4th Civil No. D077945

IN THE COURT OF APPEAL
OF THE STATE OF CALIFORNIA
FOURTH APPELLATE DISTRICT

JOHNSON & JOHNSON, a New Jersey Corporation; ETHICON, INC., a New Jersey Corporation; ETHICON US, LLC; and DOES 1 through 100, inclusive,

Defendants-Appellants,

v.

THE PEOPLE OF THE STATE OF CALIFORNIA,

Plaintiff-Respondent.

Appeal from the Superior Court of California, County of San Diego, Department 67
Hon. Eddie C. Sturgeon, Judge
Case No. 37-2016-00017229-CU-MC-CTL

APPLICATION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS AND PROPOSED BRIEF OF *AMICUS CURIAE* OF INTERESTED MEDICAL SOCIETIES

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APPLICATION FOR LEAVE TO FILE BRIEF OF AMICUS CURIAE IN SUPPORT OF DEFENDANTS

I. Introduction.

Pursuant to Rule 8.200(c) of the California Rules of Court, proposed *amici* the American Urogynecological Society (AUGS), the Society of Gynecologic Surgeons (SGS), the American Association of Gynecologic Laparoscopists (AAGL), and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) respectfully request leave to file a brief *amicus curiae* in support of Defendants. This Application is timely made.

II. Nature of the *Amici's* Interests.

Amici are national medical, public health, and policy organizations with recognized expertise and longstanding concern in women's health, including in the areas of gynecology, urology, and the treatment of pelvic floor disorders.

Together, the proposed *amici* represent thousands of health care providers in California and across the country. Proposed *amici* recognize a strong societal interest in protecting the health and quality of life of women who suffer from stress urinary incontinence (SUI) and pelvic organ prolapse (POP).

Founded in 1979, the American Urogynecological Society is the premier non-profit organization representing more than 1,900 members including practicing physicians and researchers from many disciplines, all dedicated to treating female pelvic floor disorders such as POP and SUI. As the leader in Female Pelvic Medicine and Reconstructive Surgery, AUGS drives excellence in

care for women through education, research, advocacy and interdisciplinary collaboration.

The Society of Gynecologic Surgeons is recognized as a select member group of over 400 physicians representing both private practice and academic faculty—all involved in teaching and the practice of advanced gynecologic surgery. The mission of SGS is to promote excellence in gynecologic surgery through acquisition of knowledge and improvement of skills, advancement of basic and clinical research, and professional and public education.

As a global leader in Minimally Invasive Gynecologic Surgery, the mission of the American Association of Gynecologic Laparoscopists is to elevate the quality of health care for women through excellence in clinical practice, education, research, innovation, and advocacy. Since AAGL's founding, over 7,000 members have joined the Association and share in the vision that all women have access to minimally invasive surgical options.

The Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction is a non-profit organization dedication to improving the art and science of Urology through basic and applied clinical research in urodynamics and neurology, voiding function and dysfunction, female urology and pelvic floor dysfunction, and to disseminate and teach these concepts. It is the oldest professional organization dedicated to this field consisting of interested physicians, basic scientists, and other health care professionals.

Amici have a substantial interest in the issues before this Court and believe their expertise can help the Court assess more fully the merits of respondent's position. As organizations whose members treat pelvic floor disorders, *Amici* are well aware of the effects of and treatment for SUI and POP. These disorders can cause a negative impact on the productivity and quality of life of women, affecting them physically, psychologically, socially, and sexually. Women with pelvic floor disorders are often unable to engage in normal day-to-day activities, and can suffer embarrassment, loss of self-esteem, depression, and withdrawal from physical and social activities. Surgery for SUI and POP typically leads to a major improvement in the productivity and quality of life in these women.

Amici's brief will assist the Court by explaining the medical and scientific context behind use of surgical mesh to treat pelvic floor disorders. Broadly accepted medical, public health, and scientific evidence supports the use of surgical mesh to treat SUI and, in specific circumstances, POP.

Beyond providing the medical context in which *Amici*'s members use, research, and discuss surgical mesh, *Amici*'s brief will provide the Court with needed information about the harm that may result from the trial court's decision and how doctors actually practice medicine in California. Contrary to the trial court's findings, medicine is a lifelong learning endeavor focused on evidence and research, where surgeons bring their cumulative experience and training to their operating rooms before using and informing patients about surgical mesh. This context will help

the Court understand the error of the trial court's conclusion that surgeons were misled.

For the foregoing reasons, *Amici* respectfully request permission to file the accompanying amicus curiae brief in support of Respondents.

DATED: September 27, 2021 Respectfully submitted,

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DISCLOSURE OF AUTHORSHIP AND MONETARY CONTRIBUTION

No party, counsel, or other person other than amicus and its counsel have made a monetary contribution to fund the preparation or submission of this brief or have participated in authoring it. (*See* Cal. Rules of Court, Rule 8.200(c)(3).)

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INTRODUCTION

Pelvic floor disorders, such as stress urinary incontinence (SUI) and pelvic organ prolapse (POP), are often devastating conditions that impair a woman's quality of life. These conditions, and treatment options for them, have been widely studied and researched. For example, polypropylene mesh midurethral slings are the standard of care for the surgical treatment of SUI following extensive study, follow-up, and publications regarding their use.

The trial court found that surgeons were misled by Ethicon's statements about pelvic mesh devices and Instructions for Use and imposed a $344 million penalty. *Amici*, medical organizations whose members treat pelvic floor disorders and often use surgical mesh in SUI procedures, submit this brief in support of Defendants' request for reversal.[1] In particular, *Amici* agree with Defendants that the trial court impermissibly failed to consider the target audience of Defendants' statements—surgeons who treat pelvic floor conditions—and failed to account for the reality of *how* surgeons practice medicine and engage in lifelong learning and education. Additionally, *Amici* submit that the trial court's decision, and its confusion about mesh science

[1] *Amici*—the American Urogynecological Society (AUGS), the Society of Gynecologic Surgeons (SGS), the American Association of Gynecologic Surgery (AAGL), and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)—are all medical organizations seeking to improve the quality of life of women who suffer from SUI and POP.

and how doctors actually treat patients, is likely to harm patients, as they may be less likely to seek necessary treatment for pelvic floor conditions, specifically SUI, if the trial court's decision stands.

ARGUMENT

I. The Trial Court Impermissibly Ignored the Reality of Physician Experience, Training, and Education.

Central to the trial court's decision was its belief that Defendants' marketing and Instructions For Use (IFU) deceived and misled highly educated specialist surgeons. As the trial court bluntly claimed, "Defendants have been deceiving physicians—including their own witnesses—for years." (Statement of Decision, available at volume 26 of the Appellant's Appendix, pages 5586-5673, hereinafter "Opinion," at 84:18 (26. AA.5669).)

This idea fundamentally misunderstands how physicians practice medicine and improperly treats specialists as easily-misled lackeys, instead of the scientific, evidence-based practitioners they are. In support of the claim that doctors were misled, the trial court created a fictional world whereby specialist surgeons never read medical literature, never perform their own research, and never participate in relevant continuing medical education. Instead, according to the trial court, these specialist surgeons *exclusively* listen to device manufacturers for their training and education. The trial court claimed that Defendants' marketing "likely worked to convince those doctors" regarding the risks of mesh, in lieu of doctors' knowledge from years of medical

training, specialization, and ongoing research. (Opinion at 81:10-14 (26.AA.5666).) This erroneous finding, which underpinned the trial court's entire decision, misunderstands the practical realities of how doctors—especially surgical specialists focused on a specific medical problem—practice medicine.

Amici believe that the trial court simply got it wrong in concluding in Part V.G of its decision that *doctors* were misled by the IFU and marketing materials. (Opinion at 52:17 to 60:13 (26.AA5637-45).) The trial court proceeded by first explaining that doctors read and rely on the IFU, although contrary testimony was presented at trial, as many doctors prefer only to review primary source material. (Opinion at 53:19-20 (26.AA.5638).) But even accepting that doctors review the IFU, what the trial court got wrong is the idea that the IFU is the *only* source of material regarding the risks and benefits of pelvic mesh products.

Also problematic is the trial court's unsupported conclusion that because doctors *read* the IFU, those doctors must have been *deceived* by it. (Opinion at 54:14-18 (26.AA.5639).) For example, the trial court held that surgeons were misled into believing that "any complications not listed [in the IFU] were simply not associated with the device." (Opinion at 34:19 (26.AA.5619).) This holding is implausible. Pelvic floor surgeons are trained to understand that pain, for example, may follow all pelvic floor surgeries; an IFU's omission of pain as a risk would never mean that a surgeon believes that pain would not be associated with procedures involving mesh sling. Doctors rely on their

experience, training, education, and research; they do not blindly accept secondary source material and marketing summaries as the only basis of their knowledge of risks and benefits when counseling patients, as the trial court asserted.

The trial court next claimed that "there is no basis to conclude that mesh-specific risks are generally known to the gynecologists, urologists, and urogynecologists that J&J targeted with their marketing." (Opinion at 55:11-12 (26.AA.5640).) To support this claim, the trial court relied on three arguments: First, that because some testifying witnesses disagree with the science as presented by the People, those witnesses *must* have been misled by the Defendants' materials, ignoring the research and experience those specialists have. Second, that the "biomaterial properties" of mesh are not within the baseline medical knowledge of reasonable doctors, also noting that doctors do not read all scientific articles, ignoring what doctors *actually* knew about mesh in the relevant time frame. Third, that "there is no uniform source of information on device-specific risks except from the manufacturer's IFU," ignoring the position statements, registries, and other information gathered by physician groups, including some from *Amici*, as well as the specialized credentialing and training process for mesh surgeons. Each is discussed in turn.

A. Surgeons were not misled regarding mesh slings.

First, the trial court wrongly assumed that surgeons *must* have been misled by Defendants' IFU because they continue to

believe in the science behind mesh products. (Opinion at 56:9 to 57:21 (26.AA.5641-42).) In other words, the trial court found that because the witnesses—who actually use and research mesh products—disagreed with the People's science claims, the Defendants' materials must have led them down that path of disagreement.

California surgeons were *not* deceived regarding the risks of surgical mesh slings. Putting aside the circular nature of such a claim, the trial court's only "evidence" of how doctors were misled by Defendants comes from the testimony of three witnesses, who each testified that the only risks unique or specific to surgical pelvic mesh, as opposed to other procedures, are mesh exposure and mesh erosion. (Opinion at 56:14-23, citing 8/20/19 Tr. 122:8-11 (Nager), Opinion at 56:23-27, citing 8/26/19 Tr. 164:21-165:3 (Lane), Opinion at 56:27 to 57:4, citing 8/21/19 Tr. 146:5-13 (Kahn) (26.AA.5641-42).) The Court then claimed that these surgeons implanted mesh slings "while being under the impression that they pose minimal risks and do not cause the type of debilitating and long-term risks and complications that the company admits to knowing about." (Opinion at 81:5-10 (26.AA.5666), citing *only* the quoted testimony from Opinion at 56:21 to 57:4.) This is simply wrong.

It defies common sense to believe that California surgeons were unaware of the risks of surgical procedures involving mesh because they testified consistently with FDA. Consistent with how the witnesses testified, FDA warns that "use of mesh in transvaginal SUI repair introduces a risk not present in

traditional non-mesh surgery for SUI repair, which is mesh erosion, also known as extrusion."[2] FDA then notes common complications for surgical mesh slings, including "pain, mesh erosion through the vagina (also called exposure, extrusion, or protrusion), infection, urinary problems, recurrent incontinence, pain during sexual intercourse (dyspareunia), bleeding, organ perforation, neuro-muscular problems and vaginal scarring. . . . With the exception of mesh erosion, the above complications can occur following a non-mesh surgical repair for SUI."[3]

Of course surgeons treating pelvic floor disorders *also* know the risks of pelvic surgery; counseling patients about those risks is part and parcel of their clinical practice. These doctors go through an extensive training and credentialing process (*see infra* Part I.C), and it is *their* views on the science of mesh that should hold weight. Scientists and doctors must guide any discussion of risks and benefits of a particular medical device; the law should not parrot the Attorney General's claims without actual medical opinions.

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[2] FDA, Considerations about Surgical Mesh for SUI, *available at* https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/considerations-about-surgical-mesh-sui.

[3] *Id.* The FDA makes similar statements regarding the use of mesh to treat POP. *See* FDA, Pelvic Organ Prolapse (POP): Surgical Mesh Considerations and Recommendations, *available at* https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/pelvic-organ-prolapse-pop-surgical-mesh-considerations-and-recommendations ("With the exception of mesh erosion, these complications can occur following a non-mesh surgical repair for POP.").

B. Risks of mesh surgeries are within a reasonable doctor's baseline training and education.

The trial court next wrongly concluded that the risks of mesh sling surgeries are not within a reasonable doctor's baseline training and education for three separate reasons: (1) that doctors do not understand biomechanics of mesh, (2) that doctors do not read every article in the literature, and (3) that doctors are not trained on mesh surgeries in residency. The trial court's reasoning is inconsistent with medical practice in California.

First, the trial court asserted that doctors do not understand the "biomaterial properties of mesh." (Opinion at 59:10-24 (26.AA.5644).) Doctors need to understand how to use mesh and what its risks are, but understanding the specific engineering properties of a medical device is not required for them to do that. Lebron James may be able to describe the mechanics of his form or give a play-by-play of each shot in a basketball game after the fact, but he likely could not describe the metallurgic properties of the rim or the tensile strength of the backboard. The same is true for a surgeon—she should be able to describe the risks and benefits of mesh, but the specific biomaterial used is not needed to do that. Additionally, qualified surgeons *do* have knowledge of the biomechanics of surgical mesh. By way of example, in a 2013 publication regarding a different type of pelvic floor surgery utilizing mesh (sacrocolpopexy), AUGS published recommendations in the peer-reviewed literature that, to be credentialed in this particular surgery, surgeons must be able to explain the "differences of the

biomechanical properties of marketed synthetic mesh or other grafts."[4]

The trial court next discussed how doctors are busy, and therefore do not read every new journal article about a particular topic. (Opinion at 57:24 to 58:4 (26.AA.5642-43).) Though doctors are undoubtedly busy, they are not proverbial ostriches burying their heads in the sand, oblivious to the many articles that have been written on the very topic of their day-to-day surgeries, the risks and benefits of mesh.[5] As explained in AUGS' position paper on mesh, "The monofilament polypropylene mesh MUS is the most extensively studied anti-incontinence procedure in history. . . . No other surgical treatment for SUI before or since has been subject to such extensive investigation."[6]

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[4] *American Urogynecologic Society's Guidelines Development Committee* Guidelines for Privileging and Credentialing Physicians for Sacrocolpopexy for Pelvic Organ Prolapse, 19(2) Female Pelvic Medicine & Reconstructive Surgery 62 (March/April 2013), *available at* *https://journals.lww.com/fpmrs/Fulltext/2013/03000/Guidelines_for_Privileging_and_Credentialing.2.aspx*.

[5] *See, e.g.*, Joseph Ogah et. al, *Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women*, 2009(4) Cochrane Database Sys. Rev. CD006375, *available at* https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD006375.pub2/full (analysis of 62 trials involving suburethral slings).

[6] AUGS & SUFU, Position Statement (2018), *available at* https://www.augs.org/assets/1/6/AUGS-SUFU_MUS_Position_Statement.pdf.

The doctors who use mesh and counsel patients on its risks and benefits are highly specialized surgeons. (*See infra* Part I.C.) Though seemingly recognizing this specialized training, the Court used surgeons' experience *against* them in this case, explaining that because the products at issue in this case were introduced to market in the late 1990s and beyond, very few surgeons trained on the benefits of the device in medical school or even residency, and thus needed to depend on manufacturers to teach them how to use new devices. (Opinion at 58:18-24 (26.AA.5643).) Though the first statement may be true, the Court's inference is simply not—doctors simply do not approach a new medical device with blinders. To the contrary, as the Court recognized, much of what doctors are taught will depend on the knowledge of a professor or mentor (Opinion at 60:1-8 (26.AA.5645))—not an IFU. That educational techniques vary by professor or mentor points to the specialized knowledge mesh surgeons have, not their unfailing belief in every word in an IFU. Regardless, these specialized surgeons *did* learn—in medical school, in residency, in specialty training and in their personal clinical experience—about the common sense risk, for example, that pain may result whenever *any* foreign implement is inserted or implanted in the body. The trial court ignored what doctors already know about risks of pelvic floor procedures and misrepresented surgeons as being incapable of understanding the risks of the very procedures they perform without manufacturer statements.

C. Medical societies provide information regarding the risks and benefits of pelvic mesh to the highly trained surgeons who use mesh products.

Finally, the trial court assumed that "there is no uniform source of information on device-specific risks except from the manufacturer's IFU." (Opinion at 55:16-17 (26.AA.5640).) This is, again, simply wrong, and ignores the reality of medical societies like *Amici*.

For example, a joint task force between the American Urogynecological Society (AUGS) and the Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) developed and published a position statement on the use of mesh midurethral slings for stress urinary incontinence in January 2014. AUGS and SUFU have updated the position statement with additional information repeatedly, based on clinical and scientific advances. The position statement concludes:

> The polypropylene midurethral sling has helped millions of women with SUI regain control of their lives by undergoing a simple outpatient procedure that allows them to return to daily life very quickly. With its acknowledged safety and efficacy, it has created an environment for a much larger number of women to have access to treatment. In the past, concerns over failure and invasiveness of surgery caused a substantial percentage of incontinent women to live without treatment. One of the unintended consequences of this polypropylene mesh controversy has been to keep women from receiving any treatment for SUI. This procedure is probably the most important advancement in the treatment of stress urinary incontinence in the last 50 years and

> has the full support of our organizations which are dedicated to improving the lives of women with urinary incontinence. [7]

The position statement lists its numerous justifications, including scientific, regulatory, and medical evidence for its beliefs. In addition to being published by AUGS and SUFU, it is supported by *Amici* AAGL and SGS, as well as the American College of Obstetricians and Gynecologists (ACOG), the National Association for Continence (NAFC), and the International Urogynecological Association (IUGA).[8] The position statement is precisely the type of "uniform source" from medical experts that practitioners can, and do, rely on regarding the use of mesh.

Other societies have published similar statements. For example, the American Urological Association (AUA) published a position statement explaining how multiple clinical trials support the efficacy of mesh slings. "Mesh-related complications can occur following polypropylene sling placement, but the rate of these complications is acceptably low. Furthermore, it is important to recognize that many sling-related complications are not unique to mesh surgeries and are known to occur with non-mesh sling procedures as well. It is the AUA's opinion that any restriction of the use of synthetic polypropylene mesh

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[7] AUGS & SUFU, Position Statement (2018), *available at* https://www.augs.org/assets/1/6/AUGS-SUFU_MUS_Position_Statement.pdf.

[8] *Id.*

suburethral slings would be a disservice to women who choose surgical correction of SUI."[9]

AUGS also maintains a national patient registry to have accountability for outcomes associated with pelvic floor disorders. This registry evaluates the effectiveness, quality of life and safety associated with both surgical therapy (including mesh and non-mesh options) and nonsurgical management.[10] The registry provides a framework for quality improvement studies to be conducted within the registry and allows healthcare providers to track surgeon volume and patient outcomes.[11]

The highly specialized surgeons who use pelvic mesh also have a lifelong process of learning that comes from conferences, research articles, experience and training. All California doctors are required by law to take 50 hours of continuing medical education biennially.[12] The practice of medicine involves continuous learning, and doctors counsel patients based on their *cumulative* knowledge. Unfortunately, the trial court's view of doctors as myopically only reviewing industry marketing materials to understand risk discounts and disrespects the

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[9] American Urological Association, Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence (SUI), *at* https://www.auanet.org/guidelines/guidelines/use-of-vaginal-mesh-for-the-surgical-treatment-of-stress-urinary-incontinence.

[10] PFD Research Registry, *at* https://www.augs.org/clinical-practice/pfd-research-registry/.

[11] *Id.*

[12] 16 Cal. Code Reg. § 1336.

lifelong process of a doctor's education. That process is part and parcel of the Hippocratic oath.

AUGS has also published papers outlining the significant process for credentialing surgeons qualified to perform pelvic floor surgeries involving mesh. As stated in one peer-reviewed paper, "[s]urgically complex procedures require a balance of *knowledge*, *surgical skill*, and *experience* as well as an appropriate ongoing surgical volume, an adequately trained and equipped surgical team, and the ability to monitor outcomes and adverse events."[13] The trial court's holding that surgeons performing procedures with mesh believed risks were not associated with particular pelvic floor surgeries unless specifically enumerated on a manufacturer's IFU defies logic.

Surgeons must demonstrate knowledge of the risks of pelvic floor surgery before performing the same, regardless of whether that surgery involves mesh or not. For example, a 2013 peer-reviewed paper regarding a particular type of pelvic floor surgery noted that a surgeon planning to perform this procedure should document knowledge of the following before being granted privileges:

- Preoperative evaluation

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[13] American Urogynecologic Society's Guidelines Development Committee, *Guidelines for Privileging and Credentialing Physicians for Sacrocolpopexy for Pelvic Organ Prolapse*, 19(2) Female Pelvic Medicine & Reconstructive Surgery 62 (March/April 2013), *available at* https://journals.lww.com/fpmrs/Fulltext/2013/03000/Guidelines_for_Privileging_and_Credentialing.2.aspx.

    - Bothersome prolapse symptoms and objective evaluation of POP
    - Evaluation of bowel function
    - Assessment of bladder function including risk of postoperative incontinence and/or voiding dysfunction
    - Documentation of sexual activity and possible dysfunction
- Relevant pelvic surgical anatomy
- Perioperative management including discussion of methods to prevent, identify, and treat common complications of pelvic reconstructive surgery
- A discussion of the strengths and weaknesses of the existing comparative effectiveness studies of POP procedures
- A description of differences in biomechanical properties of marketed synthetic mesh or other grafts.[14]

Beyond this general knowledge, surgeons must have specific knowledge of the procedure and be able to obtain informed consent from patients on whom they perform any type of pelvic floor surgery. It defies logic to suggest, as did the trial court, that surgeons do not properly obtain informed consent from their patients. For example, as explained in the 2013 paper, adequate informed consent includes:

- Specific indications for the choice of graft material (synthetic, autologous, allograft, and xenograft).
- Relative contraindications to the procedure
- Alternatives including nonsurgical options (eg, pessary) and other surgical treatments such as vaginal prolapse

[14] *Id.* (citation omitted).

repairs.

- Potential complications of graft materials including mesh exposure/extrusion through the vaginal epithelium or erosion into pelvic viscera, fistula formation, sinus tract formation, dyspareunia, infection, and/or pelvic pain, which may require additional intervention and may not be completely resolved with mesh removal.
- Potential complications of the procedure including wound infection, bowel and bladder injury, vascular injury, ileus or small bowel obstruction, and sacral discitis or osteomyelitis.kir[15]

Although this paper relates specifically to sacrocolpopexy, the principles are equally applicable to all pelvic floor procedures including midurethral slings, and surgeons performing these types of procedures routinely do all of these things *as a matter of course* when providing informed consent. But under the trial court's view, surgeons do none of these things, and instead depend exclusively on what a manufacturer tells them about the risks of surgeries they have spent their careers performing.

Lifelong learning is more than just a token phrase. For example, to maintain board certification in obstetrics and gynecology, doctors must annually read 30 board-selected articles about the practice of gynecology (and, for those sub-specializing, articles within their sub-specialty) and correctly answer questions about what they read to the American Board of Obstetrics and Gynecology.[16] Many doctors performing mesh

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[15] *Id.*

[16] ABOG, Lifelong Learning & Self-Assessment, *available at* https://www.abog.org/maintenance-of-certification/moc---four-parts/lifelong-learning-self-assessment/overview.

surgeries are boarded in the subspecialty of Female Pelvic Medicine and Reconstructive Surgery (FPMRS). To even just sit for the FPMRS qualifying exam, a physician must have 24 months of clinical training in this specific discipline and complete 12 months of research relevant to the discipline.[17]

Had the trial court given credence to a surgeon's cumulative, ongoing knowledge base, it would have easily concluded that Defendants' marketing materials did *not* mislead doctors, because those doctors already knew of the risks about which the People now complain. The trial court's decision should therefore be reversed.

II. Patients Deserve Options for Treatment Guided by Science.

If left unreversed, the trial court's decision will negatively impact the health of women who suffer from stress urinary incontinence (SUI), pelvic organ prolapse (POP) and, potentially, those suffering from other medical conditions treated with medical devices.

Given the breadth of the decision, and the likelihood of confusion that may result from the trial court's foray into the science of pelvic mesh, patients suffering from pelvic floor conditions may no longer seek treatment for these quality of life altering conditions. Surgical treatment for SUI and POP typically leads to major improvement in the productivity and

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[17] ABOG, FPMRS Qualifying Exam, *available at* https://www.abog.org/subspecialty-certification/female-pelvic-medicine-and-reconstructive-surgery/qualifying-exam.

quality of life in women with these conditions. Given the trial court's decision, women may be further dissuaded from discussing treatment for these prevalent and sometimes debilitating conditions with their doctors, as the trial court's decision contains numerous statements about mesh that are simply not supported by the science. Such statements may cause unwarranted fear and concern in patients suffering from pelvic floor conditions.

Despite the overwhelming evidence that they are the best treatment option for SUI and an appropriate option for POP when used by a trained surgeon, the trial court's decision decries the use of surgical pelvic mesh. If upheld, the trial court's decision has the ability to functionally force mesh manufacturers out of the California marketplace. Although that outcome may have been the aim of the Attorney General, it is an outcome not supported by medical science, or even the FDA.[18] Removal of mesh products should be done *only* through a reasoned, evidence-based approach by regulatory agencies, doctors, and manufacturers. The law must lag science; it should not lead it.[19]

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[18] *See, e.g.*, FDA, Considerations about Surgical Mesh for SUI, *available at* https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/considerations-about-surgical-mesh-sui; FDA, Pelvic Organ Prolapse (POP): Surgical Mesh Considerations and Recommendations, *available at* https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/pelvic-organ-prolapse-pop-surgical-mesh-considerations-and-recommendations.

[19] *Cf. Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316 (7th Cir. 1996) ("But the courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it.")

Even beyond the harm done to patients needing treatment for SUI and POP, the trial court's decision has the potential to have far-ranging effects. The trial court treats manufacturer information as the *only* source of relevant knowledge for surgeons. But what if—as occurs with many doctors—a physician does not read manufacturer information and instead reviews only primary source materials? Would the physician be considered negligent for not counseling a patient on what is contained in a manufacturer's marketing materials? Such a scenario is absurd, but marketing materials and instructions for use are but a single, small part of the panoply of information a doctor brings to the operating room before surgery. The doctor brings experience, training, review of medical journals and textbooks, attendance at continuing medical education, discussion with colleagues, and analysis of medical society guidelines to the OR. Those materials indicate that pelvic mesh is an appropriate treatment, something the trial court's decision impermissibly threatens to take away.

CONCLUSION

For the foregoing reasons, this Court should reverse the trial court's decision.

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CERTIFICATE OF COMPLIANCE

[Cal. Rules of Court, Rule 8.204(c)]

This brief consists of 3,918 words as counted by the Microsoft Word version 2010 word processing program used to generate the brief.

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