

A PUBLICATION BY THE NEW JERSEY DEFENSE ASSOCIATION / FALL 2021

# NEW JERSEY DEFENSE



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# PRESIDENT'S LETTER



I am honored and humbled to serve as the 56th President of the New Jersey Defense Association. As the pandemic lingers, and we live in a new world of virtual appearances and remote working, the NJDA has some great upcoming events, such as some of the NJDA's flagship seminars, including, the 12th Annual Women and the Law and Auto Liability seminars in November, and the Civil Trial Seminar in December. We thank our members and sponsors for supporting our very successful golf outing at Copper Hill Country Club on October 5, 2021, after a one-year hiatus due to the pandemic (a big

thank you to Maryanne Steedle and Chad Moore for the return of this event).

I would like to thank our outgoing President, and Chairperson of the Board, John Mallon, for guiding, very successfully, the NJDA through one of the most challenging years of our lifetime. I can say without reservation that John faced the challenge head on, and despite the trying times, knocked it out of the park. I am very pleased to report that Mr. Mallon is the NJDA's 2021 recipient of the NJSBA Professionalism Award. Extremely well deserved. I would also like to thank McCarter & English, for always supporting my journey through this organization, in particular, Ed Fanning, Natalie Watson, and Natalie Mantell, who introduced me to this organization.

This is a very exciting time for the NJDA as we attempt to return to some in-person events. We are continuing to take a pro-active role to ensure that the AOC has input from our members on the Supreme Court's invitation for written comments regarding the proposal to continue certain court events in a remote format. We most recently submitted a letter to the AOC on August 16, 2021, with input from our membership based on the feedback you have provided. We continue to welcome your input and feedback. The Supreme Court has

called a Judicial Conference on Jury Selection in *State v. Andujar*, decided on July 13, 2021.

We understand that implicit bias and preemptory challenges will be a primary focus at the Judicial Conference. The NJDA has requested permission to participate in the upcoming Judicial Conference, and was invited to, and has been participating in the NJ State Bar Association's Working Group on Jury Selection. The court's September 28, 2021, Notice to the Bar indicates that Chief Justice Stuart Rabner will host the Judicial Conference at the New Jersey Law Center on Wednesday, November 10 and Friday, November 12, 2021.

Thank you for your continued support of our organization. I very much look forward to seeing you at our upcoming events. Please do not hesitate to reach out to me with any suggestions for the NJDA or if you would like to become more involved substantively at: [richman@mccarter.com](mailto:richman@mccarter.com). I also implore all to write an article for the New Jersey Defense, which can be submitted to our new editor, Michelle O'Brien ([MOBrien@fbolawfirm.com](mailto:MOBrien@fbolawfirm.com)).



RYAN RICHMAN, ESQ.



# MANDATORY COVID-19 VACCINATION POLICIES IN THE WORKPLACE

BY NICOLE SOROKOLIT CRODDICK, ESQ.

Under the Occupational Safety and Health Administration's General Duty clause, employers must maintain a workplace that is free of known hazards. New Jersey Governor Murphy's recent Executive Orders, coupled with state and federal health agency guidance, including the New Jersey Department of Health, have motivated many employers to consider implementing mandatory COVID-19 vaccination policies, as a condition of employment, in their workplace. Although seemingly a simple task, implementing a mandatory vaccination policy must be thoroughly and thoughtfully executed.

Generally, employers can require employees to be vaccinated against certain infectious diseases, such as the flu. Following this, in late July, President Biden mandated COVID-19 vaccination for federal employees, or else they would be subject certain requirements, such as frequent testing. Recently, New Jersey's Governor Murphy passed Executive Orders 252 and 253. In EO 252, Governor Murphy mandated vaccines for employees in health care and other "high risk congregate" settings (i.e.- county jails or assisted living facilities) or they would be subject to at least weekly COVID-19 testing. In EO 253, all New Jersey school personnel in preschool to 12th grade, must be fully vaccinated or will be subject to at least weekly COVID-19 testing.

The employer mandated vaccination proposition was clear, even prior to the pandemic, as numerous employers required employees to receive the FDA approved vaccines, like the flu shot. It is noteworthy, however, in that the analysis comparing mandatory flu vaccines with mandatory COVID-19 vaccines is not exactly parallel as prior to August 23, 2021, none of the COVID-19 vaccines were fully approved by the Food and Drug Administration (FDA). In response, the United States Department of Justice issued an opinion that employers are permitted to require vaccines despite the fact that some vaccines are only subject to FDA emergency use approval. That said, on August 23, 2021, the FDA granted full (versus emergency) approval to

the Pfizer-BioNTech vaccine. This is significant because prior to full FDA approval, employers were understandably more cautious with COVID-19 vaccine mandates, as all COVID-19 vaccines were only granted fast-tracked emergency FDA approval.

If employers want to require employee vaccination, it is important for employers to craft a properly drafted mandatory vaccine policy. The policy must address various issues. Some of these issues include: what can be required to prove vaccination and how such information will be stored. Additionally, the policy must be enforced in a consistent manner so as to not discriminate against / treat differently other employees so as to violate Title VII of the Civil Rights Act and the New Jersey Law Against Discrimination. It is of note that generally the Americans with Disabilities Act (ADA) limits employers from making "disability related" inquiries, but the United States Equal Employment Opportunity Commission ("EEOC") provided guidance that states that employer inquiries, surrounding COVID-19 vaccination status, is not a disability related inquiry under the ADA.

If a mandatory vaccination policy is implemented, employers have a legal obligation to consider employee requests for "reasonable accommodations," in declining vaccination, for both "sincerely held religious beliefs" and for medical / disability related reasons (i.e.- allergies to the vaccine / pregnancy). Simply being "anti-vaccination" would not be a basis for a reasonable accommodation. Currently in New Jersey, there is at least one pending lawsuit alleging wrongful termination of an employee, who worked in a health care setting, who refused a vaccine for a "sincerely held religious belief."

It is also critical that the mandatory vaccination program and policy comply with the ADA in that the vaccination requirement is "job related" and "consistent with business necessity." One such query should include an analysis on the level of threat that an unvaccinated employee poses in the work-

place. This would include a fact-sensitive, case by case analysis. If an employee does request a reasonable accommodation, the employer must engage in "an interactive process," ensure that the employee is still "qualified" and ultimately must provide the accommodation, unless doing so would cause an "undue hardship" for the employer. Undue hardships could include significant expense or difficulty. Examples of reasonable accommodations include: weekly COVID-19 testing; required face coverings; teleworking; or staggered work schedules.

Due to the various legal uncertainties and risks, surrounding vaccination mandates, certain employers offered incentives to promote employee COVID-19 vaccinations, as opposed to mandating the vaccines. These include reasonably sized gift cards or cash gifts; granting of extra paid time off; and other benefits to encourage vaccination. Employers also can provide education and information on the virus and vaccine to their workforce so that they are informed. Also, under the American Rescue Plan Act, and as per company policies, employers can grant paid time off for vaccination and vaccination recovery and employers may even get tax credits for giving such paid time off.

In addition, employers also should consider some logistical and workplace concerns. Some of these include whether mandatory vaccination would affect their already-difficult staffing needs and also if all of their employees would be eligible to be vaccinated.

In short, employers can mandate COVID-19 vaccines, but should proceed with caution as there are legal, financial, and business risks associated with doing so.

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**Nicole Sorokolit Croddick is Counsel in the Labor and Employment Department of Davison, Eastman, Muñoz, Paone in Freehold, New Jersey.**



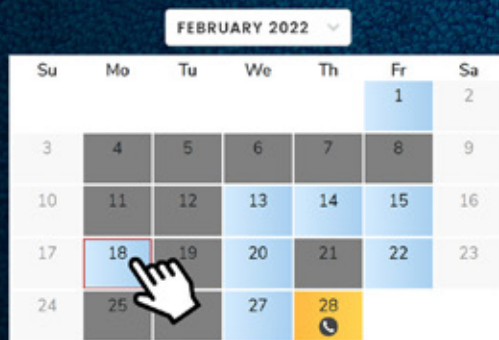
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# NJDA 56TH ANNUAL CONVENTION

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# THE NATIONAL PRACTITIONER DATA BANK: A SILENT FACTOR AT PLAY

BY NANCY CROSTA LANDALE

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Of all the factors impacting the decision to settle a medical malpractice case, perhaps the least known or appreciated is the National Practitioner Data Bank (NPDB). This article gives a basic explanation of the NPDB and considers ways in which the NPDB may affect settlement decisions.

## WHAT IS THE NPDB?

Finding that the “need to improve the quality of medical care” was a “nationwide problem,” Congress passed the Health Care Quality Improvement Act of 1986 (HCQIA)<sup>1</sup>

In it, Congress declared a “national need to restrict the ability of incompetent physicians to move from State to State without disclosure or

discovery of the physician’s previous damaging or incompetent performance”<sup>2</sup> with an eye toward making “greater efforts than those that can be undertaken by any individual State.”<sup>3</sup> Regulations<sup>4</sup> promulgated under the HCQIA authorize the Secretary of Health and Human Services (HHS) to establish a NPDB<sup>5</sup> to collect and release certain information relating to the professional competence and conduct of health care practitioners.<sup>6</sup> On the state side, as established by the New Jersey Health Care Consumer Information Act in 2004,<sup>7</sup> New Jersey also has such a database. New Jersey’s Division of Consumer Affairs, in consultation with the State Board of Medical Examiners and the New Jersey State Board of Optometrists, is charged with collecting and maintaining information concerning all licensed physicians, podiatrists and optometrists to create a profile of each such practitioner.<sup>8</sup>

## WHAT IS REPORTED?

Hospitals, insurance companies, and other entities paying under a policy of insurance, self-insurance, or otherwise in settlement or satisfaction of a judgment in a medical malpractice action or claim must report to the NPDB:

(1) the name of any physician or licensed health care practitioner for whose benefit the payment is made, (2) the amount of the payment, (3) the name (if known) of any hospital with which the physician or practitioner is affiliated or associated, (4) a description of the acts or omissions and injuries or illnesses upon which the action or claim was based, and (5) such other information as the Secretary determines is required for appropriate interpretation of information reported under this section.<sup>9</sup>



Eligible entities must report medical malpractice payments and other required actions within 30 calendar days of the date the action was taken or payment was made.<sup>10</sup> Each report must include a narrative section limited to statements of fact including “what the subject of the report is alleged to have done and the nature of and reasons for the event upon which the report is based.”<sup>11</sup>

When payments are made on behalf of multiple practitioners, if the amount paid for the benefit of each individual practitioner cannot be determined then the total amount is reported for each practitioner. If an apportionment is possible, then the actual amount paid for the benefit of that practitioner is reported.<sup>12</sup>

In the case of “high-low” agreements,<sup>13</sup> payments are required to be reported unless the fact-finder rules in favor of the defendant and assigns no liability to the practitioner.<sup>14</sup> Individuals are not required to report payments they make from personal funds.<sup>15</sup>

Under New Jersey law, information included in the profile of a health care provider must include:

All medical malpractice court judgments and all medical malpractice arbitration awards reported to the applicable board, in which a payment has been awarded to the complaining party during the most recent five years, and all settlements of medical malpractice claims reported to the board, in which a payment is made to the complaining party within the most recent five years....<sup>16</sup>

#### **MAY A PRACTITIONER DISPUTE A REPORT?**

Federal law provides a procedure for a practitioner to dispute the accuracy of NPDB information. If the NPDB revises its information, entities to whom reports have been sent are alerted that information has been revised.<sup>18</sup> If no revision is made, upon request the HHS Secretary will review the information and include a brief statement by the practitioner describing the disagreement and an explanation for the decision.<sup>19</sup>

New Jersey law provides a limited procedure for practitioners to correct factual errors. Before a profile is made public, it is provided to the practitioner who then has 30 days to correct any factual inaccuracy and advise the Division of Consumer Affairs.<sup>20</sup>

#### **WHO MAY SEE WHAT IS REPORTED?**

NPDB reports are confidential, and limited disclosure is regulated by the Code of Federal Regulations.<sup>21</sup> Unless otherwise provided by state law, all information collected by the NPDB and reported as stated above is released only as specifically mandated by the HCQIA.<sup>22</sup>

NPDB information may be used only by eligible entities, such as a board of medical examiners or other state licensing board or hospital or health plan officials as they assess applications for medical staff appointments, clinical privileges, or other affiliation.<sup>23</sup> Other than to these entities and the practitioners involved, information is not disclosed “except with respect to professional review activity.”<sup>24</sup>

Under New Jersey law, provider profiles that include claims and settlements are accessible to the public free of charge.<sup>25</sup> A disclaimer is included, however, explaining that settlement of a claim “and, in particular, the dollar amount of the settlement may occur for a variety of reasons, which do not necessarily reflect negatively on the professional competence or conduct of the physician... A payment in settlement of a medical malpractice action or claim should not be construed as creating a presumption that medical malpractice has occurred.”<sup>26</sup>

#### **THE IMPACT OF THE NPDB**

Practitioners have long been concerned with NPDB reports as well as state reports about claims or suits. Concerns range from how payment is allocated among several practitioners and/or entities against whom allegations have been made; to whether insurance premiums or insurability itself will be impacted; to whether applications to obtain or maintain hospital privileges will be affected; to whether such reports will bode negatively for future applications or promotions.

In addition, as many professional liability insurance policies contain consent provisions allowing the insured to authorize or withhold authority to settle, a practitioner’s decision to grant authority to settle often includes deliberation over how the settlement may be reported. Once authority to settle is granted by the insured, however, they may be relinquishing control over the timing of settlement offers and the amounts offered.

A 2005 New Jersey Appellate Division decision provides a vivid example of the interplay of these concerns. In *Webb v. Witt*<sup>27</sup> at issue was whether a practitioner had the right to exercise control over settlement as well as the required reporting to the NPDB and the New Jersey Division of Consumer Affairs where the practitioner had no express right to approve settlement.<sup>28</sup> In ruling the practitioner had no such control, the *Webb* court explored not only insurance contractual considerations but also the potential effects of reporting the settlement on future insurability, insurance premiums, and even the practitioner’s employability.

The underlying suit centered on injury to a baby’s brachial plexus during delivery, resulting in loss of use of the baby’s right arm.<sup>29</sup> Deposition discovery produced divergent testimony as to the delivery events, including the roles and responsibilities of the three providers involved.<sup>30</sup>

The defendant hospital was the sole named insured on a policy that afforded coverage to the defendant physicians as “other insureds.”<sup>31</sup> The policy required the insurance company to obtain consent from the hospital before settling, but only to make a “reasonable attempt” to consult with other insureds.<sup>32</sup>

The insurance company decided to settle.<sup>33</sup> Believing she did not deviate from the standard of care, however, one of the providers indicated she did not want a settlement on her behalf.<sup>34</sup> In a series of pleadings and motions, the provider sought to preclude settlement absent her consent; and to bar the hospital and its insurer from apportioning liability to her if there was any settlement.<sup>35</sup> In support of her position, the provider argued that there would be

adverse consequences to her participation and/or membership in health insurance organizations, HMOs, and/or managed care organizations; adverse consequences to her memberships in the medical staffs of other hospitals at which she maintains privileges, a reduction or elimination of her ability to secure employment as a physician, a reduction or elimination of her ability to provide obstetric and gynecological services and, ultimately, a reduction or elimination of her ability to practice medicine.<sup>36</sup>

The provider's professional liability insurance expert additionally certified that if the insurance company settled and reported to the NPDB that the three physicians involved had "undivided responsibility," it would be extremely difficult or even impossible for the provider to obtain insurance coverage in the future.<sup>37</sup> The expert went as far as to say that even if the provider was able to obtain coverage, the premiums would increase to a point that she would be forced out of the practice of obstetrics.<sup>38</sup> *Amicus curiae* Medical Society of New Jersey added that an insurance carrier

must not be given unfettered discretion to settle a medical malpractice action without giving due consideration to the impact of such settlement upon the affected physician, and without some mechanism in place, consistent with the requirements of due process, to protect the physician's interests.<sup>39</sup>

The *Webb* court was unpersuaded, finding that the HCQIA "is silent on apportionment among multiple defendants" and is required by federal law to "report all settlements, along with the names of any physicians for whose benefit payments are made, the amount of any payments, the names of the hospitals with which the physicians are affiliated and a description of the acts or omissions and injuries alleged in the claim."<sup>40</sup>

Next, answering the provider's citation of the NPDB Guidebook published by HHS<sup>41</sup> to support an "independent fact-finding process to fix the percentage" of responsibility, the *Webb* court noted that the guidebook "does not have the force of law, nor is it a regulation."<sup>42</sup> More important was the guidebook's silence "as to how a determination of liability apportionment is to be decided and in what forum."<sup>43</sup> The *Webb* court also observed that even where an apportionment can be made, it is the insurer's responsibility to do so and there is no provision for a provider to contest an apportionment.<sup>44</sup> Indeed, the sole statutory remedy for a practitioner dissatisfied with a lack of apportionment or the level of apportionment assigned to them is the opportunity to correct a factual error.<sup>45</sup>

Finally, as to arguments that an absence of a consent to settle clause violates public policy, the *Webb* court observed that an insurance policy is a contract, the terms of which define the parties' rights and obligations.<sup>46</sup> It found the provider defendant failed to show that a

consent clause had to be included as a matter of public policy, especially since such clauses often are the subject of specific negotiation between the parties, and the premiums charged reflect this negotiation and choice.<sup>47</sup> The *Webb* court refused to endorse what amounted to an argument to reform the policy, especially in light of New Jersey's public policy encouraging settlements.<sup>48</sup>

## THE SILENT FACTOR REVISITED

First implemented in the late 1980s, NPDB reporting was designed to prevent "incompetent" physicians from moving around anonymously. The internet age seems to have vaulted the original purpose of the NPDB, however. Modern day underwriting practices and measures such as form interrogatories to be answered by defendant practitioners,<sup>49</sup> combined with the vast amount of information available through public and paid internet searches have dramatically increased the historical data available.

The NPDB now seems to invoke an additional, unintended concern as practitioners consider settlement. Practitioners must face not only that settlements will be reported and may be accessible to state licensing boards, employers, potential employers, and insurance carriers, but also that the decisions made by the reporting entity about how the settlement is apportioned among several practitioners is subjective and out of their control. In some instances, these additional considerations may even cause a practitioner to withhold consent to settle.

Awareness of these considerations may be valuable to parties on both sides during settlement negotiations. This, in turn, may produce more thoughtful and successful negotiations, and prepare practitioners to take a more active role in the reporting process.

***As a New Jersey Supreme Court Certified Civil trial attorney and partner of Farkas & Donohue, LLC, Nancy Crosta Landale handles cases on behalf of medical providers and medical entities of all specialties. Her experience includes medical and nursing home malpractice, general liability, mass tort, environmental, and insurance coverage disputes.***

<sup>1</sup>42 U.S.C. § 11101

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> See 45 C.F.R. § 60.1

<sup>5</sup> 42 U.S.C. § 1320a-7e; see also <https://www.npdb.hrsa.gov/index.jsp> (last visited May 1, 2021)

<sup>6</sup> 42 U.S.C. § 11131

<sup>7</sup> N.J.S.A. 45:9-22.21 to -22.25

<sup>8</sup> N.J.S.A. 45:9-22.22; see also [njdoctorlist.com/](http://njdoctorlist.com/) (last visited May 1, 2021)

<sup>9</sup> 42 U.S.C. § 11131

<sup>10</sup> NPDB Guidebook, October 2018, p. E-2- see [npdb.hrsa.gov/resources/aboutGuidebooks.jsp](https://www.npdb.hrsa.gov/resources/aboutGuidebooks.jsp) (last visited May 1, 2021)

<sup>11</sup> *Id.* at E-11

<sup>12</sup> *Id.* at E-21

<sup>13</sup> A "high low" agreement is one in which the parties, or some of them, agree that if a verdict is above a specified range of numbers agreed upon by such parties, the defendant's liability for damages shall be the highest number in that range, and that if a verdict is less than the lowest number in that range, including a verdict of no cause for action against such defendant, defendant shall pay the plaintiff the lowest number in the range. If the verdict against the defendant falls within the range, the damages the defendant shall pay is the verdict reached by the jury. *New Jersey Court Rules, 1969*, R. 4:24A

<sup>14</sup> NPDB Guidebook, *supra*, p. E-23

<sup>15</sup> *Id.* at E-18, citing *American Dental Association v. Shalala*, 3 F.3d 445 (D.C. Cir. 1993)

<sup>16</sup> N.J.S.A. 45:9-22.23

<sup>17</sup> 45 C.F.R. §60.21

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> N.J.S.A. 45:9-22.23c

<sup>21</sup> 45 C.F.R. § 60.20

<sup>22</sup> *Medical Soc. Of New Jersey v. Mottola*, 320 F.Supp. 254, 259 (D.N.J. 2004)

<sup>23</sup> NPDB Guidebook, *supra*, p. A-10, p. B-2

<sup>24</sup> 42 U.S.C. 11137(b)(1)

<sup>25</sup> N.J.S.A. 45:9-22.22

<sup>26</sup> N.J.S.A. 45:9-22.23a(10)(d)

<sup>27</sup> 379 N.J. Super. 18 (App. Div. 2005)

<sup>28</sup> *Id.* at 22

<sup>29</sup> *Id.*

<sup>30</sup> *Id.* at 24-25

<sup>31</sup> *Id.*

<sup>32</sup> *Id.* at 23-24

<sup>33</sup> *Id.* at 25

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* at 26

<sup>36</sup> *Id.*

<sup>37</sup> *Id.* at 27

<sup>38</sup> *Id.*

<sup>39</sup> *Id.* at 27-28

<sup>40</sup> *Id.* at 29-30, citing 42 U.S.C 11131(b) and C.F.R. §60.5(a)

<sup>41</sup> See [npdb.hrsa.gov/resources/aboutGuidebooks.jsp](https://www.npdb.hrsa.gov/resources/aboutGuidebooks.jsp) (last visited May 1, 2021)

<sup>42</sup> *Id.* at 30

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* at 32

<sup>46</sup> *Id.* at 33, citing, *inter alia*, *Mancuso v. Rothenberg*, 67 N.J. Super. 248, 254 (App. Div. 1961)

<sup>47</sup> 379 N.J. Super. at 33

<sup>48</sup> *Id.* at 33-34, citing, *inter alia*, *Nolan by Nolan v. Lee Ho*, 120 N.J. 465, 472 (1990)

<sup>49</sup> Form C(3) interrogatories 5 and 6 require defendant physicians to disclose whether their "full rights or privileges to practice medicine been suspended, revoked or terminated in any state or hospital since [they] started to practice medicine" and, if they have "ever been a defendant in a malpractice suit other than the present one, identify the case by name, court and docket number, and summarize the allegations ... and the outcome of the case, including the terms of any settlement." *New Jersey Court Rules, 1969*, Appendix II



# A SHIVER IN THE INDUSTRY: THE VULNERABILITY OF EXPERTS AFTER ACCUTANE AND LANZO

BY MICHAEL J. MCCAFFREY

In a case of mass tort litigation, in which plaintiffs asserted that Accutane caused Crohn's disease, the Supreme Court of New Jersey clarified the proper role of the trial court as the gatekeeper of expert witness testimony. *See, in re Accutane Litigation*, 234 N.J. 340 (2018). There the Court affirmed the conclusion of the trial court that the testimony of plaintiffs' experts was unreliable and inadmissible. *Id.* at 396. Recently, an appellate court held that the trial court had not performed its required gatekeeping function, and had mistakenly exercised its discretion by permitting an expert witness to opine on the cause of a plaintiff's mesothelioma. *See, Lanzo v. Cyprus Amax Minerals Co.*, 467 N.J. Super. 476 (App. Div. 2021). *Lanzo* is notable for its unusual exclusionary conclusion in a narrow context.

The discussion in those cases, and the principles of legal analysis commended therein, may be of interest to those attorneys who would challenge a plaintiff's medical expert's opinion on causal relationship, in a case of claimed spinal injury, and who may wish to demand a hearing under *N.J.R.E.* 104 (on the admissibility of evidence). Let us consider the analysis *Accutane* and *Lanzo* require of our gatekeepers, and how that analysis may be used to benefit the defense at trial.

Likely, most readers here have observed a plaintiff's doctor testify that plaintiff's magnetic resonance imaging (MRI) provides sophisticated, objective proof that a singular event

traumatically caused damage to an intervertebral disc (some experts go far to say that clinical or historical correlation with images is irrelevant). In support of that opinion the expert relies upon nothing more than his or her vaguely summarized expertise in the interpretation of diagnostic images. We all have seen such expert rely upon no authoritative, peer-reviewed study. He or she describes no characteristic of an image by which one is to distinguish a disc herniated by decades of wear from one damaged in an instant of unquantified force. One neuro-radiologist supported her opinion on temporal, causal relationship by saying simply: "You can just tell."

Such an expert thus relies upon no prescribed methodology or underlying data. Yet, with essentially no effort made at the analysis required of a gatekeeper, the trial court routinely allows such testimony. One could conclude that such expert would not survive the court's consideration of the factors articulated in *Accutane*.

*Accutane* requires the trial court to engage in the role of "gatekeeper" when called upon to assess the reliability and admissibility of scientific evidence proffered in support of an opinion on causation, under *N.J.R.E.* 702. *See, In re Accutane Litigation*, 234 N.J. at 388 (approving generally the approach prescribed in *Daubert v. Merrell Dow Chemicals Inc.*, 509 U.S. 579 (1993). That is, the trial court should

exclude junk science. The court is to assess both the methodology used by the expert to arrive at an opinion, and the underlying data used in the formation of the opinion. *Id.* at 396-97.

The courts in *Accutane* and *Lanzo* acknowledge the general factors upon which the trial court should rely when acting as a gatekeeper:

- 1) whether the scientific theory can be, or at any time has been, tested;
- 2) whether the scientific theory has been subjected to peer review in publication;
- 3) whether there is any known or potential rate of error and whether there exist any standards for maintaining or controlling the techniques of operation; and
- 4) whether there does exist a general acceptance in the scientific community about the scientific theory.

*In re Accutane Litigation*, at 398; *Lanzo v. Cyprus Amax Minerals Co.*, at 510.

That summary is a capitulation, and distillation, of holdings and dictum in a line of cases before and after *Daubert*. The rule excluding an expert's net opinion is a mere restatement of the established rule that an expert's bare conclusions, unsupported by factual evidence, are inadmissible. *Bucklelew v. Grossbard*, 87 N.J. 512, 524 (1981); *Nguyen v. Tama*, 298 N.J. Super. 41, 48-49 (App. Div. 1997). The expert must demonstrate that his opinion or theory is generally accepted within

the scientific community. Creanga v. Jardal, 185 N.J. 345 (2005). A mere platitude, such as a conclusory medical phrase, is not sufficient to establish admissibility. Id. The expert must winnow his list of hypotheses by using sufficient diagnostic techniques, to arrive at his conclusions. See, e.g., Id.; Heller v. Shaw Indus., Inc., 167 F.3d 146, 156 (3d Cir. 1999). Plaintiff's burden of proving causal relationship "must be carried by the presentation of competent credible evidence which proves material facts; it cannot be satisfied by conjecture, surmise or suspicion." Lamb v. Barbour, 188 N.J. Super. 6, 12 (App. Div. 1982), cert. denied, 93 N.J. 297 (1983). Net opinions are of "no assistance to the trier of fact" and are insufficient to establish causation. Tannock v. New Jersey Bell, 223 N.J. Super. 1, 7 (App. Div. 1988). See also, Stanley Co. v. Hercules Powder Co., 16 N.J. 295 (1954). An expert's opinion is rightfully excluded where his or her testimony goes beyond the scope of the expert's skill and competence. Nesmith v. Walsh Trucking Co., 123 N.J. 547, 548 (1990).

In the common trial of claimed injury to the spine, the defense attorney rarely requests a hearing under N.J.R.E 104, to challenge the expert's interpretation of MRI, and so the trial court perfunctorily qualifies the witness to be an expert and allows the opinion on the MRI and causal relationship. Rarely, if ever, in such circumstance is the trial court asked to apply the Accutane/Lanzo factors in an analysis of the ground for the expert's opinion on causal relationship. The court is not asked to determine if the plaintiff's expert shows objective testing of the hypothesis; an identified rate of error; published studies of the methodology; proof of the reliability of his method; the rigor of the process by which alternative conclusions are excluded; the list of hypotheses from which the conclusion is winnowed; the data, the samples, the studies, from which the conclusion is purportedly derived; and the defining characteristics of an acute change shown on imaging.

A trial court's consideration of the factors in Accutane and Lanzo would require, all but surely, exclusion of most plaintiffs' experts' testimony on MRI and causal relationship, and our industry would be upended. The court's avoidance of that consideration, and its probable consequence, suggests a systemic bias imposed not by contemplation but only by systemic inertia and decades of habit.

That thoughtless bias is evinced not only by the routine failure of analysis, but also by the demands of qualification imposed in the trial court upon the relatively new expert, one employed almost exclusively, and with increasing frequency, by defendants, i.e., the biomedical expert. Were the trial court to require of the usual expert on spinal injury what it requires of the biomedical expert, the court would exclude most experts' interpretations of MRI offered to support an opinion on causal relationship.

A biomedical expert who purports to give an opinion on causal relationship, who "has not himself conducted or observed tests of low impact collisions on humans"... should be permitted to testify to causal relationships only if literature on which he relied "provides a reliable scientific foundation for the conclusion" that a specific automobile accident caused "a herniated disc." See, e.g., Suanez v. Egeland, 353 N.J. Super. 191, 196 (App. Div. 2002). The expert must describe studies with more than "general and vague references to various articles." See, Id. at 200. The expert must refer to specific scientific tests performed under controlled conditions similar to the conditions of the automobile accident at issue. See, Id. The testimony of a medical expert, regarding causal relationship, may not exceed the scope of his expertise and may not venture into the world of mechanics or biomechanics. See, e.g., Id. at 201.

To give an evidentiary opinion of how a person's body's movement would be effected by an impact, such as in an automobile accident, and what injury resulted from the movement, one must be a biomechanical engineer or an expert in biomechanics, or have some expertise in the fields of biomechanics or biomedicine. It is not enough to have studied anatomy and physiology.

Biomechanics is defined as 'the mechanical bases of biological, especially muscular, activity; also: the study of the principles and relations involved.' For purposes of simplicity, we define biomechanics as the study of the effects of forces and motion on the human body. Accordingly, we recognize that an individual demonstrating knowledge, skill, experience, training or education in the field of biomechanics may be qualified to testify *generally* about how the human body will react to the impact of forces exerted upon it during an automobile accident.

Hisenaj v. Kuehner, 194 N.J. 6 (2008). Hisenaj advises that it is not enough for an expert to have studied anatomy and physiology. Hisenaj says that to give an opinion on what injury resulted from a body's movement in an accident, one must be an engineer, or have expertise in biomechanics or biomedicine. The typical plaintiff's expert has no such expertise.

Commonly an expert in biomechanics or biomedicine will have a Ph.D., and will have completed coursework in fields of biomechanics, injury tolerance, biomaterials, neuroscience, structural mechanics, impact mechanics, materials engineering and physiology. Such expert has investigated the distribution of forces using three-dimensional motion analyses, mathematical modeling, clinical studies, animal models, MR imaging, mechanical testing and finite element analyses. Usually the expert has attended classes at a medical college. The typical plaintiff's orthopedic, neurologic, or radiologic expert has no such education.

Typically a biomedical expert is asked to assess a human body's response to a specific load, force or impact. To do that the expert must define or identify the mechanism of injury. He must identify the load or force applied to the plaintiff's body. He must quantify that force, the acceleration or change in velocity of the vehicle occupied by the plaintiff. He must then define the movement of plaintiff's body as the result of the accident. He must identify the interaction between the body and the interior components of the vehicle; either those components that cause an injury or those components that cushioned or protected the body. The expert must then determine whether the interaction between the vehicle and the body created a load known to cause injury in subjects similar in characteristics to the plaintiff. The expert finally must evaluate the personal tolerance of the plaintiff for a specific force applied to a specific part or area of the body, to determine whether that force caused injury in a specific case.

To properly demonstrate those things an expert must engage in techniques of engineering analysis, including conservation of momentum analyses and parametric energy-based crush analysis. He must consider Newton's third law of motion. He must consider the plasticity of the vehicles involved and the components in the

passenger's compartment. He must calculate the delta-v (change in velocity of the plaintiff's vehicle). The typical plaintiff's medical expert can do, and has done, none of that.

An expert who has no ability to identify the delta-v, to identify the force excerpted upon the plaintiff's body, to identify the vector of force and who is not informed by scholarly or authoritative writings, cannot possibly provide a scientifically derived conclusion about what force was applied to the plaintiff's body in a specific accident or whether the force applied, were it identified, was sufficient to cause specific injury to a specified organ or body part. The plaintiff's typical medical expert has no such ability.

In the testimony of a typical plaintiff's medical expert, one interpreting MRI, there is no suggestion that the expert has considered, much less calculated, the force of impact, the vector of force, the speed of the vehicles, or the delta-v. Such expert invariably has not calculated how plaintiff's body moved in the impact. The testimony of such expert proffers no measurement of, calculation of, or opinion on, what force specifically was transmitted to

the plaintiff's body generally, or to any specific part of plaintiff's spine. Such expert always lacks the expertise to competently opine that the specific, calculated force applied to any intervertebral disc in this accident was sufficient to cause a herniated disc or other injury.

Such plaintiff's expert on MRI relies upon no standard, no protocol, no data, no method, and no list of characteristics set forth in a peer-reviewed study, by which to support scientifically the opinion that on MRI a herniated disc looks fresh. Yet, such expert's opinion simply stating that a herniated disc on MRI looks like something new is universally enough, in the eyes of the court, for admission of the opinion on causal relationship.

Notwithstanding the foregoing, the analysis required of the gatekeeper at trial should convincingly demonstrate that the common plaintiff's expert is unqualified to link medical images to a specific, instantaneous cause. Standards and thresholds articulated in Accutane, Lazaro, Suarez, and Hisenaj are compatible, and complimentary, with one another. Those cases may be, and should be, read as monolith directing the gatekeeper.

The conclusion must be that the trial court, exercising its duty as gatekeeper, in a common cases of bodily injury, should routinely and even-handedly impose upon plaintiff's orthopedist, neurologist or radiologist, the burden imposed upon the biomedical expert by precedent, and should engage in the analysis demanded by Accutane and Lanzo. At trial the defendant should demand a hearing under N.J.R.E. 104, regarding competence of the opinion on causal relationship, and if unsuccessful upon that hearing, should cross-examine the plaintiff's expert using the verbiage of analysis in the cases identified above.

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**Michael J. McCaffrey since year 1992 has been certified by the Supreme Court of New Jersey as a Civil Trial Attorney. He received a B.A. (philosophy) from Rutgers University in 1978, and was graduated from the Indiana University School of Law, Bloomington, where he was selected through a program of competitive writing to serve on the Indiana Law Journal.**

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# DEFENSE WINS

## MCCARTER TEAM SECURES PRODUCT LIABILITY WIN FOR GENIE INDUSTRIES, INC.

McCarter partners Kenneth Meyer and Ryan Richman recently obtained a major product liability win in the District of New Jersey for aerial lift maker Genie Industries, Inc., a subsidiary of Terex. The team successfully excluded Plaintiff's engineering expert with a *Daubert* motion and then prevailed on summary judgment as a result in a case where one of the company's lifts tipped over while the plaintiff was elevated on the platform.

This case related to an aerial work platform (AWP-30s) manufactured by Genie. This machine is designed to be a portable, stationary, work platform that can be raised up to 30 feet in the air. To maintain stability while the platform is raised, the AWP-30s has four outriggers that must be installed before raising the platform, and is also equipped with an electronic interlock system that prevents the platform from being raised until all four outriggers are properly installed and the machine is stabilized. Critically, for stability reasons, the outriggers are required to remain installed while operating the machine, and the machine should never be moved when the platform is raised. There are multiple, clear, warnings to this effect and both plaintiff and his co-worker acknowledged understanding the danger associated with their actions.

On February 24, 2014, plaintiff and a coworker, both welders and set builders for a production company, were putting a fence up in a warehouse. While Plaintiff was elevated in the platform of the AWP-30s, Plaintiff's coworker intentionally removed, with Plaintiff's knowledge and consent, all four outriggers. While elevated about 20 feet, the machine tipped over while Plaintiff's coworker was pulling the machine. As a result of the tipover, Plaintiff suffered significant injuries. Despite the intentional and voluntary chain of events that led to the tip over, Plaintiff filed claims against Genie under the New Jersey Product Liability Act claiming a design defect.

Genie filed a *Daubert* motion arguing that Plaintiff's design defect claim against Genie should be dismissed because Plaintiff did not offer admissible expert testimony of a practical, technically feasible and safer alternative design for the machine. Plaintiff's theory was that the AWP-30s was defective because the outriggers can be removed when the platform is elevated. Plaintiff hired an expert, Russ Rasnic, P.E. Mr. Rasnic proposed an alternative "safer" design involving installing multiple safety devices to prevent the outriggers from being removed while the platform is elevated. Genie's experts identified easy defeats for Rasnic's initial design. Mr. Rasnic admitted that his first design was no safer than Genie's design and conceded at his deposition that any design, including his own, can be defeated. Mr. Rasnic thereafter submitted a supplemental report with a second design, which involved installing a 2012 coded proximity switch. We argued that this second alternate design was flawed in three significant ways: (1) it can be as easily defeated as the first design; (2) the proposed technology did not exist when the subject machine was manufactured and sold in 2006; and (3) the proposed design causes system failures. We also challenged Mr. Rasnic's lack of and insufficient testing on both designs, which the Court found troubling and determined Mr. Rasnic did not sufficiently test either of his designs, given that Genie's testing found that both designs were easily defeated and failed to function properly. In doing so, the Court found Mr. Rasnic offered an incomplete analysis, particularly given his lack of testing and lack of consideration of the possibility of defeat of his designs. Mr. Rasnic also offered opinions about human behavior relating to overriding his alternate design that the Court determined he was not qualified to give.

After District Court Judge Esther Salas granted Genie's motion and excluded Mr. Rasnic's expert testimony as unreliable and inadmissible on at least five different grounds, Her Honor also granted Genie's motion for summary judgment.

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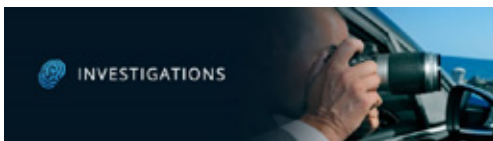


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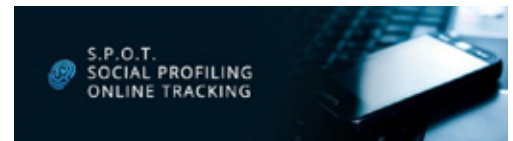
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# O'TOOLE'S COUCH: DRIVE-IN MOVIES

Every June my mother would get the family ready for our two weeks at the shore in Manasquan. One of the shore activities we all enjoyed was the drive-in movie theatres. There were three in our immediate area - Brielle at the Brielle Circle, the Shore Drive-In in Asbury, and the Fly-In Drive-in in Wall Township. When I say "we all enjoyed the drive-in movies," that isn't exactly accurate. My father definitely wasn't a "drive-in kind of guy," but wouldn't have missed a good Western such as "One Eye Jacks" with Marlon Brando, "The Searchers" with John Wayne," or "Gunfight at the OK Corral" with Kirk Douglas and Burt Lancaster, to name a few.

Our routine for drive-in movie nights was to get to the beach early so we could be back home in plenty of time for me (at 8 years old,) to have a nap and be ready for an early dinner. I think this was a requirement of my dad's to get some quiet time for him and my mom. For us kids it was a small price to pay for the chance to see a double-feature and a cartoon. (At the Fly-In Drive-In there were many planes landing on the strip

prior to the start of the movies. How exciting it was to see them land. Although I rarely made it through both movies, the evening was a treat, and we always had warm blankets around us. If we stayed awake after the first movie, we were treated with snacks from the drive-in snack bar while the Intermission Clock on the movie screen let us know how much time was left until the next show began. Additionally, my Mom was always a hero when it came to intermission. If we saw people we knew during intermission, especially those we knew were struggling financially, we would share Mom's home-made snacks with them. (Thus it was said of my Mom that "Helen was going straight to heaven.") Our family never went to drive-ins in the winter, even though they did provide small window heaters. Dad would insist that "Enough is Enough!" The only exception was one winter when "It's A Wonderful Life," starring Jimmy Stewart was playing during the Christmas season. Who could say no to that?

Fast forward ten years - Although the drive-in had the reputation as the "Passion Pit," unfortunately,

that was never my experience. The girls always took the position that there was strength in numbers, and wanted to have several of their girlfriends crowded into the car. Most theatres had a promotion that allowed as many people in the car as would fit; obviously a distraction from the passion pit. (It was not unusual for us to have 8 to 10 kids jammed into one car. Not unlike the clown car act in the circus.) To get even with the Romeos in other cars, we would use "Flashlight Attacks." Hey, that was the only excitement we got!

Unfortunately, the drive-in business dwindled over the years. (I would venture a guess that many of you never attended such a movie site.) I imagine the land value was greater when used for other commercial ventures. If, after reading this article you feel like you may have missed out on something, you can check the website "Drive-In Movies Coming To Morris County and Beyond." Don't forget to bring some pop corn!

Have a healthy, fun-filled and productive 2022!

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### NOVEMBER 11, 2021

#### 12TH ANNUAL WOMEN AND THE LAW

Webinar by Zoom  
8:30 a.m. - 1:00 p.m.

### NOVEMBER 23, 2021

#### NJDA/ICNJ AUTO LIABILITY SEMINAR

APA Hotel Woodbridge  
8:30 a.m. - 1:00 p.m.

### DECEMBER 3, 2021

#### ANNUAL HOLIDAY PARTY

Spring Lake Golf Club, Spring Lake, NJ  
6:30 p.m.

### DECEMBER 10, 2021

#### 2021 CIVIL TRIAL SEMINAR

Webinar by Zoom  
9:00 a.m. - 12:30 p.m.

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