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PARADIGM SHIFT OR SAME-OLD-SAME-OLD?

THE ADVANCING LANDSCAPE OF MEDICAL DEVICE SUBMISSION EXEMPTIONS

50-STATE SURVEY OF DESIGN DEFECT REQUIREMENTS

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DEAR CLIENT,

Fall has descended upon us, along with that nip in the air and the aroma of pumpkin spice. All of these herald our latest edition of *Pro Te: Solutio,* which contains three fascinating articles on topics of current interest in our field.

In *Paradigm Shift or Same-Old-Same-Old?,* we look at the New Jersey Supreme Court's recent decision in *In Re: Accutane* and how it may affect the courts' review of expert medical testimony going forward in New Jersey.

Then, in *The Advancing Landscape of Medical Device Submission Exemptions,* we address the recent changes in laws and regulations that signal a movement toward expanding 510(k) exemptions for Class II devices.

Lastly, in *50-State Survey of Design Defect Requirements,* we surveyed state laws to determine which states had adopted the "risk-utility" test and which remained committed to the "consumer expectations" test.

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TABLE OF CONTENTS

PARADIGM SHIFT
OR SAME-OLD-SAME-OLD?

THE NEW JERSEY SUPREME COURT'S AUGUST 1, 2018, *IN RE: ACCUTANE* DECISION MAY HELP STEM THE TIDE OF UNRELIABLE EXPERT TESTIMONY[1]

With deepest apologies to Charles Dickens, the Accutane litigation could be dubbed "A Tale of Two Cities"[1] in one critical respect: the trial courts' varying treatment of expert testimony.[2] Over the span of 13-plus years, the courts in two different jurisdictions diverged in their exclusion/admission of Plaintiffs' general causation experts, who claimed that Accutane — a prescription drug that treats recalcitrant nodular acne — was capable of causing Irritable Bowel Disease (IBD) or Crohn's Disease, a specific type of IBD.

One city (Tampa, Florida) was home to a federal court that applied the federal "*Daubert*"[3] standard to Plaintiffs' general causation testimony. The district court excluded Plaintiffs' experts' testimony under *Daubert*, then entered the logical corollary of summary judgment because Plaintiffs could not prove their claims. After the Eleventh Circuit Court of Appeals affirmed the district court's decisions a couple of different times in 2008 and then in 2010, the litigation eventually whimpered to a close.[4]

But in the other city (Atlantic City, New Jersey), the trial court applied New Jersey's then-current "*Kemp*" expert testimony standard, generally considered to be a more relaxed standard in favor of admission than the federal standard.[5] For many years, applying *Kemp* and its progeny, the New Jersey state court permitted Plaintiffs' general causation expert testimony on the alleged connection between Accutane and Crohn's Disease. That landscape changed, however, on August 1, 2018, with the New Jersey Supreme Court's issuance of *In Re: Accutane Litigation*, 2018 WL 3636867, - A.3d - (N.J. Aug. 1, 2018).[6] *In Re: Accutane* defeated Plaintiffs' general causation theory in New Jersey by affirming the trial court's exclusion of Plaintiffs' general causation experts. The primary basis for exclusion was that Plaintiffs' experts disregarded epidemiological studies and, instead, relied upon evidence "at the bottom of the evidence hierarchy."[7] Finding their opinions lacked sound methodology, their testimony was excluded, which resulted in the dismissal of more than 2,000 cases in the New Jersey Accutane Multicounty Litigation (MCL).

The New Jersey Supreme Court's decision in *In Re: Accutane* is a significant victory for the Defendants in that litigation, Hoffmann-La Roche Inc. and Roche Laboratories Inc. Overall, from the defense standpoint, the era of new "Accutane motions" is a paradigm shift that aligns New Jersey law with federal law expert testimony standards. Plaintiffs will, in contrast, argue there's "nothing to see here" and that New Jersey law is basically unchanged in this aspect. This article discusses the key points from *In Re: Accutane*'s key components and shares a few suggestions of how to attack Plaintiffs' general causation theories in the new "*Accutane* motion" era.

THE ERA OF NEW "ACCUTANE MOTIONS" IS A PARADIGM SHIFT THAT ALIGNS NEW JERSEY LAW WITH FEDERAL LAW EXPERT TESTIMONY STANDARDS.

I. IN RE: ACCUTANE: TRIAL COURT PROCEEDINGS

A. GENERAL CAUSATION WAS "THE" ISSUE.

The first New Jersey Accutane case was filed in July 2003 — and the Accutane litigation in Atlantic City, New Jersey, was designated as an MCL or "mass tort" in May 2005.[8] Thousands of cases were filed in the New Jersey MCL, with Plaintiffs alleging that they had developed Crohn's Disease from taking Accutane.[9] To prove these product liability claims, Plaintiffs had to establish that Accutane was *capable of causing* the alleged injury (general causation) and that it *did, in fact, cause* the claimed injury for a particular Plaintiff (specific

1. Full disclosure: Butler Snow represents the manufacturer of Accutane, Hoffmann-La Roche Inc. and Roche Laboratories Inc., in a number of cases. This article was prepared strictly from public filings as cited herein.

causation). The key issue of *In Re: Accutane* — and the reason it is such an important decision — is general causation. Without expert testimony to establish general causation, Plaintiffs' claims fail, and there is no need to evaluate specific causation.

B. EPIDEMIOLOGICAL STUDIES REVEALED A LACK OF CAUSAL CONNECTION BETWEEN ACCUTANE AND CROHN'S DISEASE.

Regarding general causation, there had been a "series of epidemiological studies" in the years since many of the earlier Accutane cases had been decided; studies conducted and papers published from 2009 to 2014 examined whether there was a causal relationship between Accutane and Crohn's Disease, including the following:

- ***2009:*** *One of the first studies in 2009, with approximately 21,500 subjects, concluded there "may be anecdotes" of Accutane causing inflammation of the colon, but the data suggested that "[Accutane] is not likely to cause chronic IBD."*[10]
- ***2010-2013:*** *Another epidemiological study in 2010 examined approximately 29,000 subjects and found no apparent association between Accutane and Crohn's Disease.*[11] *A 2013 study of 45,000 women, similarly, found no increase in the risk for IBD, including Crohn's Disease.*[12]
- ***2013-2014:*** *An even larger-subject study in 2013 with almost 177,000 subjects,*[13] *as well a study of nearly 1,100 subjects in 2014,*[14] *both concluded that Accutane was not causally related to IBD. A 2013 study of nearly 47,000 subjects found "no significant association" between Accutane use and IBD.*[15] *Another 2014 study of approximately 44,000 subjects concluded that use of Accutane was associated with a decreased risk of Crohn's Disease.*[16]

As the Court noted, "all of [these studies] concluded that Accutane is not causally associated with the development of Crohn's disease."[17]

C. THE TRIAL COURT REQUESTED SCIENTIFIC LITERATURE, CONDUCTED A KEMP HEARING, AND RECEIVED TESTIMONY FROM EXPERTS.

To establish general causation, Plaintiffs produced two experts: a gastroenterologist (Dr. Arthur Kornbluth) and a statistician (Dr. David Madigan). Defendants moved to exclude those experts under New Jersey Rule of Evidence 702 in accordance with *Kemp ex rel. Wright v. State,* 174 N.J. 412, 809 A.2d 77 (2002).

In addition to the briefing, the trial court asked the parties to provide "all such reports, abstracts, peer-reviewed studies, etc." relied upon by the witnesses in formulating their opinions — which totaled more than 400 items, and which the trial court described as being "invaluable in preparing for the *Kemp* hearing."[18]

At the *Kemp* hearing, the trial court heard testimony from the experts.[19] The court explained that "the inquiry at a *Kemp* Hearing must be 'flexible,'" the "focus must be on principles and methodology and not necessarily on the conclusions/opinions that such scientific methodology may generate," and the "expert must be able to identify the factual basis for his/her conclusion, explain his/her methodology, and demonstrate that both the factual basis and underlying methodology are scientifically reliable . . . ."[20]

D. THE TRIAL COURT EXCLUDED PLAINTIFFS' GENERAL CAUSATION EXPERTS, PRIMARILY BASED ON THEIR DISREGARD FOR SCIENTIFIC STUDIES THAT WERE CONTRARY TO THEIR OPINIONS.

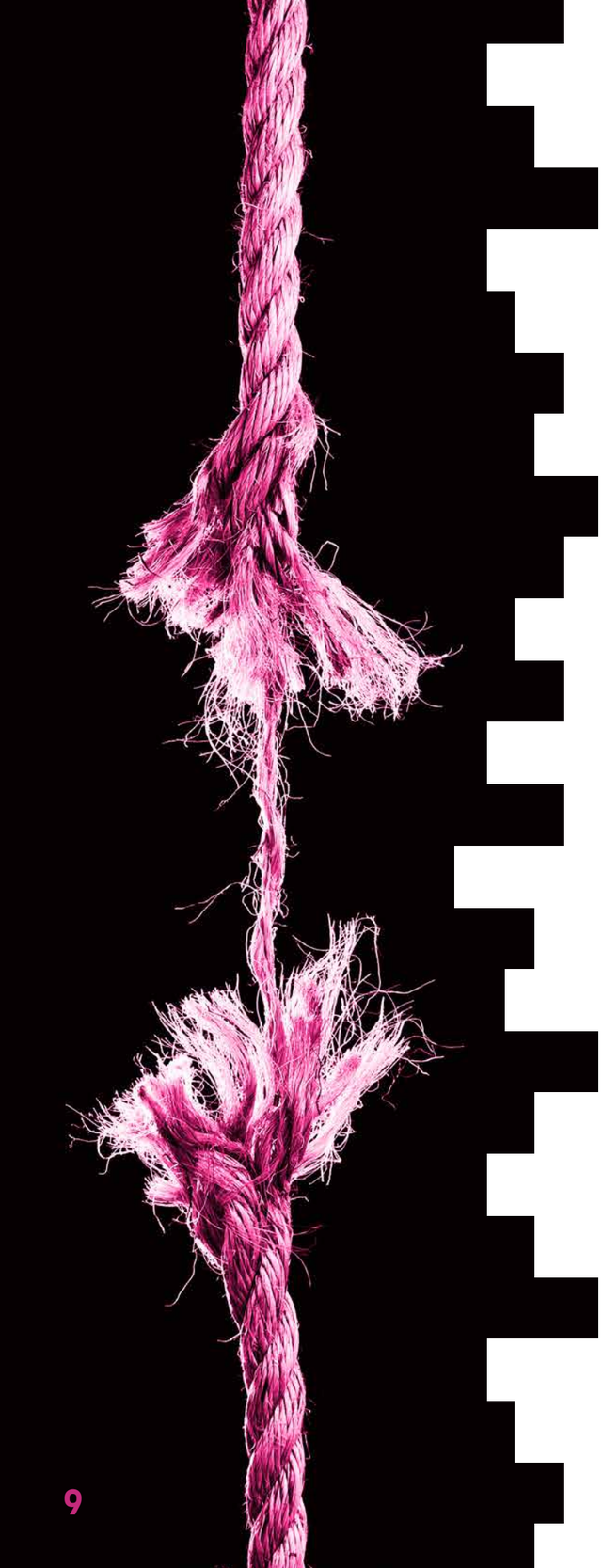
After addressing the grounds upon which Plaintiffs' experts relied in forming their general causation opinions, the trial court ultimately granted the motion to exclude. The court introduced its ruling by stating:

> It is one thing to stand alone in the world of science, advancing a hypothesis that others do not accept. **It is quite another thing to advance a hypothesis that can only be supported by disregarding valid scientific research.** The court embraces its obligation to be flexible in applying scientific evidence to novel personal injury claims falling within the penumbra of "toxic torts" nonetheless, such claimants have a reciprocal obligation to be mindful of the standards of the scientific community. The foundations of the hypothesis for general causation of an injury cannot be contrived; they must be based upon sound methodology sufficiently reliable to be presented to a jury.[21]

The phrase emphasized above pointing out Plaintiffs' experts' effort "to advance a hypothesis that can only be supported by disregarding valid scientific research" — i.e., an attempt to "cherry-pick evidence supportive of their opinion while dismissing other, better forms of evidence that did not support their opinion" — was the lynchpin for both the trial court's ruling and the Supreme Court's affirmance, which reversed the Appellate Court.[23]

II. THE NEW JERSEY SUPREME COURT UPHOLDS EXCLUSION OF PLAINTIFFS' GENERAL CAUSATION EXPERTS

Three aspects of the New Jersey Supreme Court's rulings are important to pharmaceutical defense practice and are discussed briefly below. First, the Court sought to clarify New Jersey's expert testimony standard vis-à-vis *Daubert*. Second, the Court rejected the "less deference" standard and reaffirmed that appellate review of expert decisions in civil cases is the "pure" abuse of discretion standard. Third, the Court affirmed the trial court's approach to excluding Plaintiffs' general expert testimony, thereby reaffirming the trial court's important role in performing "rigorous gatekeeping that is necessary when faced with a novel theory of causation, particularly one . . . that flies in the face of consistent findings of no causal association as determined by higher levels of scientific proof."[24]



A. THE "NEW" NEW JERSEY EXPERT TESTIMONY STANDARD: #DAUBERTNOTDAUBERT?

As noted, the New Jersey Supreme Court accepted review of the case to address the proper standard to evaluate expert testimony under Rule 702:

> We intend by this case to clarify and reinforce the proper role for the trial court as the gatekeeper of expert witness testimony. Defendants and several amici have good reason to ask for clarification of the judicial gatekeeping role to be performed in New Jersey courtrooms.[25]

A detailed analysis of the history behind New Jersey's expert testimony standard is beyond the scope of this article; review of *In Re: Accutane* is recommended for those who desire a deeper dive on that issue. Suffice to say that the Court, in *In Re: Accutane*, took pains to both align itself with, but at the same time distance itself from, the federal *Daubert* standard.[26] At the end of the day, the Court concluded that although it was "adopting use of the *Daubert* factors, 'we stop short of declaring ourselves a *Daubert* jurisdiction.'"[27]

AT THE END OF THE DAY, THE [NEW JERSEY SUPREME COURT] CONCLUDED THAT ALTHOUGH IT WAS "ADOPTING USE OF THE *DAUBERT* FACTORS, 'WE STOP SHORT OF DECLARING OURSELVES A *DAUBERT* JURISDICTION.'"

Despite the Court's careful crafting of boundaries on its clarified standard, revealed by its "hesitat[ion] to sweep in" adherence to *Daubert* given the "various approaches taken among the circuits and state jurisdictions when applying the *Daubert* factors,"[28] several aspects of the opinion are familiar and favorable. All of the following issues should resonate with students of *Daubert*, as these items focus on the key inquiry — i.e., whether "sound methodology" has been demonstrated:

- *Plaintiff bears the burden to establish that his/her general causation expert has employed a sound methodology: this requires the plaintiff to demonstrate "that the expert applies his or her scientifically recognized methodology in the way that others in the field practice the methodology."*
- *Sound methodology has two aspects: both (1) its approach to reasoning and (2) its use of data.*
- *Sound methodology is viewed "from the perspective of others within the relevant scientific community."*[29]

In Re: Accutane also highlighted the trial court's role as "gatekeeper" of testimony. The Court explained that:

- *The trial court is not just permitted, but is obligated when faced with a novel theory of causation, to perform "rigorous gatekeeping."*[30]
- *"The trial court is the spigot that allows novel expert testimony in areas of evolving medical causation science, provided the proponent of the expert can demonstrate that the expert adheres to scientific norms in distinct ways that we have identified."*[31]
- *Trial courts "should exclude the proposed expert testimony on the basis that it is unreliable" if the proponent fails to establish sound methodology.*
- *"Difficult as it may be, the gatekeeping role must be rigorous."*[32]

Even if *Daubert* has not been "formally" adopted in New Jersey, these clarifications/affirmations are familiar stalwarts in keeping unreliable expert opinions out of the courtroom. Indeed, *In Re: Accutane* itself cited to recent federal cases, including expert-excluding-rulings in the *Lipitor* litigation that demonstrate the rigorous gatekeeping employed by the trial court.

B. THE "PURE ABUSE OF DISCRETION" STANDARD APPLIES; THE LESS-DEFERENTIAL STANDARD APPLIED BY THE APPELLATE DIVISION IS NOT PROPER IN CIVIL CASES.

The New Jersey Supreme Court also addressed the proper standard of appellate review. The Court explained that "[a] reviewing court must apply an abuse of discretion standard to a trial court's determination, after a full Rule 104 hearing, to exclude expert testimony on unreliability grounds. . . . [But] Here, the Appellate Division was persuaded to veer off that standard of review."[33]

More specifically, the Appellate Division stated that it would apply the abuse of discretion standard, but determined that it "owe[d] 'somewhat less deference to a trial court's determination' regarding expert testimony." The Supreme Court rejected that approach, finding that the appellate panel had wrongly relied on the standard from the criminal setting; "it is not appropriate in the context of a civil mass tort case, where the trial court has been entrusted with methodology-based review as the gatekeeper of expert testimony." Instead, *In Re: Accutane* confirmed that the "pure abuse of discretion standard" applies in civil matters concerning expert testimony.[34]

C. THE TRIAL COURT PROPERLY EMPLOYED RIGOROUS GATEKEEPING TO EXCLUDE PLAINTIFFS' GENERAL CAUSATION EXPERTS, WHO TRIED TO DISREGARD VALID EPIDEMIOLOGICAL STUDIES WHILE RELYING ON THE WEAKEST FORMS OF SCIENTIFIC PROOF.

Applying that standard of review, the Supreme Court concluded that the appellate court should be reversed, as the trial court "did the type of rigorous gatekeeping that was necessary when faced with a novel theory of causation." The Court emphasized that rigorous examination was indeed needed where, as was the case with Drs. Kornbluth and Madigan in the Accutane MCL, their opinions "fl[y] in the face of consistent findings of no causal association as determined by higher levels of scientific proof."[35]

In affirming the exclusion of the testimony, the Supreme Court focused primarily on Plaintiffs' experts' reasoning, which sought to discredit the epidemiological evidence and instead rely on weaker forms of evidence. Both of Plaintiffs' experts "disregarded eight of nine epidemiological studies and relied on case reports and animal studies to support their opinion."[36]

To this point, with heavy reliance on the *The Reference Manual on Scientific Evidence* (3d ed.) issued by the Federal Judicial Center and the National Research Council of the National Academies, the Court explained the role of various forms and levels of scientific evidence in establishing a valid reasoning.[37] The *Reference Manual's* section on Medical Testimony contains a likely-familiar "hierarchy of medical evidence," including the following examples:

Evidence at the top of the hierarchy:

- *Systematic review of randomized trials (meta-analysis)*
- *Single randomized trials*
- *Systematic reviews of observational studies*
- *Single observational studies*
- *Physiological studies*
- *Unsystematic clinical observations*

Evidence at the bottom of the hierarchy:

- *First signals of adverse events or associations (case reports)*
- *Animal studies*

Reviewing the trial court's "gatekeeping" in light of these principles, the New Jersey Supreme Court recognized that Plaintiffs' general causation experts had correctly been excluded. Both experts eschewed the uniform body of epidemiological studies demonstrating no causal association between Accutane and Crohn's Disease. They instead relied on the lowest forms of scientific evidence in forming their opinions. Importantly, it was not *merely* the fact that the experts relied on animal studies and case reports. Their key downfall was that they rejected published studies that had examined thousands of subjects, while instead pointing to a single, unpublished study with a small number of subjects and otherwise relying on the "lowest" forms of proof.[38]

III. IS THE BEST YET TO COME IN NEW JERSEY?

In Re: Accutane brought a long-awaited end to this aspect of Accutane litigation in the New Jersey MCL; without expert testimony, Plaintiffs' pharmaceutical product liability claims could not proceed.

Whether *In Re: Accutane* represents a sea change to litigation in this pharmaceutical-industry home state remains to be seen. Even though *In Re: Accutane* is an affirmation of rigorous scrutiny of unreliable general causation theories, each litigation — and its own corresponding history, experts, and jurists — is unique.

There are, however, takeaways from *In Re: Accutane* that bode well for defendants where a challenge to general causation appears viable. In no particular order, here are a few tips for defense practitioners with product liability cases in New Jersey:

- *Stockpile the evidence from epidemiological studies and other "higher forms" of scientific evidence. And keep updating it. The history of Accutane showed that over the years, the studies became more and more robust. No client wants litigation to drag on; but to the extent new studies are out there, and of course if they are favorable, put them at the top of your list.*
- *Think long and hard about how to organize the scientific proof, and be able to provide a succinct "elevator speech" to summarize it. If helpful, review the Supreme Court's repeated references in In Re: Accutane to the "uniform epidemiological studies" that showed no causal link to the claimed injury. That's the type of recitable snippet that a court can embrace.*
- *Present that evidence to the presiding judge (see note from the trial court proceedings in Accutane) in a user-friendly format. Ideally, you will have a jurist who will dig in to the material in advance of any testimony or hearing. On this point, it's a strategy call whether you want to ask for a "Science Day" on the front end of the litigation — or if it would be more effective to let a single case (e.g., bellwether trial pick) go through a full workup, then present testimony in a Rule 104 hearing as part of your Accutane Motion(s) to exclude Plaintiffs' experts.*
- *Reiterate, at every turn in briefs and oral arguments, that Plaintiffs bear the burden of proof to demonstrate their experts' opinions are reliable. The defense has no obligation to disprove its case. It's tempting not to try to prove the defense is right and plaintiffs are wrong, but that's not the standard. Put Plaintiffs to their burden at every turn, whether in an Accutane motion or dispositive motion.*
- *Keep In Re: Accutane front and center. The defense has a daunting task in pointing out (not proving!) that Plaintiffs' general causation experts have not employed sound methodology. That's a huge task, and as Accutane's lengthy history shows, it is not for*

the faint of heart. Even so, In Re: Accutane should be relied on and cited in every defense motion to exclude expert testimony.

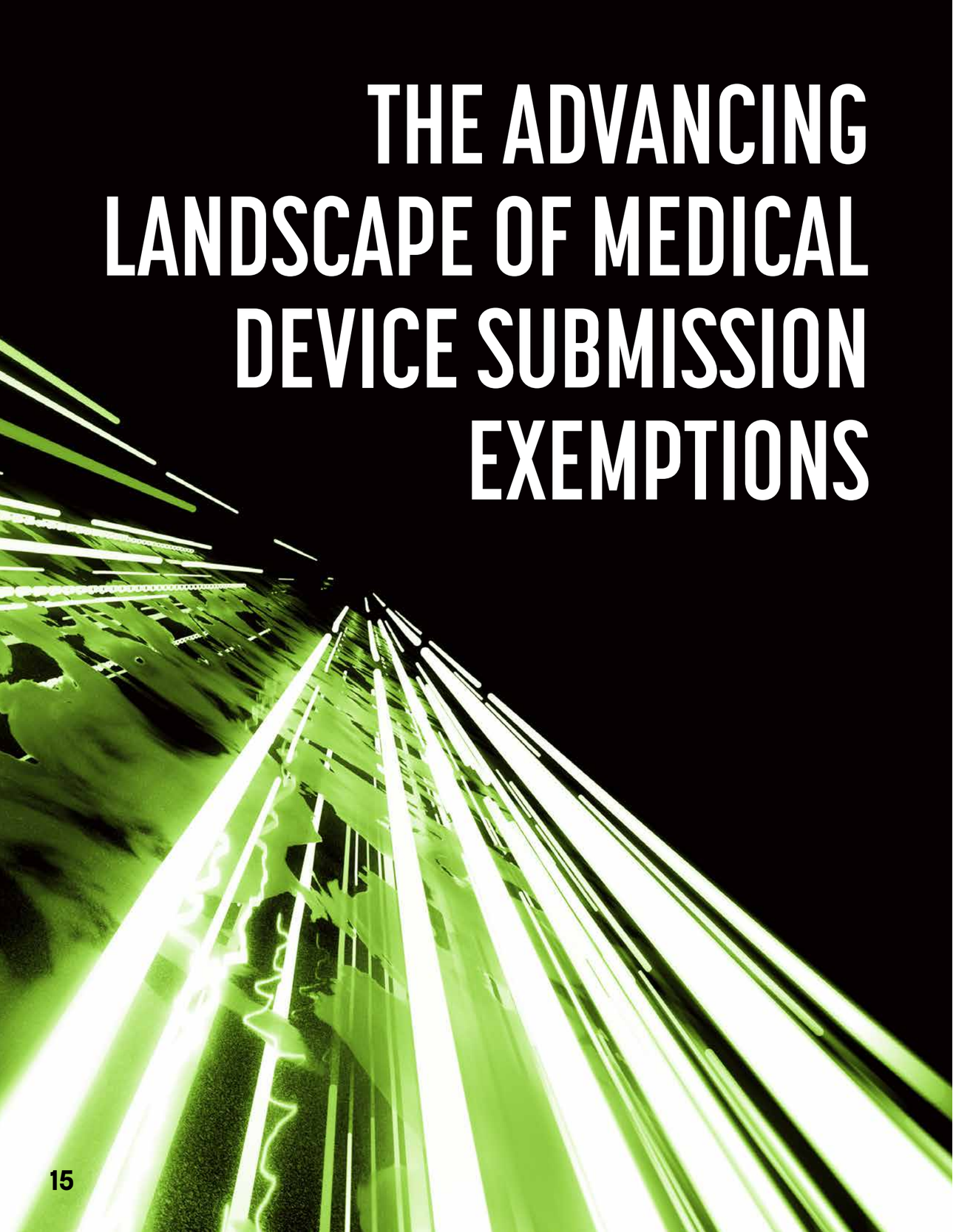
In closing, on a personal note, this author is now using the term "*Accutane* motions" to emphasize that there's a new standard in town (in New Jersey). Plaintiffs have already begun to downplay any change in the standard; and frankly, there's a fair argument in the equivocal *#DaubertNotDaubert* (my term) sections of *In Re: Accutane* to make a judge think twice. But if the defense bar can uniformly remind judges that *Accutane* motions are "the" standard, it may bode well for the pharmaceutical industry.

1. Dickens, Charles. *A Tale of Two Cities.* New York, NY: New American Library.
2. This article does not suggest that the treatment of expert testimony is the only difference in the way the federal versus state litigations progressed. There are undoubtedly several factors, including but not limited to the jurists, counsel, plaintiffs/plaintiffs' injuries, legal theories, proposed experts, legal arguments (e.g., adequacy of the warnings), respective courts of appeals, and many other issues that all played a role in different life spans of the MDL versus New Jersey MCL proceedings. To be sure, the treatment of expert testimony is just one facet.
3. *Daubert v. Merrell Dow Pharms.,* Inc., 509 U.S. 579, 585-87, 113 S. Ct. 2786 (1993).
4. *See In Re: Accutane Prods. Liab.,* 511 F. Supp. 2d 1288 (M.D. Fla. 2007), *aff'd, Rand v. Hoffmann-LaRoche Inc.,* 291 F. App'x 249 (11th Cir. 2008); *In Re: Accutane Prod. Liab.,* 2009 WL 2496444 (M.D. Fla. Aug. 11, 2009), and *In Re: Accutane Prod. Liab.,* 2009 WL 3462395 (M.D. Fla. Oct. 28, 2009), *aff'd,* 378 F. App'x 929 (11th Cir. 2010).
5. *Kemp ex rel. Wright v. State,* 174 N.J. 412, 427, 809 A.2d 77 (2002).
6. *In Re: Accutane Litig.,* 2018 WL 3636867, - A.3d - (N.J. Aug. 1, 2018).
7. *Id.* at *29.
8. https://www.njcourts.gov/attorneys/mcl/atlantic/accutane.html (last visited Aug. 22, 2018). *See also In Re: Accutane Litig.,* No. 271(MCL), 2015 WL 753674, at *1 (N.J. Super. L. Feb. 20, 2015).
9. *In Re: Accutane Litig.,* 2018 WL 3636867, at *7.
10. *Id.* at *10 & n. 7 (citing Charles N. Bernstein et al., Isotretinoin is Not Associated with Inflammatory Bowel Disease: A Population-Based Case-Control Study, 104 Am. J. Gastroenterol. 2774 (2009)).
11. *Id.* at *10 & n. 8 (citing Seth D. Crockett et al., Isotretinoin Use and the Risk of Inflammatory Bowel Disease: A Case-Control Study, 105 Am. J. Gastroenterol. 1986 (2010)). That study did find a statistically significant increased risk between Accutane and ulcerative colitis. *Id.*
12. *Id.* at *10 & n. 9 (citing Mahyar Etminan et al., Isotretinoin and Risk for Inflammatory Bowel Disease, 149 JAMA Dermatol. 216 (2013)).
13. *Id.* at *10 & n.12 (citing Sarah Fenerty et al., Impact of Acne Treatment on Inflammatory Bowel Disease, 68 J. Am. Acad. Dermatol. AB5 (2013)).
14. *Id.* at *10 & n.13 (citing Shadi Rashtak et al., Isotretinoin Exposure and Risk of Inflammatory Bowel Disease, 150 JAMA Dermatol. 1322 (2014)).
15. *Id.* at *10 & n.11 (citing Raed O. Alhusayen et al., Isotretinoin Use and the Risk of Inflammatory Bowel Disease: A Population-Based Cohort Study, 133 J. Investigative Dermatol. 907 (2013)).
16. *Id.* at *10 & n. 14 (citing Antoine Racine et al., Isotretinoin and Risk of Inflammatory Bowel Disease: A French Nationwide Study, 109 Am. J. Gastroenterol. 563 (2014)).
17. *Id.* at *7.
18. *In Re: Accutane Litig.,* No. 271(MCL), 2015 WL 753674, at *2 (N.J. Super. L. Feb. 20, 2015).
19. *Id.* at *1.
20. *Id.* at *6.
21. *Id.* at *21 (emphasis added).
22. *In Re: Accutane Litig.,* 2018 WL 3636867, at *18.
23. *In Re: Accutane Litig.,* 451 N.J. Super. 153, 165 A.3d 832 (App. Div. 2017), rev'd, 2018 WL 3636867 (N.J. Aug. 1, 2018).
24. *In Re: Accutane Litig.,* 2018 WL 3636867, at *33.
25. *Id.* at *23.
26. *Id.* at *5-6, 22-28, 31-33.

RICHELLE W. KIDDER

27. *Id.* at *27-28, 32.
28. *Id.* at *32.
29. *Id.* at *33.
30. *Id.* at *33.
31. *Id.* at *27.
32. *Id.* at *27.
33. *Id.* at *28.
34. *Id.* at *28.
35. *Id.* at *33.
36. *Id.* at *28-29.
37. The trial court explained that the "[t]*The Reference Manual* is a valuable tool, providing excellent guidance in sifting through the information generated at the Kemp Hearing because it is indicative of what the scientific community deems to be reasonable. At this hearing, the court is asked to assess whether the experts in the field would reasonably rely on methods and data as Plaintiffs' experts have done. *Through the Reference Manual,* the scientific community speaks to trial courts and confirms what may be considered to be reasonable." *In Re: Accutane Litig.,* 2015 WL 753674, at *2.
38. *In Re:: Accutane Litig.*, 2018 WL 3636867, at *28-31.

THE ADVANCING LANDSCAPE OF MEDICAL DEVICE SUBMISSION EXEMPTIONS



There have been several efforts in recent years to help reduce the lengthy, costly, and time-consuming process for U.S. Food and Drug Administration (FDA) review and clearance of lower risk devices. The requirement of a 510(k) premarket notification submission to the FDA has applied to Class II devices generally, while almost all Class I devices are exempted from this requirement. Now, FDA is moving toward expanding the 510(k) exemption to well-established Class II devices. This shift is designed to provide additional FDA resources for the evaluation of higher risk products — all in an effort to make such products and treatments available to prospective patients in a timelier fashion.

The 21st Century Cures Act (Cures Act), enacted on December 13, 2016, was designed to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently. The law expanded FDA's ongoing work to incorporate patient perspectives into the development of drugs, biological products, and devices and to help streamline the ultimate approval, clearance, and availability of such products. Section 3054

THE 21ST CENTURY CURES ACT, ENACTED ON DECEMBER 13, 2016, WAS DESIGNED TO HELP ACCELERATE MEDICAL PRODUCT DEVELOPMENT AND BRING NEW INNOVATIONS AND ADVANCES TO PATIENTS WHO NEED THEM FASTER AND MORE EFFICIENTLY.

of the Cures Act amended section 510(m) of the U.S. Food, Drug and Cosmetic (FDC) Act to permit FDA to exempt a Class II device from the report requirement under section 510(k) of the FDC Act if it determines that an additional report is not necessary to provide a reasonable assurance of the safety and effectiveness of the device. The request for exemption can be made on FDA's own initiative or upon a petition of an interested person. This means there could be an increase in the number of Class II, 510(k) exempt devices. Examples of such devices range from acid phosphatase test systems (21 CFR 862.1020) to ultrasonic pulsed echo imaging systems (21 CFR 892.1560).

The FDA Reauthorization Act of 2017 allows reclassification of certain accessories, notwithstanding the classification of the devices that use such accessories. Since accessories are usually classified the same as the primary device, there are several Class II simple devices that could now be declassified (i.e., moved from Class II to Class I). The goal of this reclassification opportunity is to reduce the regulatory burden for devices with the lowest risk and to help FDA focus its resources on the review and approval of innovative and newly developed products that require a rigorous review. Being reclassified to a Class I device means the device would likely be 510(k) exempt.

There are a number of factors FDA may consider when determining whether a 510(k) clearance is necessary to provide a reasonable assurance of the safety and effectiveness of a Class II device. To determine whether premarket notification is necessary for Class II devices, FDA considers if: (1) the device has a significant history of false or misleading claims or of risks associated with inherent characteristics of the device; (2) characteristics of the device necessary for its safe and effective performance are well established; (3) changes to the device that could affect safety and

effectiveness will either be (a) readily detectable to users by visual examination or routine testing before causing harm, or (b) not a material increase in the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would likely result in a change of the device's classification.

Exempting a well-established device from 510(k) submission is both a cost and time savings to the manufacturer. Such exemptions, however, do not preclude the manufacturer's need to establish and maintain Good Manufacturing Practices (GMP), especially design controls for Class II devices. While certain limited Class I devices identified by FDA are also exempted from the GMP regulation, Class II devices are not exempt from GMP requirements, even if they become 510(k) exempt. Therefore, maintenance of design history files with complete design controls for Class II, 510(k) exempt products, is still required and will certainly be a focus during normal, on-site FDA inspections.

It is exciting that FDA has engaged with the government and public communities to help accelerate medical product development in order to bring new innovations and advances to market. Mechanisms that allow FDA to evaluate higher risk submissions more readily include the reduction of submission requirements for lower risk devices and reclassification/exemption of lower risk devices. These changes allow FDA to allocate more people power to the review, clearance, and approval of novel treatments and devices that both the medical community and the general public desire. Manufacturers will appreciate that the submission requirements for lower risk devices may decrease but must understand that the necessity of design controls and GMP remains.

DAWN NORMAN

50-STATE SURVEY OF DESIGN DEFECT REQUIREMENTS

In the world of products liability, design defect claims arise when the product is inherently dangerous in its design. The test for whether a product is inherently dangerous has evolved in modern years from the "consumer expectations test" to the "risk-utility test."

Under the traditional consumer expectations test, the seller of a product is liable if the product is in a defective condition such that it renders the product unreasonably dangerous to the consumer. This standard allows a jury to infer the existence of a defect if the product fails to meet reasonable expectations of consumers.

The risk-utility analysis, on the other hand, allows the fact finder to consider consumer expectations in the risk-utility balancing, but the Third Restatement makes clear that "consumer expectations do not play a determinative role in determining defectiveness." Restatement (Third) of Torts: Prod. Liab. § 2 (1998), comment g. Additionally, the risk-utility analysis typically requires plaintiff to put on proof of a feasible alternative design. *Id.* at (b).

The modern trend by state supreme courts had been an adoption of some form of risk-utility analysis. See *Branham v. Ford Motor Co.,* 390 S.C. 203, n. 11, 701 S.E.2d 5, n. 11 (S.C. 2010) ("By our count 35 of the 46 states that recognize strict products liability utilize some form of risk-utility analysis in their approach to determine whether a product is defectively designed."). Despite this overwhelming trend, three states (Florida, Nevada, and South Dakota) have recently declined to adopt the risk-utility analysis, suggesting the trend could be changing.

This article surveys the current state of law across the 50 states to demonstrate which states have adopted the risk-utility test and which states remain committed to the consumer expectations test. The survey includes whether the state requires a plaintiff to demonstrate that a feasible

THE MODERN TREND BY STATE SUPREME COURTS HAD BEEN AN ADOPTION OF SOME FORM OF RISK-UTILITY ANALYSIS.

alternative product design would have prevented plaintiff's harm at a reasonable cost.

ALABAMA

Current Law: Alabama follows its own unique test under the "Alabama Extended Manufacturer's Liability Doctrine," which incorporates both the consumer expectations test and risk-utility test. *Casrell v. Altec Industries, Inc.,* 335 So. 2d 128 (Ala. 1976) and *Atkins v. American Motors Corp.,* 335 So. 2d 134 (Ala. 1976); *see also* Ala. Code § 6-5-521 (2018) (defining "product liability action").
Is Proof Required? Yes. *Beech Through Beech v. Outboard Marine Corp.,* 584 So. 2d 447, 450 (Ala. 1991); *Hosford v. BRK Brands, Inc.,* 223 So. 3d 199, 203 (Ala. 2016).

ALASKA

Current Law: Courts can apply either the consumer expectations test or risk-utility analysis. *General Motors Corp. v. Farnsworth,* 965 P.2d 1209, 1220 (Alaska 1998).
Is Proof Required? No. *Maines v. Kenworth Alaska, Inc.,* 155 P.3d 318, 331, n. 35 (Alaska 2007) ("Alaska does not require the proof of a reasonable alternative design to be an absolute requirement.").

ARIZONA

Current Law: Courts can apply either the consumer expectations test or risk-utility analysis. *See Long v. TRW Safety Systems, Inc.,* 796 F. Supp. 2d 1005, 1011 (D. Ariz. 2011) ("In Arizona, two models may be used to determine whether the product was defectively designed: the consumer expectation test and risk/benefit analysis.") (citing *Golonka v. GM Corp.,* 204 Ariz. 575, 65 P.3d 956, 962 (Ariz. Ct. App. 2003)).

Is Proof Required? It is unclear. Compare *Long v. TRW Safety Systems, Inc.,* 796 F. Supp. 2d 1005, 1011 (D. Ariz. 2011) (holding that defendant had shown no legal authority providing that plaintiffs were required to prove, *inter alia,* an alternative design) with *Welch v. Wright Medical Technology, Inc.,* 2012 WL 4711899, *2 (D. Ariz. 2012) (noting that Arizona's standard is analogous to the standard proposed by the Third Restatement of Torts, which provides that a design is defective "when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design.").

ARKANSAS

Current Law: Consumer expectations. Ark. Code § 16-116-202(7)(A).

Is Proof Required? No. *Boerner v. Brown & Williamson Tobacco Corp.,* 260 F.3d 837, 846 (8th Cir. 2001) ("[O]ur case law makes clear that a defective design can be established under Arkansas law without proof of a safer alternative design."

CALIFORNIA

Current Law: Courts can apply either the consumer expectations test or risk-utility analysis. *Ramirez v. ITW Food Equipment Group, LLC,* 686 F. App'x 435, 437 (9th Cir. 2017) ("The consumer-expectations and risk-benefit tests 'provide alternative means for a plaintiff to prove design defect and do not serve as defenses to one another,' meaning that [plaintiffs] can succeed under one test even if they fail under another.") (citing *Chavez v. Glock, Inc.,* 207 Cal. App. 4th 1283, 144 Cal.Rptr.3d 326, 343 (2012)).

Is Proof Required? No. *Perez v. VAS S.p.A.,* 188 Cal. App. 4th 658, 685, 115 Cal.Rptr.3d 590, 611 (Cal. App. 2d Dist. 2010).

COLORADO

Current Law: Risk-utility. *Barton v. Adams Rental, Inc.,* 938 P.2d 532, 537 (Colo. 1997).

Is Proof Required? No. *See Armentrout v. FMC Corporation,* 842 P.2d 175, 185 n. 11 (Colo. 1992); *see also Walker v. Ford Motor company,* 406 P.3d 845, 850 (Colo. 2017).

CONNECTICUT

Current Law: Consumer expectations, except in complex product designs in which a "modified consumer expectations" applies. *See Potter v. Chicago Pneumatic Tool Co.,* 241 Conn. 199, 219-220, 694 A.2d 1319, 1330 (Conn. 1997).

Is Proof Required? No. *Potter v. Chicago Pneumatic Tool Co.,* 241 Conn. 199, 221, 694 A.2d 1319, 1330, 1332-33 (Conn. 1997).

DELAWARE

Current Law: It is unclear. Delaware has never adopted strict liability, declaring it to be "impermissible judicial legislation." *Cline v. Prowler Industries, Inc.,* 418 A.2d 968, 974 (Del. 1980).

Is Proof Required? No. *Barba v. Carlson, No.* N11C-08-050 MMJ, 2014 WL 1678246, *5 (Del. Super. Apr. 8, 2014) ("It is legally possible for a plaintiff to prove defective design even if no alternative design has been identified.").

FLORIDA

Current Law: Consumer expectations. *Aubin v. Union Carbide Corp.,* 177 So. 3d 489, 510 (Fla. 2015) ("[I]n approaching design defect claims, we adhere to the consumer expectations test[.]").

Is Proof Required? No. *Aubin v. Union Carbide Corp.,* 177 So. 3d 489, 510 (Fla. 2015) ("[I]n approaching design defect claims, we . . . reject the categorical adoption of the Third Restatement and its reasonable alternative design requirement.").

GEORGIA

Current Law: Risk-utility. *Banks v. ICI Americas, Inc.,* 264 Ga. 732, 734, 450 S.E. 2d 671, 673 (Ga. 1994) ("[W]e hereby adopt the risk-utility analysis.").

Is Proof Required? Yes. *Jones v. NordicTrack, Inc.,* 550 S.E.2d 101, 103-04 (Ga. 2001).

HAWAII

Current Law: (i) Consumer expectations; (ii) risk-utility; and (iii) the latent danger test. *See Acoba v. General Tire, Inc.,* 92 Haw. 1, 17, 986 P.2d 288, 304 (Haw. 1999) ("A plaintiff may establish a defect for purposes of either strict liability or negligence under three approaches: (1) the 'consumer expectation' test; (2) the 'risk utility' test; and (3) the 'latent danger' test.").

Is Proof Required? It has not been directly addressed, but appears no. See *Masaki v. General Motors Corp.,* 71 Haw. 1, at 22-23 n. 10, 780 P.2d 566 at 578 n. 10 (Haw. 1989) (finding a jury instruction, which provided, *inter alia* as follows, to be consistent with Hawaii law: "In determining whether or not the benefits outweigh such risk, you may consider . . . the mechanical feasibility of a safer alternative design at the time the product was manufactured, the financial cost of an improved design, and the adverse consequences, if any, to the product and the consumer that would result from an alternative design.") (emphasis added).

IDAHO

Current Law: Risk-utility. *Toner v. Lederle Labs.,* 732 P.2d 297, 306 (Idaho 1987).

Is Proof Required? Yes. *Puckett v. Oakfabco, Inc.,* 979 P.2d 1174, 1181 (Idaho 1999).

ILLINOIS

Current Law: Either is acceptable. *Calles v. Scripto-Tokai Corp.,* 224 Ill. 2d 247, 253-54 (2007).
Is Proof Required? No. *Mikolajczyk v. Ford Motor Co.,* 231 Ill. 2d 516, 560 (Ill. 2008).

INDIANA

Current Law: Consumer expectations. *See* Ind. Code Ann. § 34-20-4-1.
Is Proof Required? Yes. *Burt v. Makita USA, Inc.,* 212 F. Supp. 2d 893, 900 (N.D. Ind. 2002).

IOWA

Current Law: Risk-utility. *Wright v. Brooke Group Ltd.,* 652 N.W.2d 159, 169-170 (Iowa 2002).
Is Proof Required? Yes. *Wright v. Brooke Group Ltd.,* 652 N.W.2d 159, 169-170 (Iowa 2002).

KANSAS

Current Law: Consumer expectations. *Delaney v. Deere & Co.,* 999 P.2d 930, 945-47 (Kan. 2000) (While also recognizing that the "validity of risk-utility analysis as a guide in determining the expectations of consumers in complex cases.").
Is Proof Required? No. *Delaney v. Deere & Co.,* 999 P.2d 930, 945-47 (Kan. 2000).

KENTUCKY

Current Law: Risk-utility analysis. *Toyota Motor Corp. v. Gregory,* 136 S.W.3d 35, 42 (Ky. 2004).
Is Proof Required? Yes. *Toyota Motor Corp. v. Gregory,* 136 S.W.3d 35, 42 (Ky. 2004).

LOUISIANA

Current Law: Risk-utility. *See* LSA-R.S. § 9:2800.56.
Is Proof Required? Yes. *See* LSA-R.S. § 9:2800.56.

MAINE

Current Law: Danger-utility test. *Guiggey v. Bombardier,* 615 A.2d 1169, 1172 (Me. 1992).
Is Proof Required? Yes. *Stanley v. Schiavi Mobile Homes, Inc.,* 462 A.2d 1144, 1148 (Me. 1983).

MARYLAND

Current Law: Consumer expectations, except when a product malfunctions, in which case risk-utility applies. *Halliday v. Sturm, Ruger & Company, Inc.,* 792 A.2d 1145, 1152-1153 (Md. 2002).
Is Proof Required? No, if consumer expectations. Yes, if risk-utility. *See Halliday,* 792 A.2d at 1153; *Lloyd v. Gen. Motors Corp.,* 275 F.R.D. 224, 228-231 (D. Md. 2011).

MASSACHUSETTS

Current Law: Risk-utility. *Evans v. Lorillard Tobacco Co.,* 465 Mass. 411, 423-428 (Mass. 2013).
Is Proof Required? Yes. *Evans v. Lorillard Tobacco Co.,* 465 Mass. 411, 428-429 (Mass. 2013).

MICHIGAN

Current Law: Risk-utility. *Gregory v. Cincinnati Inc.,* 538 N.W.2d 325, 333 (Mich. 1995).
Is Proof Required? Yes. *Croskey v. BMW, Inc.,* 532 F.3d 511, 516 (6th Cir. 2008).

MINNESOTA

Current Law: Consumer expectations. *Bilotta v. Kelley Co., Inc.,* 346 N.W.2d 616, 622 (Minn. 1984).
Is Proof Required? Yes, except in "rare cases." See *Kallio v. Ford Motor Co.,* 407 N.W.2d 92, 96 (Minns. 1987) ("to establish a prima facie case that [the product] was unreasonably dangerous normally requires production of evidence of the existence of a feasible, alternative safer design.). (emphasis added); *see also Wagner v. Hesston Corp.,* 450 F.3d 756, 760 (8th Cir. 2006).

MISSISSIPPI

Current Law: Both consumer expectations and risk-utility. *Smith v. Mack Trucks, Inc.,* 819 So. 2d 1258, 1266 (Miss. 2002).
Is Proof Required? Yes. *See* Miss. Code Ann. § 11-1-63(f)(ii).

MISSOURI

Current Law: Neither. *See Sappington v. Skyjack, Inc.,* 512 F.3d 440 (8th Cir. 2008) ("Missouri courts have consistently refused to impose any 'judicial definition [of unreasonably dangerous] whether derived from consumer expectations, risk-utility, or otherwise.'").

Is Proof Required? No. *Moore v. Ford Motor Co.,* 332 S.W.3d 749, 760 (Mo. 2011).

MONTANA

Current Law: "A design defect is one which 'presents an unreasonable risk of harm, notwithstanding that it was meticulously made according to [the] detailed plans and specifications' of the manufacturer.'" *Rix v. General Motors Corp.,* 723 P.2d 195, 200 (Mont. 1986); see also *Krueger v. General Motors Corp.,* 783 P.3d 1340, 1345 (Mont. 1989); *see also Speaks v. Mazda Motor Corp.,* 118 F. Supp. 3d 1212, 1226 (D. Mont. 2015) ("As has been consistently reiterated by the Montana Supreme Court, 'the focus in design defect cases shines on the condition of the product, rather than the manufacturer's conduct or knowledge.'").
Is Proof Required? Yes. *Krueger v. General Motors Corp.,* 240 Mont. 266, 783 P.3d 1340 (1989).

NEBRASKA

Current Law: Consumer expectations. *Freeman v. Hoffman-La Roche, Inc.,* 260 Neb. 552, 557-558, 618 N.W.2d 827, 834 (2000).
Is Proof Required? No. *Rahming v. Mosley Machinery Co.,* 226 Neb. 423, 412, 412 N.W.2d 56 (Neb. 1987).

"MISSOURI COURTS HAVE CONSISTENTLY REFUSED TO IMPOSE ANY 'JUDICIAL DEFINITION [OF UNREASONABLY DANGEROUS] WHETHER DERIVED FROM CONSUMER EXPECTATIONS, RISK-UTILITY, OR OTHERWISE.'"

NEVADA

Current Law: Consumer expectations. *Ford Motor Co. v. Trejo,* 402 P.3d 649, 655 (Nev. 2017).
Is Proof Required? No. *Ford Motor Co. v. Trejo,* 402 P.3d 649, 655 (Nev. 2017).

NEW HAMPSHIRE

Current Law: Risk-utility. *Kelleher v. Marvin Lumber & Cedar Co.,* 152 N.H. 813, 831, 891 A.2d 477, 492 (N.H. 2005) ("The jury determines whether a product is unreasonably dangerous by using risk-utility balancing test.").
Is Proof Required? No. *Kelleher v. Marvin Lumber & Cedar Co.,* 152 N.H. 813, 831, 891 A.2d 477, 492 (N.H. 2005) ("Proof of an alternative design is neither a controlling factor nor an essential element that must be proved in every case.").

NEW JERSEY

Current Law: Risk-utility. *Lewis v. American Cyanamid Co.,* 155 N.J. 544, 560, 715 A.2d 967, 975 (1998).
Is Proof Required? Not necessarily. N.J. Stat. § 2A:58C-3(a)(1) (providing that a plaintiff may succeed on a design defect claim if the plaintiff shows either that the product's risks outweighed its utility or that a practical and feasible, safer, alternative design existed that would have reduced or prevented the harm.).

NEW MEXICO

Current Law: Risk-utility, at least to some degree. *See Bustos v. Hyundai Motor Co.,* 149 N.M. 1, 13, 243 P.3d 440, 452 (N.M. Ct. App. 2010)("New Mexico's existing law, at least to some degree, applies the risk-utility considerations[.]").
Is Proof Required? No. *Bustos v. Hyundai Motor Co.,* 149 N.M. 1, 13, 243 P.3d 440, 452 (N.M. Ct. App. 2010) ("to the extent that evidence of an alternative design is required, New Mexico courts do not require a 'rigid showing in the plaintiff's prima facie case.'").

NEW YORK

Current Law: Risk-utility. *Reis v. Volvo Cars of N. Am.,* 24 N.Y.3d 35, 42, 18 N.E.3d 383, 387-88 (2014).
Is Proof Required? Yes. *Scarangella v. Thomas Built Buses, Inc.,* 717 N.E.2d 679, 681-82 (N.Y. 1999).

NORTH CAROLINA

Current Law: Risk-utility, except in firearms cases. N.C. Gen. Stat. § 99B-6(a)-(b); N.C. Gen. Stat. § 99B-11.
Is Proof Required? Yes. N.C. Gen. Stat. § 99B-6(a).

NORTH DAKOTA

Current Law: Consumer expectations. N.D. Cent. Code § 28-01.3-01(4).
Is Proof Required? Yes. *Erling v. American Allsafe Co.,* 230 F.3d 1362 (8th Cir. 2000).

OHIO

Current Law: Risk-utility. Ohio Rev. Code Ann. § 2307.75.
Is Proof Required? Yes. Ohio Rev. Code Ann. § 2307.75(F).

OKLAHOMA

Current Law: Consumer expectations. *Woods v. Fruehauff Trailer Corp.,* 765 P.2d 770, 774-76 (Okla. 1988).
Is Proof Required? No. *Graves v. Mazda Motor Corp.,* 2010 WL 5094286, *1 (10th Cir. 2010).

OREGON

Current Law: Consumer expectations. *McCathern v. Toyota Motor Corp.,* 23 P.3d 320, 331 n.15 (2001).
Is Proof Required? No. *McCathern v. Toyota Motor Corp.,* 23 P.3d 320, 331 (2001).

PENNSYLVANIA

Current Law: Either consumer expectations or risk-utility. *Tincher v. Omega Flex, Inc.,* 628 Pa. 296 (Penn. 2014).
Is Proof Required? Yes, if applying risk-utility. *Capece v. Hess Maschinenfabrik GmbH & Co. KG,* 2015 U.S. Dist. LEXIS 35145 (M.D. Pa. Mar. 20, 2015).

RHODE ISLAND

Current Law: Consumer expectations. *Austin v. Lincoln Equip. Assoc., Inc.,* 888 F.2d 934, 936 (1st Cir. 1989).
Is Proof Required? No. *Guilbeault v. R.J. Reynolds Tobacco Co.,* 84 F. Supp. 2d 263 (D.R.I. 2000) ("Although practically, a plaintiff may well have to prove that a safer feasible alternative design exists to convince a factfinder that the product is 'defective' in a way that would render it unreasonably dangerous, there is no indication that this type of proof is required as a matter of law in Rhode Island.").

SOUTH CAROLINA

Current Law: Risk-utility. *Branham v. Ford Motor Co.,* 701 S.E.2d 5, 14 (S.C. 2010).
Is Proof Required? Yes. *Branham v. Ford Motor Co.,* 701 S.E.2d 5, 14-16 (S.C. 2010).

SOUTH DAKOTA

Current Law: It is unclear. *Robinson v. S.D. Brandtjen & Kluge, Inc.,* 500 F.3d 691, 698 n.2 (8th Cir. 2007) ("It is unclear whether South Dakota has adopted, or would adopt, the so-called 'risk-utility test,' in addition to the consumer expectations test of section 402A, for determining the existence of a defective condition."); see also *Karst v. Shur-Co.,* 878 N.W.2d 604, 622-623 (S.D. 2016) (dissent) ("Because the majority opinion has declined to adopt the risk-utility test . . . as its exclusive test in strict products-liability claims for design defect, this discussion must wait for another day. In the interim, South Dakota law requires the plaintiff to prove that a product is both defective and unreasonably dangerous. An instruction that substantially complies with the consumer-expectation test must be given to meet the required 'unreasonably dangerous' element. Although Kolfraft purports to allow an election between the risk-utility test or the consumer expectations . . . instructions on both the risk-utility test and consumer-expectations test must be given to correctly instruct the jury.").
Is Proof Required? It has never been directly decided. But see *Karst v. Shur-Co.,* 878 N.W.2d 604 (S.D. 2016) (Kern, J. dissenting) (Suggesting that if risk-utility applied then an alternative design would be required.).

TENNESSEE

Current Law: Consumer expectations. See Tenn. Code Ann. § 29-28-102(8).
Is Proof Required? No. *Potter v. Ford Motor Co.,* 213 S.W.3d 264 (Tenn. Ct. App. 2006).

TEXAS

Current Law: Risk-utility. *Uniroyal Goodrich Tire Co. v. Martinez,* 977 SW 2d 328 (Tex. 1998).
Is Proof Required? Yes. Tex. Civ. Prac. & Rem. Code Ann. § 82.005(a)(1).

UTAH

Current Law: Consumer expectations. Utah Code § 78B-6-702; *Brown v. Sears, Roebuck & Co.,* 328 F.3d 1274, 1278-79 (10th Cir. 2003).
Is Proof Required? Yes. *Allen v. Minnstar, Inc.,* 8 F.3d 1470, 1479 (10th Cir. 1993).

VERMONT

Current Law: Consumer expectations. *See Zaleske v. Joyce,* 133 Vt. 150, 155, 333 A.2d 110, 113-114 (1975) (Adopting 402A); See also *Farnham v. Bombardier, Inc.,* 161 Vt. 619, 620, 640 A.2d 47, 48 (1994).
Is Proof Required? It is undetermined. *See Manning v. Goodyear Tire & Rubber Co.,* 2005 Vt. Super. LEXIS 126, fn. 6 (July 20, 2005) ("The adoption of a reasonable alternative design standard based on risk-utility analysis has moved this area of the law away from § 402A's strict liability standard toward negligence. The Vermont Supreme Court has considered this view but has not necessarily adopted it.") (internal citations omitted).

VIRGINIA

Current Law: Product is defective if it "fails to satisfy applicable industry standards, applicable government standards, or reasonable consumer

expectations." See *Redman v. John D. Brush & Co.,* 111 F.3d 1174, 1177 (4th Cir. 1997).

Is Proof Required? Yes. *See Tunnell v. Ford Motor Co.,* 385 F. Supp. 2d 582, 583 (W.D. Va. 2005).

WASHINGTON

Current Law: Either is acceptable. *See Soproni v. Polygon Apartment Partners,* 137 Wash. 2d 319, 326-27, 971 P.2d 500, 504-05 (1999).

Is Proof Required? Yes, under risk-utility. *See Ruiz-Guzman v. Amvac Chemical Corp.,* 141 Wash. 2d 493, 503, 7 P.3d 795, 800 (2000); No, under consumer expectations. *See Couch v. Mine Safety Appliances Co.,* 107 Wash. 2d 232, 237, 241, 728 P.2d 585, 588, 590 (1986).

WEST VIRGINIA

Current Law: Unique version of risk-utility. Phillip Combs and Andrew Cooke, Modern Products Liability Law in West Virginia 113 W. Va. L. Rev. 417, 425 (2011); *See also Betty v. Ford Motor Co.,* 574 S.E.2d 803 (W. Va. 2002).

Is Proof Required? It has not been directly addressed. *See Keffer v. Wyeth,* 791 F. Supp. 2d 539, 547-548 (S.D W. Va. 2011) ("To be sure, the West Virginia Supreme Court has not stated one way or the other whether a design defect claim requires proof of a safer alternative design of the allegedly defective product. . . Nevertheless, even if it is not required, offering evidence of a safer alternative design is at least one method of showing that a product is 'not reasonably safe for its intended use' for the purposes of a design defect claim."); *see also Phillip Combs and Andrew Cooke,* 113 W. Va. L. Rev. 417, 427 (2011) (noting lack of case law on the issue).

WISCONSIN

Current Law: Consumer expectations. *Green v. Smith & Nephew AHP, Inc.,* 629 N.W.2d 727, 739 - 741 (Wis. 2001).

Is Proof Required? No. *Green v. Smith & Nephew AHP, Inc.,* 629 N.W.2d 727, 739 - 741 (Wis. 2001).

WYOMING

Current Law: Consumer expectations. *Sims v. General Motors Corp.,* 751 P.2d 357, 364-65 (Wyo. 1988) (emphasis added).

Is Proof Required? Yes, but the Wyoming Supreme Court has suggested it would be inclined to consider arguments that an alternative design is not required. See *Campbell err el. Campbell v. Studer, Inc.,* 970 P.2d 389, 392 n. 1 (Wyo. 1998) ("The requirement that plaintiff show the existence of a reasonable alternative design as an element of her claim has been the subject of extensive debate. Comments b and e to this section, however, suggest an alternative design may not be necessary in every design defect case. We need not enter the debate at this time because [Plaintiff's] allegations clearly rest on her contention that a feasible alternative design was available.").

MARGARET Z. SMITH

BIOS:

PARADIGM SHIFT OR SAME-OLD-SAME-OLD?

RICHELLE W. KIDDER

Richelle Kidder focuses her practice on product liability law and all phases of briefing in litigation. She is experienced in nationwide pharmaceutical products liability cases involving over-the-counter and prescription drugs and medical devices. Her experience includes litigation in Multidistrict Litigation actions as well as federal and state individual and consolidated proceedings.

She obtained her B.A. from The Ohio State University and her J.D. from the University of Houston. Richelle clerked for Judge David Hittner in the United States District Court for the Southern District of Texas, Houston Division. She is admitted to the State Bars of Tennessee, Ohio (inactive), and Texas (inactive).

THE ADVANCING LANDSCAPE OF MEDICAL DEVICE SUBMISSION EXEMPTIONS

DAWN NORMAN

Dawn is a non-lawyer principal with Butler Snow's life science regulatory and compliance subsidiary – MRC-X. She has spent the past 19 years in the medical device industry working with venture capital backed start-ups and larger companies alike. She focuses her work on regulatory, strategy, and submissions, along with clinical study design and study execution, for products such as navigation devices for neurosurgical and cardiac indications, high intensity ultrasound for cardiac ablation, recombinant proteins for bone fusion, orthopedic trauma, vascular access, and imaging technologies.

50-STATE SURVEY OF DESIGN DEFECT REQUIREMENTS

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