellant who, in turn, claimed they would not have consented to the procedures. CLS urges the court to reject the contention of the plaintiff-appellant that causation can be established by alleging that a physician *would* have communicated the stronger warning to the patient *and* the plaintiff-appellant *would* have declined the treatment after receiving the stronger warning, because it relies on a manufacturer's speculation as to what *this specific patient would* do based on what a *provide*r *would* do. This speculative and subjective standard is contrary to the intention behind the learned intermediary doctrine that the doctor "be the intervening party in the full sense of the word" and "unaffected by the manufacturer's control." (*Bigler-Engler v. Breg, Inc.* (2017) 7 Cal.App.5th 276, 318 citing *Fogo v. Cutter Laboratories, Inc.* (1977) 68 Cal.App.3d 744, 754-755.) Therefore, the district court correctly applied the common law standard for causation in a failure to warn case under the learned intermediary doctrine. The causation standard proposed by the plaintiff-appellant would substantially weaken the learned intermediary doctrine. Just as the California Legislature rejected previous legislative attempts to weaken the learned intermediary doctrine, we urge the Court to do the same.

In addition, CLS urges the Court to reject the plaintiff-appellant's proposed causation standard on public policy grounds because of the potential for the decision to have a negative impact on California's vibrant life science sector and its development of novel therapies for rare diseases which often languish in the early-stage pipeline because of a lack of funding. In short, when biomedical research is hampered by a lack of funding, patients, especially those living with a rare disease, are the ones that suffer the most. CLS, therefore, urges the Court to reject the plaintiff-appellant's attempt to substantially weaken the learned intermediary doctrine, to better protect California's vibrant life science community, but most importantly, the patients they serve around the world.

## ARGUMENT

### I. The District Court Applied the Correct Common Law Causation Standard, When it Concluded That the Plaintiff-Appellant Failed to Establish Causation in a Failure to Warn Case Against a Manufacturer Due to an Absence of Evidence That Stronger Warnings Would Have Affected Their Learned Physicians' Decision to Prescribe, Because the Standard Applied is Consistent With the Intent Behind the Doctrine.

The key legal question in this case revolves around the causation element in a failure-to warn case against a manufacturer involving a medical device prescribed by a learned intermediary. California law in a "failure-to-warn case requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about." (*T. H. v. Novartis Pharms. Corp.*, (2016) 245 Cal.App.4th 589, 600 citing *Anderson v. Owens–Corning Fiberglas Corp.* (1991) 53 Cal.3d 987, 1002.) Thus, in California the duty to warn "runs to the physician, not the patient. This is known as the learned intermediary doctrine." (*Id*. quoting *Valentine v. Baxter Healthcare Corp.* (1999) 68 Cal.App.4th 1467, 1483.) Under the learned intermediary doctrine in

California, “if adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure [*sic*] that the warning reaches the doctor's patient for whom the drug is prescribed.' " (*Bigler-Engler v. Breg*, at 318 citing *Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51, 65.) Though this case involves a medical device prescribed by a learned intermediary, as opposed to prescription drugs, in California the learned intermediary doctrine applies when “medical devices are supplied in the context of the doctor-patient relationship” (*Webb v. Special Electric Co., Inc.*, (2016) 63 Cal.4th 167, 187.)

One explanation for the wisdom of the learned intermediary doctrine is that the “doctor is *intended to be an intervening party in the full sense of the word*. Medical ethics as well as medical practice dictate independent judgment, *unaffected by the manufacturer's control,* on the part of the doctor.” (*Bigler-Engler v. Breg*, at 319, italics added, citing *Fogo v. Cutter Laboratories* at 754-755.) Here, it is clear that the district court correctly granted summary judgment in favor of Somatics after concluding that the plaintiff-appellant failed to establish causation due to an absence of evidence that stronger warnings would have affected their physicians’ decision to prescribe ECT. If a plaintiff can establish causation by showing that a physician *would* have communicated the stronger warning to the patient *and* that a prudent person in the patient’s position *would* have declined the treatment after receiving the stronger warning, the learned intermediary defense would be substantially weakened because it relies on the manufacturer’s *speculation* as to what a *patient would* do based on what a *provide*r *would* do. (*See T. H. v. Novartis Pharms. Corp.*, at 600-01. “A manufacturer is not required to warn about speculative harm.”) Further, even though the question certified by the Ninth Circuit centers around an *objective* standard as to what a *prudent* person would have done, the plaintiff-petitioner’s opening brief focuses on the *subjective* state of mind of the plaintiff, which would require even more speculation on the part of a manufacturer as to what *a specific patient* would do, in reaction to what their provider would do. (See *Himes v. Somatics, LLC,* Opening Brief (OB) at 65 “the subjective testimony of the plaintiff that

she would not have undergone the procedure had Somatics adequately warned of the risk of brain injury and permanent memory loss, is sufficient to establish causation.") This standard of establishing causation would require a manufacturer to speculate about the subjective state of mind of any given patient, as opposed to a prudent person, and would be contrary to the intention behind the learned intermediary doctrine that the doctor "*be the intervening party in the full sense of the word*" and "*unaffected by the manufacturer's control*." (*Bigler-Engler v. Breg*, at 319, italics added, citing *Fogo v. Cutter Laboratories*, at 754-755.)

Therefore, the district court correctly applied the common law standard for causation in a failure to warn case under the learned intermediary doctrine. CLS is concerned that the plaintiff-appellant is attempting to change the causation standard in the judiciary in such a way that would substantially weaken the learned intermediary doctrine, but we urge the Court to reject this attempt just as the California Legislature has rejected such attempts in the past.

## II. The Court Should Reject Plaintiff-Appellant's Attempt to Weaken the Learned Intermediary Defense Just as the California Legislature Soundly Rejected Assembly Bill 2690 (Krekorian, 2007-2008 Reg. Session) in 2008.

### A. The Legislative History of Assembly Bill 2690 (Krekorian, 2007-2008 Reg. Sess.) Shows that the California Legislature Rejected Previous Attempts to Weaken the Learned Intermediary Doctrine.

In 2008, Assembly Bill No. 2690 (Krekorian, 2007-2008 Reg. Sess.) ("AB 2690") was introduced in the California State Assembly. The bill would have amended the California Civil Code, by adding Section 1714.46, to read:

> "Manufacturers of prescription pharmaceutical products shall not be relieved of a duty to warn consumers of the risks and side effects solely

> because the product was prescribed to a patient by a physician." (AB 2690, as introduced.[5])

The introduced language in the bill was analyzed by the Assembly Judiciary Committee on April 27th, 2008, which stated:

> "This bill would effectively eliminate the judge-made 'learned intermediary' doctrine by declaring that prescription drug manufacturers are not relieved of their common law duty to warn consumers about the risks and dangers of their products just because a physician must prescribe those products." (Assem. Com. on Judiciary, Analysis of AB 2690 (2007-2008 Reg. Sess.) at p. 1.[6])

In addition, the Assembly Judiciary Committee's analysis notes that the sponsor of the legislation was the Consumer Attorneys of California ("CAOC") which, according to the CAOC's website, is a professional organization whose "member-attorneys stand for plaintiffs" on a variety of consumer cases including "those injured or killed by defective products or drugs." (See Consumer Attorneys of California website, About CAOC.[7]) Regarding CAOC's arguments in support of the legislation, the analysis states:

> "According to Consumer Attorneys of California (CAOC), this measure "simply clarifies that a drug manufacturer's common law duty to warn the ultimate consumer about the dangers of prescription drugs is a not avoided simply because a doctor prescribes the drug." Adding "according to CAOC, 'patients influenced by advertisements ask for prescription products by name and become more active in their health

[5] https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=200720080AB2690 (last visited November 1, 2022).
[6] leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=200720080AB2690 (last visited November 1, 2022).
[7] https://www.caoc.org/?pg=history (last visited November 1, 2022).

> care decisions. Since the drug companies have chosen to bypass the learned intermediary and appeal directly to the consumer, the CAOC believes 'the common law duty to warn the ultimate consumer should apply.'" (Assem. Com. on Judiciary, Analysis of AB 2690 (2007-2008 Reg. Sess.) at p. 4.[8])

Regarding opposition to the bill, CLS is mentioned (by its previous name, CHI[9]) in the Assembly Judiciary Committee's analysis as one of the bill's main opponents. In the analysis, the Committee states:

> "First, opponents contend that this bill usurps a well-established, common sense judicial doctrine that prevails in 48 other states." Adding, "CHI adds that, if the target of this bill is direct-to-consumer advertising, it may inadvertently have the effect of forcing manufacturers to engage in more direct advertising, 'since manufacturers will be directly responsible for educating patients on the risks of their drugs.' In addition, CHI points out that even though the proponents stress direct-to-consumer advertising, it would apply to all prescription drugs regardless of the nature of the advertising. Accordingly, CHI concludes 'even manufacturers who do not use direct-to-consumer advertising would

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[8] leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=200720080AB2690 (last visited November 1, 2022).

[9] In 2015, BayBio and the California Healthcare Institute, also known as CHI, merged to form the California Life Sciences Association, or CLSA. In 2021, CLSA dropped "Association" from its name and became CLS. All references to CLS, and its history of advocacy and service, in this document include that of its predecessor organizations. See *BayBio and CHI Merge Making California Life Sciences Association the Largest Life Sciences Advocacy Group in US*, BioSpace, May 14, 2015 https://www.biospace.com/article/baybio-and-chi-merge-making-california-life-sciences-association-the-largest-life-sciences-advocacy-group-in-u-s-/ (last visited November 1, 2022).

> have exposure to increased litigation if this bill passes.' This in turn 'could potentially increase healthcare costs and jeopardize the development and production of life-saving medicines.'" ( Id.)

The bill was passed out of the Judiciary Committee on April 29th but was amended on May 7, 2008, to be more narrowly tailored to apply only to products that are advertised directly to consumers. The amended version stated:

> "A manufacturer of a prescription pharmaceutical product shall not be relieved of a duty to warn consumers of the risks and side effects *of that product* solely because the product was prescribed to a patient by a physician *if that product is advertised directly to consumers*." (AB 2690, as amended, italics note amended language to original text.[10])

Despite the narrowing of the bill's language to only apply to prescription drugs marketed directly to consumers, AB 2690 never passed out of the California State Assembly. In fact, the California Assembly declined to even take the bill up for a vote of the full Assembly, thoroughly rejecting the legislative attempt to weaken the learned intermediary doctrine. On May 29, 2008, the bill was placed on the inactive file in the Assembly and on November 30, 2008, the bill was officially noticed as dead on the inactive file. (See AB 2690, 2007-2008 Reg. Sess., Status[11])

[10] https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=200720080AB2690 (last visited November 1, 2022).
[11]https://leginfo.legislature.ca.gov/faces/billStatusClient.xhtml?bill_id=200720080AB2690 (last visited November 1, 2022).

### B. CLS Urges the Court to Reject the Plaintiff-Appellant's Attempt to Weaken the Learned Intermediary Doctrine Just as the California Legislature Did When It Rejected AB 2690 in 2008.

If the Court were to find that causation is met by a plaintiff by showing that a physician *would* have communicated the stronger warning to the patient *and* that a prudent person in the patient's position *would* have declined the treatment after receiving the stronger warning, the learned intermediary defense would be substantially weakened because it relies on the manufacturer's speculation as to what a *patient would* do based on what a *provide*r *would* do. As mentioned earlier, this is contrary to the intention that the doctor "be the intervening party in the full sense of the word" and "unaffected by the manufacturer's control." (*Bigler-Engler v. Breg*, at p. 319, italics added, citing *Fogo v. Cutter Laboratories* at 417.) As the California Assembly Judiciary Committee noted, the proponents of the bill intended for the bill to "effectively eliminate" the learned intermediary doctrine. It, therefore, is illustrative the Committee made a point to include in its analysis opposition concerns that the bill could "potentially increase healthcare costs and jeopardize the development and production of life-saving medicines." (Assem. Com. on Judiciary, Analysis of AB 2690, at p. 4.[12]) And even the bill's amended, more narrowly tailored version, failed to pass out of its own house of origin within the California Legislature. Just as our representative state government rejected attempts to substantially weaken the learned intermediary doctrine, we urge the Court to reject the plaintiff-appellant's attempt to weaken the doctrine by broadening the causation standard in a way that is in direct contrast to the intention for the doctor to be the intervenor in the "*full sense of the word*" who is "*unaffected by the manufacturer's control*." (*Bigler-Engler v. Breg*, at p. 319.)

[12] leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=200720080AB2690 (last visited November 1, 2022).

## III. The Court Should Reject Plaintiff-Appellant's Attempt to Broaden the Causation Standard on Public Policy Grounds Because Weakening the Learned Intermediary Doctrine Has the Potential to Negatively Impact California's Vibrant Life Science Sector and the Patients They Serve Around The World, Particularly Patients Living With Rare Diseases.

The California life sciences sector is an ecosystem of collaboration between foundational research conducted in universities and research centers, and the progression of that innovation into the market fueled by financial investments from the private sector. Because of the complex and challenging nature of new biomedical innovation, and the tremendous risks involved with taking research from the lab to the patient, the sector is built on a foundation of small startups relying heavily on funding or partnerships with larger biopharmaceutical and medical device companies. CLS is concerned that weakening the learned intermediary doctrine in California will dramatically expand liability for biopharmaceutical and medical device manufacturers, which risks disincentivizing research and innovation to bring novel therapies to market. According to the National Institute of Health ("NIH") approximately 10 percent of potential therapeutics that effectively pass preclinical development reach the market, and the cost for each is estimated to "average from $100 million to more than $1 billion, depending on the disease and other factors and taking the cost of failed drugs into account." (National Institute of Health, National Library of Medicine, National Center for Biotechnology Information.[13]) NIH goes on to state:

> "Given the relatively low odds of success and the high costs of drug development, pharmaceutical and biotechnology companies usually focus on potential therapies with the highest likelihood of generating a good financial return—as is the case with virtually all companies in any field. This has meant that potential therapies for rare diseases, including

[13] https://www.ncbi.nlm.nih.gov/books/NBK56179/ (last visited November 1, 2022).

therapies for life-threatening conditions, have often languished in the early development pipeline." (Id.)

The potential for the Court's decision on this certified question, if it were to find in favor of the plaintiff-appellant's attempt to weaken the learned intermediary doctrine, to have a detrimental effect on the life sciences industry and the patients they serve by discouraging research and development of novel therapies for patients cannot be overstated. California's life sciences sector is enormous, contributing $411 billion in economic output in 2020. (See *California Life Sciences Releases 2021 Sector Report*, Global Newswire, April 2022.[14]) As a result of the immense size of the life science sector in California, and its influence on the development of novel therapies, decisions that impact the California life science sector can have a ripple effect across the globe. For example, out of all seventy-nine COVID-19 vaccine developments in the United States, more than a quarter have been sponsored by, or primarily supported by, organizations in California and over half of them have or had clinical trials taking place in California. (See *Id.*)

Decisions which disincentivize research and innovation to bring novel therapies to market can have a devastating impact on the California life science industry but, perhaps most importantly, the potential negative impact is most concerning for patients living with rare diseases. Regarding the number of treatments for rare diseases, according to the NIH, "of the 7,000 identified rare and neglected diseases for which we know the molecular cause, only about 500 have approved treatments." (See *Rare Diseases*, National Institutes of Health, February 2020.[15]) Regarding the number of people that are living with a rare disease, the World Economic Forum estimates that approximately 10%

[14] https://www.globenewswire.com/en/news-release/2022/04/13/2422248/0/en/California-Life-Sciences-Releases-2021-Sector-Report.html. (last visited November 1, 2022).

[15] https://www.nih.gov/about-nih/what-we-do/nih-turning-discovery-into-health/rare-diseases (last visited November 1, 2022).

of the global population, or 475 million people, are affected by a rare condition and only 5% of the 475 million people with a rare disease have a treatment for their condition. (See *Global Data Access for Solving Rare Disease: A Health Economics Value Framework*, World Economic Forum, February 2020.[16]) In short, when biomedical research is hampered by a lack of funding, patients living with a rare disease are the ones that suffer the most. CLS, therefore, urges the Court to reject the plaintiff-appellant's attempt to substantially weaken the learned intermediary doctrine on public policy grounds, to better protect California's vibrant life science community and the patients they serve around the world.

## CONCLUSION

It is clear that the district court correctly granted summary judgment in favor of Somatics after concluding that the plaintiff-appellant failed to establish causation due to an absence of evidence that stronger warnings would have affected their physician's decision to prescribe ECT, because the causation standard put forth by the plaintiff-appellant is in direct contrast to the intent behind the common law adoption of the learned intermediary doctrine. To accept the plaintiff-appellant's proposed causation standard would substantially weaken the learned intermediary doctrine. CLS urges the Court to reject the plaintiff-appellant's attempt to weaken the learned intermediary doctrine. As the legislative history of AB 1690 shows, previous legislative attempts to substantially weaken the learned intermediary doctrine in the California Legislature were so thoroughly rejected that the bill was not even brought up for a vote by the bill's house of origin. Just as our representative state government rejected attempts to weaken the learned intermediary doctrine via legislation, we urge the Court to reject the plaintiff-appellant's attempt to weaken the learned intermediary doctrine by broadening the

[16] https://www.weforum.org/reports/global-access-for-solving-rare-disease-a-health-economics-value-framework (last visited November 1, 2022).

causation standard in a way that is in direct contrast to the intention behind the doctrine. Furthermore, weakening the learned intermediary doctrine could have a detrimental effect on the life sciences industry and the patients they serve by discouraging research and development novel therapies for rare diseases. When biomedical research is hampered by a lack of funding, patients, especially those living with a rare disease, are the ones that suffer the most. CLS, therefore, urges the Court to reject the plaintiff-appellant's attempt to weaken the learned intermediary doctrine, to better protect California's vibrant life science community, but most importantly, the patients they serve.

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

The undersigned certifies that the text of this amicus curiae brief, and its application, is typed in 13-point Times New Roman font and contains 6212 words, as counted by the Microsoft Word word-processing program used to prepare the brief. Further, the undersigned certifies that the brief complies with the form requirements set forth in California Rules of Court, rule 8.204.

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## CERTIFICATE OF SERVICE

I certify that:

- I am a resident of the State of California and over the age of eighteen years, and not a party to the within action.

  -And-

- My business address is 1215 K Street, Suite 1100, Sacramento, CA, 95814.

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**APPLICATION BY CALIFORNIA LIFE SCIENCES TO FILE AN AMICUS CURIAE BRIEF IN SUPPORT OF SOMATICS, LLC,**

on the interested parties in this action, as follows, by filing and serving the foregoing through:

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I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct and that this proof of service is executed at Sacramento, California on November 17, 2022.

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Supreme Court of California
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**STATE OF CALIFORNIA**
Supreme Court of California

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