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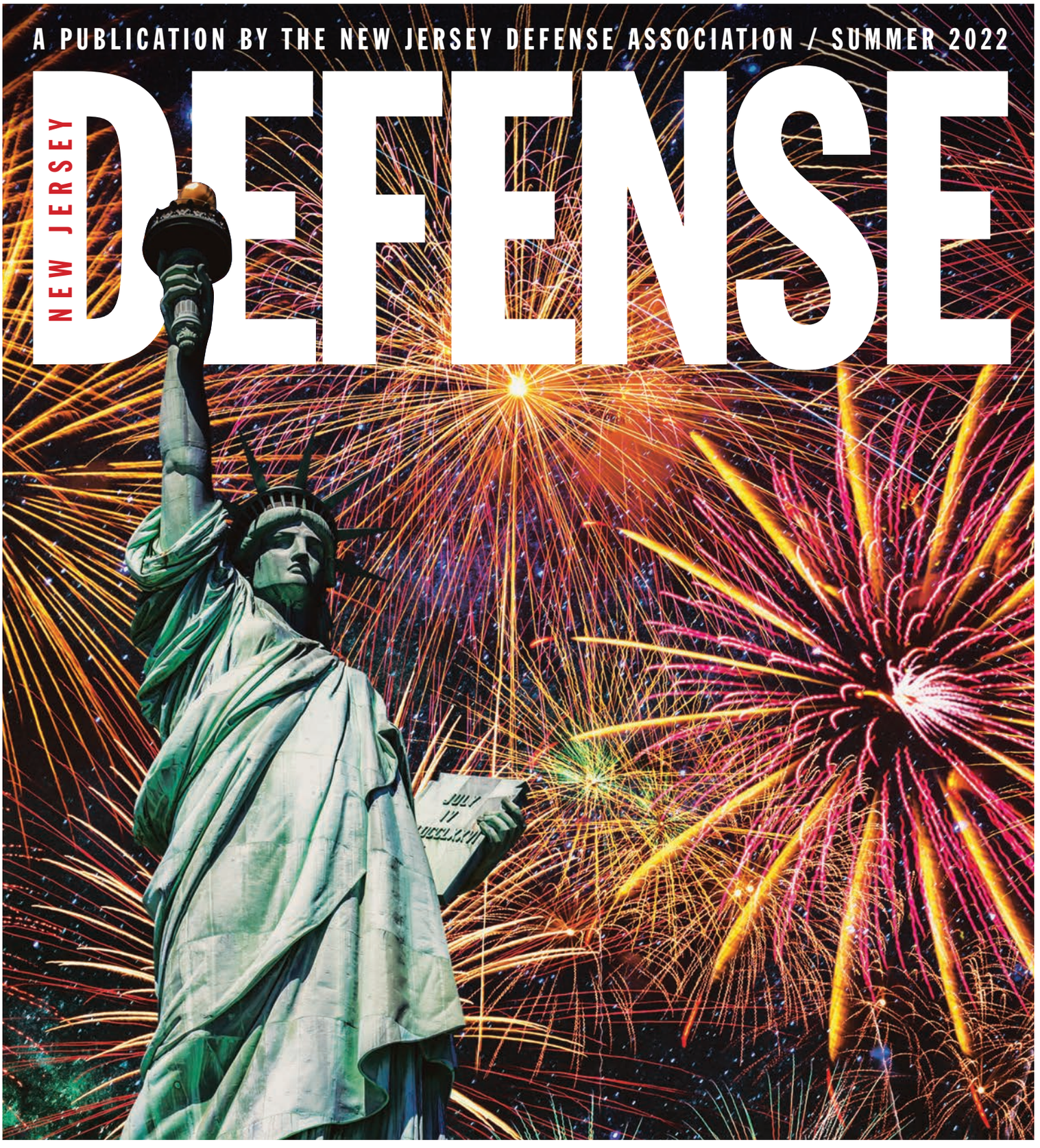
NEW JERSEY DEFENSE



PRESIDENT'S LETTER

I am very thankful and honored to have served as the NJDA's 56th President. We had a very successful year with a full calendar of events, with a mix of some returning to in person and others remaining virtual. It was great to see our speakers, members and sponsors at those events that were in person (i.e. the annual Auto seminar, holiday party, etc.), but some events remained virtual due to the continued challenges of the pandemic. The virtual seminars were also a great success and well attended that our members enjoy. I would be remiss if I did not conclude my term by giving a big thanks to our Executive Director, Maryanne Steedle, for all that she does for this organization. It would not be able to run so well without her.

I have a great confidence about the future of this organization. This organization is in great hands with our incoming President, Michelle O'Brien, who will be an excellent leader. As I have done all year, I encourage our members to continue to become more involved in this organization. Join a committee. Have your young attorneys join our Young Lawyers' Division. We have an excellent Young Lawyers' CLE and happy hour event that will take place over the summer. Write an article by contacting our incoming President-Elect, Rob Luthman. Speak at a seminar.

I very much look forward to seeing you at the Annual Convention on June 23-26, 2022, at the historic Hotel Viking in Newport, Rhode Island. We have a tremendous CLE program scheduled that I am very excited for, which will offer 6 CLE credits, including 1 DEI credit. We are very excited that the Hon. Harry G. Carroll, J.A.D. (Ret.) will join our annual Civil Case Law Update panel on Saturday morning. Our members are providing excellent presentations, including a panel discussion on defense strategies in the bad faith environment and tort law updates from our Young Lawyers Committee. There will also be a presentation from Exponent on litigation case studies in plastic construction materials.

Thank you again for your continued support of our organization and another successful year of the NJDA.

Ryan Richman

RYAN RICHMAN, ESQ.

LABEGA V. JOSHI: "A RETURN TO NORMALCY"

BY HERBERT KRUTTSCHNITT III & RYAN A. NOTARANGELO

In the defense of medical malpractice cases, it is an ongoing frustration to constantly deal with the conflation of hospital Policy & Procedure and the concept of standard of care. They are not the same. It is not that complicated. If we take an intellectually honest look at what is really going on when someone makes the argument to equate them, we easily see right through it. Policy & Procedure is not about defining the "standard of care." Said simply, they are not written in order to tell health care providers what is simply "acceptable." Yet, "acceptable" is the central issue in a medical malpractice lawsuit.

Policy & Procedure, on the other hand, are exhortations to excellence, plain and simple. The fact that plaintiff attorneys routinely use them in an effort to raise the bar to the point that standard of care is not met by anything less than perfection; wow, that's clever. So, when a case like Labega v. Joshi (approved for publication February 1, 2022) comes along, we need to celebrate it for its clarity even if it still begs the question of whether Policy & Procedure should ever have a place in a lawsuit at all.

A separate article could be written about all of the mental gymnastics that plaintiff attorneys go through in order to get Policy & Procedure before a jury, and there are solid arguments against it. Policy & Procedure are routinely argued to be relevant to standard of care. So long as plaintiff's expert testifies independently as to standard of care and then uses Policy & Procedure to buttress that conclusion they are routinely introduced into evidence. Today we won't go there, but see Johnson v Mountainside Hospital, 239 N.J. Super. 312 (App. Div. 1990).

Why all of the effort to get Policy & Procedure in to evidence? The reason, of course, is that juries are not going to understand the distinction between a practitioner meeting the standard of care, and at the same time perhaps not adhering strictly to his hospital's Policy & Procedure. Isn't there a logical difference between what is acceptable and what are best practices? Which one meets the standard of care, and which, by definition, far exceeds it. The distinction gets blurred when it is couched in terms of, 'how can conduct comport with standard of care if it violates the rules of the hospital'. One will never go broke underestimating the ability of a jury to confuse that distinction.

So, let's for a brief moment celebrate Labega. The Labega case was a medical malpractice case which had claims cleverly pled and clearly intended to replace the real issue (standard of care) with issues chosen for ease of being proven. They call that putting the rabbit in the hat. It's not magic, just slight of hand and a little feigned surprise. In Labega, the trial court was taken in. The appellate court, on the other hand, wasn't fooled at all.

Labega started like any other medical malpractice case. Plaintiff selected a medical negligence claim from a short menu of accepted and recognized medical malpractice claims. In addition to medical negligence, the other items on that short menu of appropriate causes of action in the medical malpractice context primarily consist of informed consent and battery. That is the regular menu—choose from the three. Occasionally, when the appropriate ingredients are available, there may be a choice or two from a special menu, which does not occur often. There may be a breach of contract claim, but only on an extremely

rare occasion. That claim is reserved for the exceedingly infrequent occasions when the patient made a "special agreement" with her physician to perform medical services in a special manner. There may also be, also exceedingly rare, a negligence per se claim. That would be when a physician violates a statute, written specifically with an eye toward a particular medical procedure, and with an eye toward protecting a particular class of patient. That's it.

Perhaps not being satisfied with the chances of proving the traditional causes of action, in Labega, Plaintiff amended his complaint to include, inter alia, a breach of contract claim arising from alleged breaches of hospital Policy & Procedure. Physicians routinely have contracts with hospitals, and those contracts usually contain a clause requiring the physician to adhere to hospital Policy & Procedure. Plaintiff claimed that he was an intended third-party beneficiary of that contract and, therefore, entitled to sue the physician for breach of contract for not adhering to the hospital Policy & Procedure. Plaintiff also asserted a negligence per se claim for violation of the hospital Policy & Procedure, arguing that hospital Policy & Procedure are akin to statutes. None of these claims are on that standard menu. Make no mistake about it, while clever to be sure, easing the burden of proof was clearly the point. Why not?

More than just attempting to replace the standard of care with an exhortation to excellent, it was a reformulation of the definition of the standard of care itself. Under this hospital Policy & Procedure standard of care theory, the standard of care was no longer the prudence that a reasonable healthcare provider in the community would exercise in the same or similar circumstances. According to the argument, the hospital Policy & Procedure is the hospital's own standard of care that governs and guides patient care at the hospital. There is no need to wade through the morass of what is the "reasonable standard" or to deal with the gnarly issue that reasonable people (experts) may differ on the "standard of care." So the argument goes, if there is a violation of the Policy & Procedure, then there is a breach. You do not need to battle with opposing experts, because the bar has been set well above the ability of anyone to clear. To equate the violation of Policy & Procedure with a violation of the "standard of care" reasonable minds can no longer differ on the point. You also do not need causation; only an injured plaintiff and a violation of hospital Policy & Procedure or a breach of contract claim.

And, as if upping the ante with a redefinition of the standard of care isn't enough, plaintiff also argued that the alleged violations of the hospital Policy & Procedure constituted negligence per se. Negligence per se claims are rare and limited to the exceptional situation in which the Legislature has incorporated a common law standard of care into a statute. With the advocated elevation of hospital Policy & Procedure to the level of statutory status, the trial Court had held that the hospital had thus incorporated its own exhortation to excellence (hospital Policy & Procedure) into a hospital "statute" that governs the standard of care. Negligence per se. Forget experts. Forget the old "standard of care". The court declared negligence in its purest form and for simply failing to follow hospital Policy & Procedure.

Agreeing with plaintiffs, the trial court found that breaches of hospital Policy & Procedure alone, and as incorporated by reference into the hospital physician contracts, were per se deviations from the standards of care. It didn't matter that plaintiff's own expert conceded that the hospital Policy & Procedure did not establish the standard of care in this case.

To add insult to injury, the court held that it is "not uncommon in medical malpractice/negligence cases to permit theories of breach of contract, third party beneficiary, and negligence per se claims to be asserted where implicated parties were or are required by contract to abide by hospital policies, procedures, and protocols." As to the negligence per se claim, the trial court concluded that in general a negligence per se claim can be asserted when there is "a clausal relationship between the negligence and the violation of the statute, regulation or [hospital] policy." The good news is that this did not sit well with the appellate court.

The appellate court held, and plaintiff's counsel did concede at oral argument, that it is not common "in medical malpractice/negligence cases to permit theories of breach of contract, third party beneficiary, and negligence per se claims to be asserted where implicated parties were or are required by contract to abide by hospital policies, procedures, and protocols." Likewise, the appellate court held that the limited menu of claims for relief against medical providers for malpractice consists of deviation from standard of care, lack of informed consent & battery. Where the claim is that there was a failure to treat or properly treat the patient, the claim is medical negligence. It is not a breach of contract or a breach of a Policy & Procedure.

The appellate court also dismissed plaintiff's intended third-party beneficiary breach of contract theory, because there was no support whatsoever for this novel theory in the medical malpractice context. The appellate court found the physician contracts unambiguously expressed no intent on the contracting parties to permit a patient, like the plaintiff, to sue to enforce contractual terms or to claim damages as a result. In fact, most of these contracts unambiguously exclude third-party beneficiaries.

Likewise, as to the negligence per se claim, the appellate court rejected the underlying premise. A private, non-governmental entity, such as a hospital, which issues its own guidelines (Policy & Procedure), is not the same as the common law standards of care being incorporated into a statute by the Legislature. After surveying law, the court found that to allow the jury to treat "a health care provider's violation of hospital policy as per se breach of the standard of care runs counter to the entire thrust of our case law." That, hopefully, is be the teachable moment. Policy & Procedure is not the standard against which the conduct of the defendant in a medical malpractice case is to be measured. Never mind the negligence per se argument, never mind the breach of contract argument. Those things should not have even passed the straight face test. But, if Labega can stand for the proposition that Policy & Procedure has been confused, conflated and allowed to trump the common law standard of care for too long already; then in that case the pendulum is on the way back to the middle and medical malpractice litigation is on the return to normalcy.

Labega v. Joshi, we would argue, tells us of the true meaning of the "standard of care." The standard of care is not what a hospital Policy & Procedure says; it is not what a drug package insert or the Physician's Desk Reference says; it is not what the defendant's internal policies say; and it is not what the internal bylaws or accreditation standards say. Standard of care is the caution and prudence that the reasonable medical provider would exercise in the same or similar circumstances. Plain and simple.

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SAVE THE DATE / JUNE 23–25, 2023

NJDA 57TH ANNUAL CONVENTION

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THE GRAPE IS NOT NECESSARILY THE ENEMY – UPDATES IN MODE OF OPERATION DOCTRINE – JETER V. SAM'S CLUB.

BY DENISE M. LUCKENBACH, ESQ.[1]

The ever vexing grape and its fellow produce were again recently visited by the New Jersey Supreme Court and confirmed not to create strict liability in the commercial/retail context. In mid March the Court issued its opinion in Jeter v. Sam's Club, 2022 N.J. LEXIS 242; 2002 WL 802807. In this particular case, the plaintiff claimed that she slipped and fell on loose grapes at a Sam's Club retail premises. The "twist" in this particular case is that the grapes were not on loose display for self-service purposes, but were sold in sealed "clamshell" containers. Finding that it was the intent of the retailer that customers would only help themselves to closed grape containers, the Court reasoned that no nexus existed between the self-service sale of grape containers and plaintiff's accident. The Court opined that selling the grapes in secure packaging posed no foreseeable risk that grapes would, in fact, be on the floor (as the store did not permit customers to open the containers and doing so was considered tampering with the product). Accordingly, the Court upheld the trial court's dismissal of Complaint. No summary judgment motion had been filed, however, hearing the facts of the case the trial judge conducted a *sua sponte* N.J.R.E. 104 hearing to determine if the Mode of Operation doctrine applied and, if not, whether plaintiff had evidence of actual or constructive notice. Holding that the Mode of Operation doctrine did not apply and, alternatively, under traditional negligence theories, there was no actual nor constructive notice of the presence of the grapes on the floor, the Court dismissed the case. The panel affirmed, and the New Jersey Supreme Court granted certification solely on the basis of the applicability of the Mode of Operation doctrine

Justice Solomon, writing for the Court, agreed that the Mode of Operation doctrine does not apply as the grapes were sold in closed clamshell containers. It is not the sale of the grapes that creates a reasonably foreseeable risk of harm, it is the mode in which they are made available to the customer. The dismissal was therefore upheld.

In the dissent, authored by Justice Albin, it was concluded that the retailer should have known that customers would open the grape containers to taste goods. Accordingly, it was reasonably foreseeable that loose grapes would fall to the floor. It also did not help that testimony by store personnel confirmed that the retailer was aware customers regularly opened containers to taste grapes, and that no action was taken against a customer for doing so. The burden should still shift to the retailer to show evidence of reasonable measures to alleviate responsibility. Justice Albin focused on the duty that a retailer has to provide a safe environment for its business invitee– *i.e.*, customer – noting, for example, a case involving if improperly stacked cans (*i.e.*, sealed items) do not alleviate the retailer from potential liability to the customer, therefore neither should grapes sealed in a clamshell.

The dissent cautioned that this opinion will lead to less safe conditions in retail stores and increase the number of "blameless and uncompensated victims" and the claimant was entitled to have a jury decide whether the retailer acted reasonably and prudently in its business.

WHAT IS THE DOCTRINE?

The Court has consistently acknowledged that the Mode of Operation doctrine is a judicially created rule which intends to relieve a plaintiff of proving actual or constructive notice of dangerous conditions if, as a matter of probability, the dangerous condition is likely to occur as a result of the nature of a business, the property condition, or a demonstrable pattern of conduct or incidents. The seminal case of Wollerman v. Grand Union Stores, Inc., 47 N.J. 426,428-29 (1996), resulted in the Court holding that when grapes are sold from open bins in a self-service manner, and the retailer [operator] has chosen to sell in this way, the retailer must take reasonably necessary steps to protect the customers from the risk of injury that the "mode of operation" is likely to generate. Id. at 429. The Court reasoned that patrons' carelessness should be anticipated, and therefore the retailer could be liable even without notice of the presence of the grape on the floor. It was the retailer's obligation to exculpate itself with evidence of due care.

Pursuant to Nisivoccia v. Glass Gardens, Inc., 175 N.J. 559,561 (2003), the Court noted, "Where grapes are packaged in open-top, vented plastic bags that permitted spillage," the Mode of Operation doctrine is invoked. The Court determined the customers' necessary handling of goods, employees' handling of goods, and the characteristics of the goods themselves, including the way they were packaged, was the basis for invoking the doctrine. Reaffirming Prioleau v. Ky. Fried Chicken, 223 N.J. 245 (2015), the Mode of Operation doctrine was specifically limited to the self-service setting, where customers are independently handling merchandise. For the doctrine to be applicable there must be a finding that "there is a nexus between self-service components of the defendant's business and a risk of injury where the accident occurred," and whether the injury resulted from employee handling, customer negligence, or the "inherent qualities of the merchandise itself."

In Nisivoccia, *supra*., the Court visited the issue of the "roving" grape at the checkout cashier's area. After both the trial court and panel held that the Mode of

Operation doctrine did not apply due to the area of the store where the loose grapes had been located (and alleged to be the proximate cause of the accident), the Supreme Court reversed finding that due to the manner in which the retailer chose to display its grapes and allow them to be accessed by customers, stray grapes in any area of the store where customers might have access should be foreseeable.

Stepping away from the produce context in Prioleau, *supra*., the individual slipped and fell on a wet, greasy floor at a Kentucky Fried Chicken retail store. The Supreme Court agreed with the panel which reversed the trial court's application of the Mode of Operation doctrine. Although it was alleged that either patrons or an employee must have tracked in water which added to a slippery condition on the floor, the Court reasoned that the customer was not engaged in self-service activity within the retail store and, therefore, the doctrine was not invoked.

Continuing to provide instruction as to what constitutes "self-service," the Court provided it results from customers coming into direct contact with:

- product
- product displays
- shelving
- packaging
- any other aspect of facility that may present a risk. Prioleau, *supra*. at 266-67.

Any area involved in the business may be found to be a point of self-service operation which triggers the doctrine – not merely the precise location of the "self-service." Any nexus between the self-service component and risk of injury in the area where the accident occurred is sufficient – i.e., the loose grapes which fell at the checkout counter.

The Mode of Operation Doctrine will undoubtedly continue to be a fact sensitive, case-by- case analysis. The moral of the story, however, is do not fear the grape – it is not always the nemesis of the defense bar.

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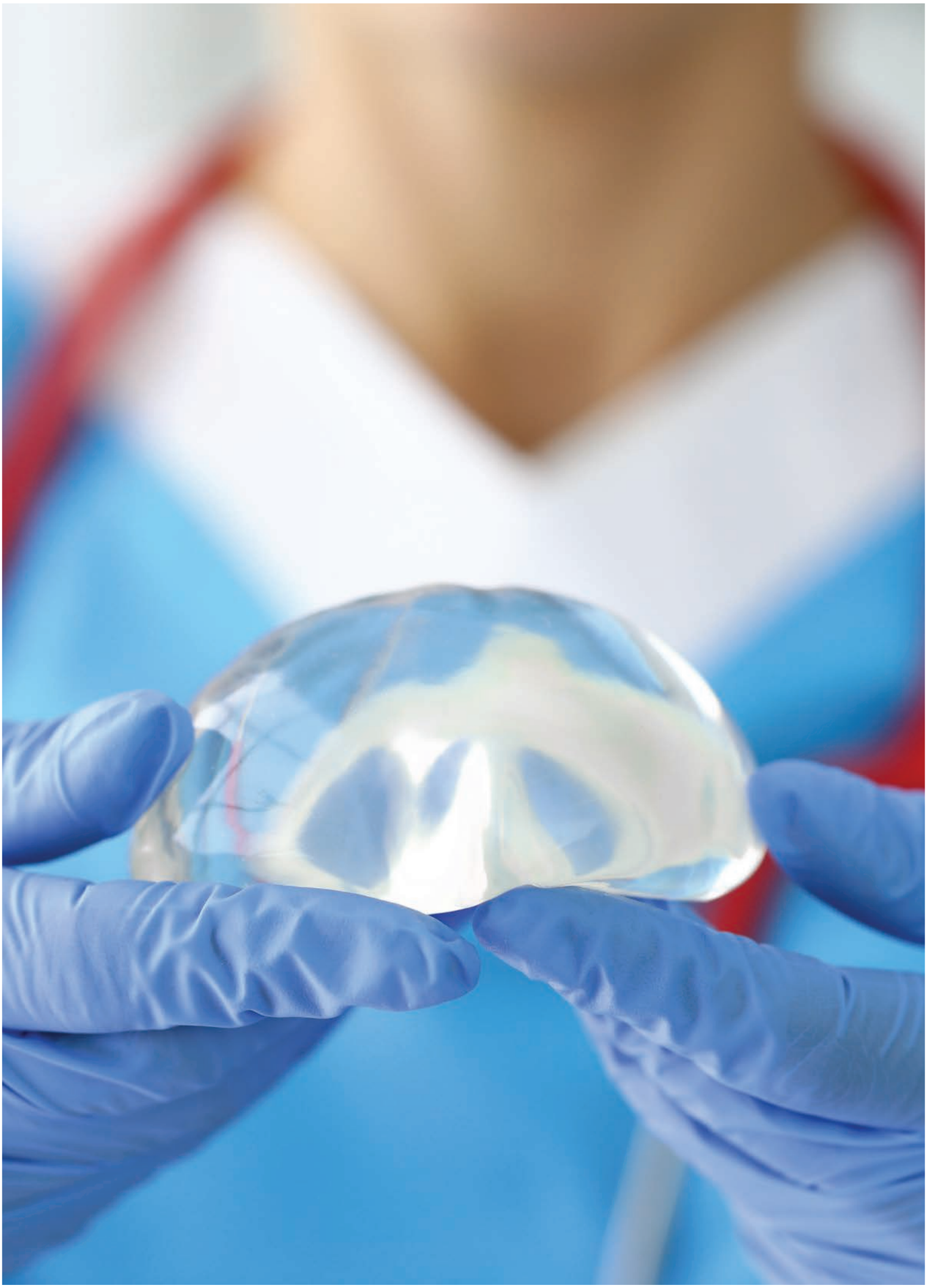
[1] Denise M. Luckenbach, Esq. is a partner with Sellar Richardson, P.C. in Livingston. She is a member of the NJDA Philanthropy and ADR Committees and regularly litigates and tries premises liability cases.

NJDA STATEMENT ON DIFIORE V. PEZIC

On April 4, 2022, NJDA's President-Elect Michelle M. O'Brien, Esq. of Flanagan, Barone & O'Brien in Bernardsville argued in support of the Association's position as amicus in three interlocutory appeals, consolidated by the Court for argument, involving the conduct of mental and physical examinations scheduled by defense counsel pursuant R.4:19. Just under a month later, on May 3rd, the Court, in a published opinion authored by Judge Sabatino, provided its guidance to trial courts and practitioners in the form of six specific holdings, including one confirming that the burden of establishing the need for "third-party presence or recording, or both" at such examinations rests with Plaintiffs. Ensuring that the burden remained with Plaintiffs was the principal focus of the arguments made on behalf of the NJDA. Ms. O'Brien also argued successfully that the Court ought to reconsider its decision in B.D. v. Carley, 307 N.J. Super. 259 (App. Div. 1998), long considered by Plaintiffs as carte blanche approval for the presence of recording devices while mental and psychological examinations are conducted. By its decision, the Court revisited that decision and made clear that Plaintiffs bear the same burden in those cases as they do in cases involving physical examinations. The Court further agreed with the Association that an examination conducted pursuant to the Rule is not "an adversarial proceeding inevitably designed to disprove claims of injury and trap plaintiffs into admitting or showing their claims are exaggerated or fabricated." Finally, as urged by our President-Elect, the Court noted that "ideally" the factors and procedures governing examinations "might be best developed by a Supreme Court Committee of stakeholders." Overall, the arguments presented so ably by Ms. O'Brien were accepted by the Court and incorporated into its well-reasoned decision, bringing clarity to a process which had become unduly complicated by ultimatums from the Plaintiffs' bar regarding the conditions under which their clients would agree to attend examinations and resulting in otherwise unnecessary motion practice. Congratulations Michelle on a hard job done well!



HUMAN BODY MEETS MEDICAL DEVICE MATERIAL, WANT TO PLAY MATCHMAKER? ARE WE BIOCOMPATIBLE?

COLLIN STABLER, PH.D., P.E., KEVIN ONG, PH.D., P.E., PRESENTED BY EXPONENT

WHAT IS BIOCOMPATIBILITY?

According to the U.S. Food and Drug Administration's (FDA) guidance on International Standard Organization (ISO) standard 10993 and the ISO standard itself,[1,2] biocompatibility is the ability of a medical device or material to perform with an appropriate host response in a specific situation. The standard itself describes a number of tests that, if applicable, should be conducted on the final finished product of a medical device. These tests typically comprise of cell, animal, and chemical studies and are viewed as the industry standard (set by the FDA) at the time of their publication, and should be considered the state of the art that FDA has at its disposal to determine safety of a product. These tests are taken in conjunction with knowledge from the scientific literature, history of clinical use, and other pre-clinical studies (e.g., animal or in-vitro) that can add to the knowledge of how the product/material potentially interacts with the body. Due to differences in patient reactions to the same material, it is possible that some patients may have adverse tissue reactions even to well-established biocompatible materials.[3]

The assessment of a device material's biocompatibility has been an evolving area of evaluation over the last few decades. Since the authorization of FDA to regulate medical devices in 1938[4] , the first guidance document (ISO 10993-1) was released in 1992, and the first mention of a "risk-based approach" was made in 2009. Overseas, the European Union (EU) was simultaneously evolving their approach to the regulation of a medical device's biocompatibility. The EU's first guidance on the manufacture of medical devices was not available until 1993 under the Medical Device Directive (MDD), and in 2017 the first mention of a "risk-based approach" was made. The transition to a risk-based approach in both the U.S. and E.U. helped manufacturers limit unnecessary animal studies, and identify key areas of risk to patient health.

HOW TO ASSESS AND MITIGATE RISK?

A "risk-based approach" inherently means the employment of a risk assessment in determining a product's performance evaluation strategy. Risk assessments are nothing new for manufacturers. In fact, ISO-14971[5] was released in 1998 as the international standard for risk management of medical devices, but was not referenced in ISO 10993-1 until 2009. The international community of medical device manufacturers uses ISO-14971 as one of the frameworks for how to assess and mitigate risk. There are several approaches to risk management, but they all begin with a risk evaluation based on known information, which then sets the stage for what mitigation steps should be taken. With regards to biocompatibility, ISO 10993-1 describes the process as a biological evaluation, referred to here as a Biological Safety Evaluation (BSE), and is a required first step in the assessment of a medical device's biocompatibility. In the EU, a similar approach is employed, termed here as a Biological Safety Risk Assessment (BSRA). Both the BSE and BSRA direct the manufacturer to consider the use case of the device material, known manufacturing steps, and preclinical/clinical history to determine the areas of risk. Both approaches require that a subject matter expert (SME) in biocompatibility conduct the risk evaluation. Once the risk categories have been identified, a testing plan is developed to help determine if the device material meets industry standards for safety (e.g., passes a cytotoxicity test). If the device fails any one of the tests prescribed in the plan, then manufacturer performs a root cause analysis and modifies the manufacturing process to address that risk. These activities are documented in a report and included in the manufacturer's regulatory filing. The efficacy of the material data can be bolstered through the use of FDA consensus standards, or reliance on a supplier's master file of the material provided. A consensus standard is one that is developed and adopted by domestic and international stakeholders, and contributes to regulatory quality through collaboration. A master file is a tool that a supplier can utilize to protect trade secrets and intellectual property of its product, facility, or manufacturing procedures, while also providing FDA with all the information needed to make a sound scientific evaluation of another applicant manufacturer's medical device that utilizes that supplier's product or facility.

THE FDA'S FOCUS IN THE PROCESS

Generally, there are several biocompatibility factors of interest to the FDA.[6] These include the nature, type, frequency and duration of contact, as well as the materials that the device is made from. The factors pertaining to contact relate to which tissue the device or portion of the device may come in contact

with, whether it is direct or indirect contact, and how long the device is in contact with the tissue. Biocompatibility assessment is intended to evaluate the potential for an unacceptable adverse biological response resulting from direct or indirect contact of the device with the body. However, if the device does not have any direct or indirect tissue contact, then the FDA does not need biocompatibility information. Based on the most recent FDA guidance, the process for the biological evaluation of a medical device generally entails the assessment of the material components, manufacturing processes, clinical use of the device (including the intended anatomical location), and the frequency and duration of exposure.[7] After the potential risks from a biocompatibility perspective have been identified, a gap assessment is performed to determine what information is already available regarding the risks and what additional information may need to be gathered. Ultimately, the overall biocompatibility evaluation is considered from a benefit-risk perspective.

EXAMPLE AREAS OF INTEREST

There are over 6,000 types of medical devices that are regulated by the FDA's Center for Medical Devices and Radiological Health[8], including pediatric, cosmetic, dental, cardiovascular, reusable, and neurological devices. General hospital devices and supplies, home health and consumer devices, in vitro diagnostics, weight-loss and weight-management devices, implants, and prosthetics are also regulated by the FDA. Over the years, the FDA has engaged with various stakeholders to determine the current state of the science and areas for ongoing research efforts.

For example, even though metals have been commonly used in a wide range of medical implants for over a century, questions have been raised recently about a patient's immune response to the presence of metal in a device and to what degree, if any, clinically significant outcomes may result.[9] A wide variety of negative responses have been reported, where the device, material, and patient-related factors, including individual patient susceptibility, may play a role. In CDRH's 2019 review of the biological responses to metal implants, they noted that although limited, the evidence suggested that some individuals may develop heightened immune or inflammatory reaction when exposed to certain metals contained in select implants.[10] However, the science is still evolving for the significance of device or metal characteristics and patient characteristics regarding the potential for adverse outcomes. The clinically meaningful levels of corrosion and wear products from metallic devices is also still not well established. Likewise, there are knowledge gaps in the predictability of adverse immune responses in certain contacting tissue type to metal.

Breast implants, which are placed during augmentation (to increase size) or reconstruction (to replace removed tissue) procedures, have also garnered discussion regarding risk communication.[11] FDA's 2020 guidance on breast implant labeling aims to address concerns that patients have not been receiving or understanding information regarding the risks and benefits of these implants, which followed new information about associated risks related to breast implant-associated anaplastic larger cell lymphoma. The recommendations sought to clarify the labeling information for both saline- and silicone gel-filled implants. The FDA further restricted the sale and distribution of breast implants to health care providers and facilities that provide the requisite risk, benefit, and other information to patients to make fully informed decisions regarding the surgery.[12]

CONCLUSION

Biocompatibility relates to the ability of a device material to perform with an appropriate host response based on the specific situation. However, this does not preclude some patients experiencing adverse tissue reactions, even to well-established biocompatible materials. The potential biocompatibility risks for a device material are assessed within the framework of a risk management process. This does not always necessitate testing, particularly when applicable prior data or experience exists. Biological evaluation should be taken in the context of whether the benefits provided by the device outweigh any potential risks produced by the device material. It is critical to note that biocompatibility is only one of a number of characteristics to be considered in the design of a medical device; the biological response to a material should not be considered in isolation from the overall design because selecting a material based solely on its biocompatibility might result in a less functional device.

[1]Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", FDA, September 4, 2020

[2]ISO 10993-1:2018. Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

[3]ISO 10993-1:2018. Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

[4]A History of Medical Device Regulation & Oversight in the United States. https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states.

[5]ISO 14971:2019 - Medical devices - Application of risk management to medical devices.

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TOXICOLOGY OF ALCOHOL: THE ROLE OF TOXICOLOGISTS IN SOCIAL HOST & LIQUOR LIABILITY

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INTRODUCTION

Commercial establishments where alcoholic beverages are served (e.g., bars, restaurants) and social hosts who serve alcohol in non-commercial settings may find themselves potentially liable for damage, injury, and/or death caused by alcohol-related accidents involving individuals they have served. Critical issues addressed by toxicologists often involve interpretation and/or estimation of blood alcohol concentration (BAC) levels, associated clinical effects, and degrees of intoxication.

This white paper outlines how toxicologists help resolve questions regarding liability in the alleged over-service of patrons or guests that has led to damage, injury, and/or death.

CLINICAL EFFECTS OF ALCOHOL

Alcohol consumption affects mental, cognitive, and other physical functions in a dose-related manner (e.g., more consumption is associated with greater effects). Toxicologists combine BACs with observed behavior to determine associated levels of impairment/intoxication.

It is generally accepted by toxicologists that the degree of physical and mental impairment from alcohol correlates with BAC. In general, higher BACs produce increased impairment and greater degrees of intoxication. For example, the typical effects of a 0.02% (or 0.02 g/dL) BAC include some loss of judgment, decline in visual function, and divided attention.[1] At a 0.08% BAC, which is the current national limit for legally driving while intoxicated in the United States,[2] typical effects include poor reaction time, balance, speech, vision, hearing, perception, and judgment.[3]

However, people who are chronic alcohol drinkers can develop a tolerance to the effects of alcohol and learn to compensate for impairment. Tolerance to alcohol means that alcohol produces less of an effect, including on behavior, than it would for non-tolerant individuals. These individuals may not exhibit gross signs or symptoms of impairment even when their BAC is above the legal limit, even though they are actually impaired.[3] A person who consumes alcohol does not appear "intoxicated" merely because he or she has consumed alcohol. Rather, intoxicated behavior occurs when the quantity of alcohol the person consumed has exceeded the individual's tolerance for alcohol and produced mental, cognitive, or physical abnormalities. Whether an individual appears intoxicated depends on multiple factors other than alcohol consumption, including body weight, gender, race/ethnicity, the amount of food consumed before drinking, use of drugs or prescription medicines,[4] and social behavioral changes learned during multiple drinking episodes.[5]

INTERPRETATION OF ALCOHOL TEST RESULTS

When interpreting alcohol test results to determine how much alcohol was consumed by an individual at an earlier time, the toxicologist considers the quality of the sample collected and the analysis method used.

The "gold standard" tissue sample collection for measuring BAC is a peripheral venous sample of blood or serum. Alternatively, a breathalyzer test is a non-invasive method to obtain an immediate result of the individual's breath alcohol concentration.[5] Interpretation of postmortem (i.e., collected after death) samples can be complex as discussed later in this paper. Forensic analyses for BAC analyze whole blood samples using gas chromatographic (GC) methods, which provide accurate and selective alcohol (i.e., ethanol) quantitation. In clinical settings (e.g., hospitals, emergency rooms), BAC is generally evaluated in serum or plasma samples using enzymatic methodologies with lesser accuracy but faster turnaround times (and lesser cost).[6] Due to the differences in the methodologies and the types of biological samples analyzed, BACs quantitated in clinical settings

using enzymatic methodologies are generally higher than the same samples quantitated using forensic GC analyses.[7] Toxicologists guide the interpretation of results considering the various factors from the different assays. The appropriateness of using BAC from postmortem samples to reflect BAC levels prior to death (i.e., antemortem) can be complex due to after-death redistribution and the potential for decomposition-related alcohol production. Each assessment to determine postmortem sample suitability (i.e., correlation to the concentration at time of death) is unique. One approach is to compare the postmortem BAC to alcohol concentrations measured in other biological fluid/tissue samples that are inherently less influenced by redistribution and decomposition-related issues (e.g., vitreous humor fluid of the eye, urine); correlation between the different assessments increases confidence that the postmortem BAC accurately reflects the antemortem level.[4]

An assessment for proper sample storage conditions may occur as improper storage may alter samples such that alcohol levels may no longer reflect an individual's BAC at the time of collection. For example, it is well known that loss of alcohol from biological specimens may result from evaporation and/or oxidation. Alcohol is volatile and will evaporate from blood samples if the specimen containers are not properly sealed, resulting in loss of alcohol by evaporation. Loss of alcohol can also result from oxidation of alcohol (ethanol) to acetaldehyde in stored biological specimens. Alcohol concentrations in biological specimens may increase when sterility is lost, as alcohol (ethanol) production can occur as a byproduct of biological growth. Under sterile conditions, the concentration of alcohol in blood specimens would not be expected to increase.[4]

BLOOD ALCOHOL CONCENTRATION CALCULATION

Toxicologists estimate BAC for individuals based on the known pharmacokinetics of alcohol (i.e., the time and dose-profile for how it is absorbed, distributed, metabolized, and excreted) together with specific attributes of the individual and the drinking event under consideration. BAC assessments are generated to assess different parameters important for the evaluated issue, such as:

- Was the reported consumption profile and timing (e.g., what and when drinks were served and consumed) consistent with the measured BAC?
- How much alcohol would the individual have needed to consume to generate the measured BAC?
- Given the BAC was measured at a later timepoint, what was the individual's BAC when leaving the serving establishment and/or when the accident occurred?
- When assessing the BAC at the time of the accident (and if appropriate), what was the contribution of alcohol intake from the service event under consideration compared to additional alcohol consumed by the individual (either before arriving and/or after leaving the serving establishment)?

The tool toxicologists generally use for BAC extrapolations is the Widmark equation, named after the early 20th-century seminal work conducted by the Swedish physician, E.M.P. Widmark.[8] The equation uses a set of variables to mathematically describe alcohol pharmacokinetics in the human body. Specifically, the equation incorporates a uniform distribution of alcohol (a one-compartment model) and a constant elimination/metabolism rate per unit time (zero-order elimination kinetics), together with human-specific factors (e.g., body weight and distribution volume) and time-specific variables (e.g., time elapsed since drinking began, time of accident, and/or time of BAC measurement). The resulting equation describes BAC as a function of an individual's human factors together with the timing and amount of alcohol consumed.[9] The accuracy of estimates associated with the Widmark equation depends on the reliability of input parameters. Uncertainties arise with the number of assumptions made regarding an individual's body weight, the type and alcohol content of consumed beverages, and the individual's alcohol elimination/metabolism rate.

CONCLUSION

Social host liability issues generally hinge on the alleged over-service of guests subsequently involved in incidents resulting in damage, injury, and/or death. Key issues in these matters hinge on the amount of alcohol served by the establishment, the resulting BAC of the consuming individual, and the associated clinical effects and degree of intoxication.

Toxicologists can address these issues and more, including assessments of sample validity and methodology; extrapolations of BAC to earlier timepoints; assessments to determine whether the service profile (i.e., what and when) correspond with the measured BAC; and, if appropriate, assessments to determine the contribution of alcohol from the service event under consideration to the BAC at the time of the accident.

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O'TOOLE'S COUCH: NOT AN AIRBNB

On one of our early Caribbean cruises, when the boat docked for the day, we strolled independently touring the island; local bars, eateries, shops and various attractions. It was a beautiful day. Our only restriction was to be back on-board by 3 pm; the ship would weigh anchor at 4 pm. On our walk back to the ship, as we approached the dock, there was a beautiful, 16-floor, high-rise hotel, which certainly would have a magnificent view. Sunny did not share my enthusiasm for ascending to the top of the hotel. She walked to the dock. The elevator only went to the 12th floor. When I got off the elevator, I ran into Jake Levinson, a Plaintiff Attorney and Senior Partner of the Levinson, Axelrod law firm in New Brunswick. Jake "insisted" that I join him on his veranda for a customary cocktail. I expressed my concern about the time, but Jake assured me it was only 2:30 and our ship was just a short walk away. (If you know me at all, you know how carefree I am about time!) Jake and I each enjoyed a fantastic Manhattan, taking in the magnificent view. It was the perfect way to end the island tour. I barely walked outside the hotel when I heard the ship's departing whistle. (Jake and I did not take into consideration that island time was one hour behind ship time. It was now 3:45.) Again, if you know me at all, you know what a fast walker I am – NOT. As I approached the gate, I saw Sunny arguing with the crewman who said we would have to take a cab to the next cruise ship destination. Sunny refused to step back from the gate, and I finally arrived. Passengers were applauding Sunny's determination.

Okay, years later, we book another cruise. This one to Costa Rica. As Sunny perused the on-land tourist attractions, she suggested a Zip Line. She asked if I wanted to try it and did not share the lengthy description of this tour. I said sure, thinking it was going to be like a ski lift, with magnificent views. (I should have realized it was more than that when we were on the bus and had to sign a disclaimer.) I survived the first part of the ride in complete terror, and was thankful it was over. No way, this zip line went on forever, from one tree to the next over the extremely thick forest. I am not kidding, we were swinging from tree to tree, like Tarzan. There was probably 100 feet between these tree stops. Each stop had a small platform to stand on. And I mean small! Also, there were really large ants on each platform. I say they were 4 inches long, but Sunny contradicts that description. (I kept pulling on the line to slow down, but that sometimes made it stop completely and I was stranded between two trees! Believe me, the guides were as unhappy that I was there as I was.) There was a woman before us who was also unaware of what this "ride" entailed. She assured the guide that she could not continue. He said OK, but the only way out was to climb down the tree and walk through the jungle woods to the end of the trails, where there were animals roaming through the forests. Hearing her spared me the embarrassment of saying I couldn't continue. I made it to the end, but had a tremendous headache and swore it was the worst day of my life – No kidding!

It never stops. On another vacation we flew to Mexico and took some wonderful tours. One was to walk among the Mayan Pyramids. What a sight! This was our last day and it was great, stopping on the way back at a small local eatery to end the day. Authentic foods, local wait staff and cooks. How neat. There was just one problem. On this entire trip we only drank bottled water, and ate food that was washed by sterilized water. This was not the case in this small, local café. I never had a problem, I think because I had a high enough alcohol level. Sunny, however was terribly sick that night and the next day. (Nothing ends "a good vacation" like throwing up in trash cans as you walk through the airport.) I keep telling her booze is good for you, but she still doesn't believe me. She'll have to learn the hard way.

Obviously, these are just a couple of our great vacations and the many escapades along the way, but we never give up. Let the journey continue!

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