SHOOK
HARDY & BACON

June 22, 2022

Supreme Court of California
350 McAllister Street
San Francisco, California 94102-4797

Re: *People v. Johnson & Johnson*, 4th Civil No. D077945
Amicus Letter of the National Association of Manufacturers
Supporting Petition for Review

Dear Honorable Justices:

The National Association of Manufacturers ("NAM") asks the Court to grant Johnson & Johnson's Petition for review the Court of Appeal's decision in *People v. Johnson & Johnson*.

The NAM is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs more than 12.7 million men and women, contributes $2.71 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for nearly two-thirds of all private-sector research and development in the nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

The NAM is dedicated to manufacturing safe, innovative, and sustainable products that provide consumer benefits while protecting human health and the environment. The NAM has a particular interest in this case because the lower courts improperly applied the "likely to deceive" standard under the Unfair Competition Law (UCL) and the False Advertising Law (FAL). This standard protects against speculative allegations of deceit that are not grounded in the real-world context in which the communications were made. When applied properly, it also helps to maintain rational boundaries on the liability these laws can generate, which, as demonstrated here, can be exceedingly large for mass marketed products.

Amicus respectfully requests that the Court grant the Petition and provide needed guidance that a business can be subject to liability under the UCL and FAL only to the extent its communications were "likely to deceive" reasonable people in the real-world setting in which it was communicating with them.

I. THE COURT SHOULD GRANT THE PETITION TO REQUIRE CALIFORNIA COURTS TO PROPERLY CONSIDER THE CONTEXT IN WHICH THE COMMUNICATIONS AT ISSUE WERE MADE.

The Petition raises two ways California courts are failing to apply the "likely to deceive" standard in UCL and FAL cases: how omissions in risk communications are assessed and the way violations are counted. The theme common to both parts of the Petition is that some lower courts, as here, are focusing on theoretical violations, not communications based on the real-world context in which they were made.

The Court should grant the Petition to clarify that courts must determine that for an omission or communication to violate the UCL or FAL, the audience must actually receive the communication and that it must be "probable that a significant portion" of them could be misled when "*acting reasonably in the circumstances.*" (*Lavie v. Procter & Gamble Co.* (2003) 105 Cal.App.4th 496, 508 [emphasis added].) Context matters.

Here, the circumstances are the sales and marketing practices associated with a medical device cleared by the U.S. Food and Drug Administration (FDA) for use in this country—a highly regulated area of the law. Medical devices, along with prescription medicines and certain other products, have inherent risks. (*See* Restatement (Second) of Torts § 402A, Comment k [discussing unavoidably unsafe products]; *Brown v. Superior Court* (Cal. 1988) 751 P.2d 470.)

When seeking to market a medical device, the manufacturer works with the FDA on the controls needed to manage those risks. *See* 21 U.S.C. § 360c(a)(1)(B). The FDA tailors the pre-market review process to the class and risk profile of each device, balances the key factors in determining whether the device is safe and effective for public use, and works with the manufacturers on the needed controls. (*See Buckman Co. v. Plaintiffs' Legal Comm.* (2001) 531 U.S. 341, 348-50.) No medical device is risk free, and no medical device is right for everyone.

It is within this regulatory regime that California courts must assess whether a reasonable patient or physician is "likely to be deceived" by a manufacturer's communications about a device's risks. These benefit-risk communications are intended to facilitate the ability of patients and doctors to engage in an informed-consent discussion to determine whether the benefits of the product—here, a mesh medical device—outweighs its risks for that particular patient. (*Flores v. Liu* (2021) 60 Cal.App.5th 278, 290-293, citing *Cobbs v. Grant* (1972) 8 Cal.3d 299, 243-245.)

As Petitioner points out, there are numerous ways medical device manufacturers communicate these benefits and risks with patients and physicians; each has a different purpose. For example, direct-to-consumer communications help patients learn about treatments for conditions they may be experiencing and prompt them to speak with physicians to determine if the device is right for them. Some communications with physicians have detailed risk discussions, whereas other communications, including Instructions for Use (IFUs) and marketing materials, may refer to risks more broadly. (See 21 C.F.R. § 801.109(c).)

No communication can be looked at in isolation; a patient or physician acting reasonably in the circumstances evaluates each communication within this larger context. Courts should be required to do so as well.

This context, though, was missing throughout the lower courts' rulings and the State's briefing. For example, in its Answer, the State implies it would be sufficient for courts to find that physicians were led "to expect that J&J's pelvic mesh products were safe and effective." (Br. at p. 20.) As indicated, FDA-cleared medical devices *are* safe and effective for classes of patients, and physicians know well that all such devices have risks, including serious ones, and how to learn about them. In fact, the FDA continues to

clear mesh products as safe and effective for use because they can correct uterine prolapse or vaginal apical prolapse.

The Court should grant the Petition and require courts to hold evidence-based inquiries to determine whether each communication or omission was *likely to deceive a member of the target audience acting reasonably under the circumstances*. This assessment requires courts to consider the expectations of reasonable consumers, where else they learn about the product's risks, and count as violations only those communications or omissions that, in the real world, were likely to deceive them.

As seen here, failure to do so can focus the courts on theoretical violations and invoke subjectivity in how the UCL and FAL are applied, the statements courts can find to be deceptive, and the ways in which penalties are calculated.

II. THE COURT SHOULD GRANT THE PETITION TO ENSURE THAT OMISSIONS IN RISK COMMUNICATIONS ARE BASED ON THE TYPE OF INFORMATION A CONSUMER WOULD REASONABLY EXPECT TO BE INCLUDED IN THAT COMMUNICATION.

A court cannot determine whether the omission of certain risk information is "likely to deceive" the reasonable consumer unless it puts that communication into context. As Petitioner explains, there is a split in the Court of Appeal as to which test applies in these situations. (*See Gray v. Toyota Motor Sales, U.S.A.* (C.D. Cal. Jan. 23, 2012) 2012 WL 313703, at *4 [acknowledging split of authority].)

Some courts apply the consumer expectation test, which looks at the level of risk information the reasonable consumer would expect to see in that communication given the circumstances. Others, including the court below, use the test for common-law fraud, which does not include such contextual factors. The Court should grant the Petition to resolve this split and hold that the consumer expectation test is the proper test in UCL and FAL cases; otherwise, there is no guarantee that the alleged omission is truly "likely to deceive" a reasonable consumer.

The problem with allowing California courts to export the common law fraud factors for deceptive omissions into the UCL and FAL is that the purpose and other elements of the UCL and FAL are completely different from common-law fraud. (*See Buller v. Sutter Health* (2008) 160 Cal.App.4th 981, 986 [explaining ways in which these statutes are "unlike common law fraud"].) The common-law fraud factors invoked by the court below look solely at the omission itself, not the real-world circumstances, because the other elements of the tort provide contextual grounding. The plaintiff must have justifiably relied on the deceptive statement and sustained actual damages. (Lazar v. Superior Court (1996) 12 Cal.4th 631, 638.)

There are no such reliance or damages requirements in the UCL or FAL. Therefore, the "likely to deceive a reasonable consumer" standard is necessary to maintain the real-world rudder for the UCL and FAL claims. The context for how a reasonable consumer would view the communication, including any omission in risk information, may make the omission immaterial. For example, no reasonable patient

expects full risk information in an advertisement, and no reasonable physician expects it in IFUs. Yet, omissions in each of these contexts were the basis for liability here.

The court's observations as to whether the challenged omissions would be likely to deceive a reasonable physician treating a case of pelvic organ prolapse was particularly off base. The court essentially adopted a "least sophisticated physician" standard. It expressed concern that many physicians did not learn about mesh surgery in medical school or residency because the products went onto the market after they graduated, that general OB/GYNs may not be as familiar with literature on pelvic mesh surgeries as specialists, and that many physicians are overworked and tired. (*People v. Johnson & Johnson* (2022) 77 Cal.App.5th 295, 333-34.)

Physicians are clearly responsible for keeping up with medical developments and procedures that post-date their graduation from medical school. (*See* Cal. Code Regs., tit. 16, § 1336) [requiring 50 hours of education every two years].) More to the point, the question under the UCL and FAL is not whether omissions would deceive overworked, under-informed doctors in a generic practice; it is whether it could deceive a "significant portion" of doctors who were acting reasonably under the specific circumstances, which would be treating a case of pelvic organ prolapse.

A reasonable physician, before performing any procedure, would review the medical literature and learn about its risks. (*See Flores*, *supra*, 60 Cal. App.5th at 292-93.) The physician must then disclose to the patient "all material information—that is, information which the physician knows or *should know* would be regarded as significant." (*Id.* (emphasis added, cleaned up).) Such disclosures include "the risks involved in accepting and rejecting each proposed procedure, particularly the potential of death or serious harm and the complications that might possibly occur." (*Id.* at 293.) A reasonable physician knows where to find this information and is not likely to be deceived by marketing materials or IFUs that do not include the same amount of risk information as studies and other detailed sources.[1]

By expanding the standard of deception to include physicians and patients who were not acting reasonably, the Court of Appeal failed to apply the statutes properly and weakened a key guardrail against unfounded litigation. The UCL and FAL have already spawned a number of product lawsuits premised on idiosyncratic readings of existing representations or demands that every conceivable malfunction be disclosed prominently before purchase.[2] Ensuring that any omission of risk information is assessed through a

[1] *See, e.g., Patricia A. Murray Dental Corp. v. Dentsply Int'l, Inc.*, (2018) 19 Cal.App.5th 258, 273-74 [representation not deceptive where it was not "likely to deceive a significant portion of licensed dentists acting reasonably"]; *South Bay Chevrolet v. Gen. Motors Acceptance Corp.* (1999) 72 Cal.App.4th 861, 870 [use of "365/360" method of calculating interest not deceptive for loans made to "a financially sophisticated automotive dealership" acting reasonably].

[2] *See, e.g., Moreno v. Vi-Jon, LLC,* (S.D. Cal. Dec. 6, 2021) 2021 WL 5771229, at *1 [dismissing class action challenging hand sanitizer because it did not kill food-borne or sexually-transmitted pathogens as implausible under "reasonable consumer" standard];

rigorous "likely to deceive" standard keeps the most highly speculative UCL and FAL lawsuits from clogging the judicial system.

III. THE COURT SHOULD GRANT THE PETITION TO ENSURE THAT VIOLATIONS ARE CALCULATED BASED ON COMMUNICATIONS THAT ARE ACTUALLY "LIKELY TO DECEIVE" CONSUMERS.

The Court should also grant the Petition to clarify that, in counting violations under the penal provisions of the UCL and FAL, the lower courts must similarly adhere to the "likely to deceive" standard. Here, in advocating for a maximum penalty, the State counted as violations every printing of the challenged documents, rather than determining which documents were actually likely to deceive its intended audience. The trial court and the Court of Appeal accepted this definition. Put simply, no person is likely to be deceived by marketing materials or IFUs they never saw.

As Petitioner points out, the lower courts' method of counting violations is not consistent with this Court's precedent. As the Court described in *People v. Superior Court (Jayhill Corp.)* (1973) 9 Cal.3d 283, "the Legislature intended that the number of violations is to be determined by the number of persons to whom the misrepresentations were made." (*Id.* at 289.) Focusing on people, not documents, grounds the likely-to-deceive standard in the real-world context in which the statements were made. It also guards against the UCL and FAL from being leveraged to impose extensive penalties over theoretical or incomplete communications.

This real-world approach is also consistent with rulings by the Supreme Court of the United States in addressing speculative class actions. (*See TransUnion LLC v. Ramirez* (2021) 141 S.Ct. 2190; *Spokeo, Inc. v. Robins* (2016) 578 U.S. 330.) The issue in these cases was whether plaintiffs have Article III standing to sue a defendant who technically violated a statute, but not in a way that led to real-world harm. In *TransUnion*, misinformation about customers was put in their credit files, but most of the files were corrected before the misinformation was disclosed to anyone. The Court cautioned against using such technical violations to create litigation when there was no "concrete harm." (*TransUnion, supra*, 141 S.Ct. at 2203).

The Court's analysis is particularly instructive here because it drew from several areas of liability law, explaining that litigation over theoretical or incomplete violations lead to unfounded liability. For example, it pointed out that for defamation, publication is "essential to liability." (*Id.* at 2209, citing Restatement of Torts §577, Comment a.) There can be no defamation claim if the statement was not heard by anyone.

Here, the printing of marketing materials and IFUs may create a risk of deception, but they cannot "likely deceive" its audience unless they are received and read. If a flyer is discarded or press release does not generate an article to its intended audience, the communication with that audience was never completed, the risk of deception with that

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Nacarino v. Chobani, Inc. (N.D. Cal. Aug. 9, 2021) 2021 WL 3487117, at *5 [dismissing class action alleging "vanilla" label on yogurt meant flavor derives entirely from the vanilla plant as implausible under "reasonable consumer" standard].

audience cannot materialize, and no violation has occurred. Yet, the lower court never sought to ascertain which of the alleged communications it counted as violations were actually likely to deceive reasonable consumers.

The Court of Appeal acknowledged that "[t]he UCL and FAL do not specify what constitutes a single violation." (*Johnson & Johnson* at 352.) The Court should grant the Petition to make sure that the counting of UCL and FAL violations is properly tethered to actual people being communicated with and the likelihood that those people would be deceived when acting reasonably under the circumstances.

Conclusion

The approach to risk communications this case presents would make it challenging for a manufacturer or seller of any product—let alone of a product that has inherent risks and can be purchased only through a physician—to have a clear understanding of which risks need to be included in which communications. The result would be over-warning, which as this Court has appreciated, "invite[s] mass consumer disregard and ultimate contempt for the warning process." (*Finn v. G.D. Searle & Co.* (1984) 35 Cal.3d 691, 701.) Warnings that truly benefit consumers will become lost, and warnings that improperly scare people away from beneficial medical devices could cause people to suffer needlessly rather than get the help they need.

The "likely to deceive" standard must be the guiding star for each element of the UCL and FAL. For these reasons, *amici* requests that the Court grant the Petition.

Respectfully Submitted,

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PROOF OF SERVICE

I am employed in the County of Orange, State of California. I am over the age of 18 and not a party to the within action. My business address is 5 Park Plaza, Suite 1600, Irvine, California 92614.

On June 22, 2022, I served on the interested parties in said action the within:

AMICUS LETTER BRIEF DATED JUNE 22, 2022

by placing a true copy thereof in a sealed envelope(s) addressed as stated on the attached mailing list.

X **U.S. MAIL:** By placing the documents listed above in a sealed envelope with postage thereon fully prepaid, in the United States mail at Los Angeles, California, addressed as set forth below. I am readily familiar with the firm's practice of collecting and processing correspondence for mailing. Under that practice it would be deposited with the U.S. Postal Service on the same day with postage thereon fully prepaid in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if the postal cancellation date or postage meter date is more than one day after date of deposit for mailing in affdavit.

☒ (BY ELECTRONIC SERVICE) By electronically mailing a true and correct copy through Shook, Hardy & Bacon L.L.P.'s electronic mail system to the e-mail address(es) as stated on the attached service list.

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X **WEBSITE UPLOAD: By causing to be uploaded to the Attorney General's official website for service of papers under Cal. Bus. & Prof. Code§§ 17209 and 17536.5, https://oag.ca.gov/services-info/17209-brief/add.**

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

I declare that I am employed in the office of a member of the bar of this court at whose direction the service was made.

Executed on June 22, 2022, at Irvine, California.

Rose Featherstone
(Type or print name)

/s/ *Rose Featherstone*
(Signature)

SERVICE LIST

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