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IN THE
COURT OF APPEALS OF INDIANA

Stephen W. Robertson,
Commissioner, Indiana
Department of Insurance, as
Administrator of the Indiana
Patient’s Compensation Fund,
Appellant / Intervenor,

v.

Anonymous Clinic¹, (Defendant
Below) and Terri J. Rethlake, *et
al.* (Plaintiffs below),
Appellees.

November 7, 2016

Court of Appeals Cause No.
71A03-1512-CT-2199

Interlocutory Appeal from the St.
Joseph Superior Court

The Honorable David C. Chapleau,
Judge

Cause Nos.
71D06-1405-CT-136,
71D06-1406-CT-181,
71D06-1406-CT-211,
71D06-1406-CT-257,
71D06-1406-CT-320,
71D06-1406-CT-300

Stephen W. Robertson,
Commissioner, Indiana
Department of Insurance, as
Administrator of the Indiana
Patient’s Compensation Fund,
Appellant / Intervenor,

v.

Orthopedic and Sports Medicine
Center of Northern Indiana;
ASC Surgical Ventures, LLC;

Court of Appeals Cause No.
71A03-1512-CT-2199

Appeal from the Elkhart Superior
Court

The Honorable Evan S. Roberts,
Judge

Cause No. 20D01-1410-CT-216

¹ Although some plaintiffs in the St. Joseph cases refer to the defendant as “ABC Clinic” to retain anonymity, we shall refer to the defendant as “Anonymous Clinic” in an effort to reduce the potential for confusion. As it happens, there is an actual “ABC Clinic” in South Bend, which is a spay/neuter clinic operated by Pet Refuge. See <http://petrefugeabcclinic.com/> (last visited on October 26, 2016).

OSMC; John Doe Company;
Medical Protective Corporation;
Medical Insurance Services, Inc.
(Defendants Below) and Joe and
Linda Alcozar, *et al.* (Plaintiffs
below),
Appellees.

Bradford, Judge.

Case Summary²

- [1] Beginning in 2012, patients around the country began suffering meningitis after being injected with preservative-free methylprednisolone acetate (“MPA”), a steroid purchased from New England Compounding Pharmacy, Inc., a/k/a the New England Compounding Center (“NECC”). It was soon discovered that some lots of MPA had become contaminated with fungus. This consolidated appeal concerns claims brought by injured patients (or those suing on their behalf) (collectively, “the Plaintiffs”) against Anonymous Clinic in St. Joseph County and Orthopedic and Sports Medicine Center of Northern Indiana (“OSMC”) and affiliated entities in Elkhart County (collectively, “the Defendants”). Plaintiffs contend that the Defendants were negligent in choosing to administer preservative-free MPA and in failing to properly

² We heard oral argument in this case on October 19, 2016. We would like to commend all counsel on the high quality of their written and oral advocacy.

evaluate NECC before using it as a supplier. Some of the Plaintiffs brought suit without using the procedures laid out in the Indiana Medical Malpractice Act (“the MMA”), and Defendants moved either for dismissal or summary judgment on the basis that Plaintiffs’ claims were claims of medical malpractice.

[2] Stephen W. Robertson, acting in his capacity as Commissioner of Indiana Department of Insurance, which administers the Indiana Patient’s Compensation Fund (“the PCF”) intervened, arguing that Plaintiffs’ claims were of general negligence and therefore not subject to the provisions of the MMA. The trial courts ultimately agreed with Defendants and Plaintiffs (who had reversed their initial position) that Plaintiffs’ claims were governed by the MMA. In this consolidated appeal, the PCF contends that the trial courts erred in concluding that Plaintiffs’ claims are claims of medical malpractice. Plaintiffs, Defendants, and *Amici Curiae* (health-care providers facing similar claims in other cases), contend that Plaintiffs’ claims are subject to the MMA as they involve actions informed by the exercise of professional medical judgment. Because we conclude that Plaintiffs’ claims are subject to the MMA, we affirm the judgments of the trial courts and remand for further proceedings consistent with this opinion.

Facts and Procedural History

I. St. Joseph County Litigation

[3] The St. Joseph Superior Court set forth the facts underlying the claims filed in St. Joseph County in its order dismissing Plaintiffs' claims:

PRELIMINARY DETERMINATIONS OF FACT

1. This proceeding arises as a result of an outbreak of fungal meningitis, fungal infections and other related complications that affected individuals in at least twenty states and caused, at a minimum, 64 deaths. The outbreak resulted in deaths and injuries to Hoosiers and Michigan residents who received treatment in Indiana. Indiana and Michigan were hit particularly hard. The [Centers for Disease Control] identified 93 cases of Hoosiers diagnosed with fungal infections linked to contaminated epidural injections, with 11 of those resulting in death. Michigan was the hardest hit state, with a case count of 264, and 11 of those resulting in death. There are many more individuals who received a contaminated injection who suffered injury from the injection, but who have not been identified as a "case" by the CDC.

2. Plaintiffs are individuals or their representatives who suffered injury or death as a direct result of being administered one or more contaminated epidural injections.

....

Plaintiffs also include the spouses of certain individuals who received such contaminated injections. Those plaintiffs who received services from [Anonymous Clinic] sought treatment of back pain and related spinal conditions. Such services included physical therapy, epidural injections, pain medications and surgery. Each of the patient-plaintiffs was a "patient", as defined by the MMA, of [Defendants] when they received their epidural steroid injections.

3. [Anonymous Clinic is a] qualified health care provider under MMA which was and is engaged in the business of providing health care and selling medical related products. The plaintiffs' complaints, filed before the St. Joseph Circuit and

Superior Courts, each allege a claim arising out of the patient-health care provider relationship.

4. The intervening party in this litigation is the Patient's Compensation Fund (hereafter referred to as "PCF"). Under the provisions of the Indiana Medical Malpractice Act (hereafter referred to as "MMA"), the PCF is responsible for payment of a plaintiff's claim which is determined by trial or through settlement to be a recoverable claim and where the health care provider in question, through its insurer, had paid as required under the MMA.

5. Plaintiffs' proposed complaints filed with the IDOI ... pleaded factual allegations about the patient-health care provider relationship each plaintiff had with [Anonymous Clinic]. Each proposed complaint alleges that the plaintiff was "injected with a contaminated epidural product" when he or she was treated at [Anonymous Clinic].

6. Plaintiffs allege in 1998, Gregory Conigliaro and Barry Cadden co-founded the New England Compounding Pharmacy, Inc., known as New England Compounding Center ("NECC"), in Massachusetts. Other members of the Conigliaro and Cadden families came to be involved with NECC either as owners, officers or employees. Other related entities to NECC were established by the Conigliaros and Barry Cadden, including Medical Sales Management, Inc., Ameridose, LLC and Alaunus Pharmaceutical, LLC in the State of Massachusetts.

7. Plaintiffs allege NECC operated as a compounding pharmacy. Plaintiffs assert that compounding pharmacies are prohibited from mass production of pharmaceutical products but may only produce products that have a particular demand need, such as a drug for a patient who is allergic to an ingredient in a mass produced, FDA regulated product or a pharmaceutical product that is no longer manufactured.

8. Plaintiffs allege [Anonymous Clinic] purchased preservative-free methylprednisolone acetate ("MPA") from NECC. MPA is a steroidal product that can be injected into the area of the lumbar spine to provide pain relief to individuals who suffer with low back pain and related symptoms.

9. Plaintiffs allege there are particular safety and product quality risks associated with purchasing pharmaceuticals from a compounding pharmacy. The risk is heightened for those pharmaceutical products that are made without preservatives, due to the increased risk of their being or becoming contaminated.

10. Plaintiffs allege an outbreak of fungal meningitis, lumbar fungal infections and related injuries and complications arose in September, 2012. [CDC] was notified by the Tennessee Department of Health of a patient who developed fungal meningitis after receiving an epidural steroidal injection. Additional patients developing fungal meningitis were next identified in Massachusetts and the outbreak continued spreading to 19 states, including Indiana and Michigan. The outbreak was the result of patients receiving one or more contaminated injections from three different lots of MPA compounded by NECC (lot numbers 05212012@68, 06292012@29 and 08102012@51) or from another contaminated NECC medication.

11. Plaintiffs allege The Food and Drug Administration (“FDA”) and the Massachusetts Department of Public Health (“MDPH”) began investigating NECC, along with the involvement of other state and federal agencies. On September 26, 2012, NECC recalled the three lots of MPA found to be contaminated. The suspected lots contained 17,676 dosage vials. Of this number, more than 14,000 were used for injections. Only about 3,000 doses were returned through the recall process.

12. Plaintiffs allege the investigation of NECC revealed black particulate matter in sealed, returned vials of MPA. Vials also contained a greenish black foreign matter and others a white filamentous material. Sterility analysis later confirmed the presence of “viable microbial growth” in all of the 50 vials tested.

Appellant’s App. pp. 93-97 (record citations omitted).

- [4] A total of six claims against Anonymous Clinic were consolidated to address the threshold legal issue of whether the claims are claims of general negligence or are subject to the MMA. On May 15, 2015, in the consolidated action captioned *In re Steroid Litigation*, Anonymous Clinic filed a motion to dismiss all of the Plaintiffs' claims for lack of subject matter jurisdiction on that basis that MMA requirements had not been met.
- [5] On June 26, 2015, the PCF filed a response to the motion to dismiss, opposing it on the ground that the MMA did not apply to Plaintiffs' claims. Also on June 26, 2015, Plaintiffs reversed their earlier position and filed a response urging the trial court to conclude that their claims were covered by the MMA. On August 27, 2015, the St. Joseph Superior Court heard oral argument on Anonymous Clinic's motion to dismiss.
- [6] On October 12, 2015, the St. Joseph Superior Court granted Anonymous Clinic's motion to dismiss in part, concluding that Plaintiffs' claims were governed by the MMA. The St. Joseph Superior Court stayed proceedings until compliance with MMA procedures could be accomplished. On November 12, 2015, the PCF moved the St. Joseph Superior Court to certify the case for interlocutory appeal, which motion was granted on November 16. This court accepted jurisdiction.

II. Elkhart County

- [7] The Elkhart Superior Court set forth the facts underlying the claims filed in Elkhart County in its order entering summary judgment in favor of OSMC:

FINDINGS OF FACT

1. Plaintiffs are residents of Indiana and Michigan.
2. OSMC operates medical clinics in Indiana.
3. Medical Protective provides medical malpractice insurance to OSMC.
4. Broadly, the medical malpractice insurance coverage policy requires Medical Protective to defend and indemnify OSMC “[i]n any claim based upon professional services,” subject to four exclusions:
 - a. Criminal acts and willful torts,
 - b. Claims that fall under OSMC’s general liability policy,
 - c. Punitive damages, or damages above and beyond compensatory damages, and
 - d. Any amounts that exceed policy limits.
5. The New England Compounding Center (“NECC”) was a compounding pharmacy located in Massachusetts.
6. In 2005, OSMC began purchasing betamethasone and hyaluronidase from New England Compounding Center.
7. OSMC began purchasing drugs from NECC after Elkhart General Hospital, which is not a party to this case, began ordering compounded pharmaceuticals from NECC.
8. Before Elkhart General Hospital ordered pharmaceuticals from NECC, two pharmacists from the hospital traveled to NECC’s facilities.
9. Dr. Gene W. Grove, Sr., M.D. works as the medical director of OSMC and as chairman of the pharmacy and therapeutics board at Elkhart General Hospital.
10. While acting as chairman of the pharmacy and therapeutics board, Dr. Grove became aware that the Elkhart General Hospital medical staff had authorized NECC as a supplier.
11. OSMC hires Elkhart Hospital pharmacists to act as consultants.
12. OSMC’s trust in Elkhart General Hospital’s vetting process for pharmaceutical suppliers played a role in OSMC’s authorization of NECC as a supplier.
13. In 2006, OSMC decided to use preservative-free [MPA].

14. Physicians at OSMC determined that preservative-free steroids are safer for patients because preservatives may cause arachnoiditis and damage the spinal cord.

15. Commercial drug manufacturers do not produce MPA in a preservative-free form.

16. OSMC decided to purchase preservative-free MPA from NECC because OSMC was already purchasing betamethasone and hyaluronidase from NECC.

17. OSMC did not seek other potential suppliers of preservative-free MPA.

18. The medical board at OSMC authorized the use of preservative-free MPA.

19. The medical board at OSMC authorized NECC as a supplier of medications.

20. Plaintiffs allege that compounding pharmacies may not mass produce pharmaceuticals, but rather must produce drugs for individual patients.

21. Mass producers of pharmaceuticals must receive special licenses and are subject to greater FDA oversight.

22. Drugs acquired from a compounding pharmacy generally involve greater risk than drugs acquired from a mass producer.

23. In 2012, the [CDC] began investigating an outbreak of fungal meningitis, lumbar fungal infections, and similar diseases.

24. The CDC traced the outbreak to three lots of preservative-free MPA that NECC produced.

25. Approximately 17,676 vials of preservative-free MPA originated from the contaminated lots.

26. A recall was issued, and only approximately 3,000 vials were returned, with approximately 14,000 doses having been previously administered.

27. A number of the returned vials contained visible particulate and other foreign matter.

28. Fifty (50) of the returned vials were tested for sterility, and all of them contained viable microbial growth.

Appellant's App. pp. 116-31.

[8] Beginning on October 27, 2014, several Plaintiffs sued OSMC to recover for injuries allegedly suffered because of the injection of defective MPA.³ On May 15, 2015, the PCF moved for summary judgment on the ground that the Plaintiffs' claims were not covered by the MMA. Also on May 15, 2015, OSMC moved for summary judgment, asserting that the Plaintiffs' claims were covered by the MMA. On June 25, 2015, Plaintiffs responded to the summary judgment motions, seeking a determination that their claims were covered by the MMA. On August 7, 2015, the Elkhart Superior Court heard oral arguments on the summary judgment motions. On November 13, 2015, the Elkhart Superior Court issued its order entering summary declaratory judgment in favor of OSMC on the ground that the MMA applies to Plaintiffs' claims.

III. Appellate Procedure

[9] On February 17, 2016, Plaintiffs moved this court to consolidate the St. Joseph appeal with the Elkhart appeal, a motion the PCF did not oppose. On March 7, 2016, this court granted the motion to consolidate the appeals, consolidating appellate cause numbers 20A03-1512-CT-2148 and 71A03-1512-CT-2199 under the latter cause number.

Discussion and Decision

³ At the time of the Elkhart Superior Court's order, a total of twenty-six cases were before the court involving the same question about whether the MMA applied to their claims.

[10] All agree that the only issue in this appeal is whether Plaintiffs’ allegations against Anonymous Clinic and OSMC are claims of general negligence or are covered by the provisions of the MMA. The parties also agree that the issue, as ultimately one of jurisdiction, is to be reviewed *de novo* by this court. *See Kondamuri v. Kondamuri*, 799 N.E.2d 1153, 1156 (Ind. Ct. App. 2003) (“A court’s jurisdiction either exists or does not, and the question of a court’s jurisdiction is therefore a question of law that is not entrusted to the trial court’s discretion but rather is reviewed *de novo*.”), *trans. denied*.

I. Background—The MMA

[11] Plaintiffs, Defendants, and *Amici Curiae* argue that Plaintiffs’ claims are covered by the MMA while the PCF argues that they are not.

[T]he MMA [is] a statute that applies to claims of personal injury or death proximately caused by a “health care provider,” as that term is defined in the MMA.... We will usually refer to this type of claim in this opinion as “medical malpractice” or just “malpractice.” The MMA did not create or establish the medical malpractice claim; it only imposed procedural requirements on the prosecution of them. *Chamberlain v. Walpole*, 822 N.E.2d 959, 961 (Ind. 2005).

One of the requirements of the MMA is that a proposed medical malpractice complaint first be filed with the Department of Insurance for review by a medical panel before the complaint is filed in court.

Ellenwine v. Fairley, 846 N.E.2d 657, 660 (Ind. 2006).

The MMA ... set up a system under which health care providers meeting qualifications set forth in the act (“Qualified Provider”)

would enjoy certain benefits, including a limitation on liability. For an act of malpractice occurring after June 30, 1999, the total amount recoverable for an injury or death is now capped at \$1,250,000. *See* Ind. Code § 34-18-14-3(a)(3). A Qualified Provider’s liability for an occurrence of malpractice is now limited to \$250,000. *See* Ind. Code § 34-18-14-3(b). Any remaining amount due from a judgment or settlement is to be paid from the Fund. *See* Ind. Code § 34-18-14-3(c).

In re Stephens, 867 N.E.2d 148, 150 (Ind. 2007).

[12] At the heart of both the Elkhart and St. Joseph Superior Courts’ decisions is their conclusion that the MMA governs Plaintiffs’ claims against Defendants. Defendants and *Amici Curiae*, who are also health care providers under the MMA, wish to have this court declare Plaintiffs’ claims subject to the MMA. Plaintiffs, despite the fact that they would face the additional procedural burdens of compliance with the MMA as well as the limitations on recovery, take the same position. The PCF contends that Plaintiffs’ claims are claims of general negligence, not governed by the MMA.

II. The Arguments

[13] Pursuant to Indiana Code section 34-18-2-13, “‘Health care’ means an act or treatment performed or furnished, or that should have been performed or furnished, by a health care provider for, to, or on behalf of a patient during the patient’s medical care, treatment, or confinement.” The question is whether the negligence alleged against Defendants qualifies as “health care.” If so, Plaintiffs’ claims are subject to the MMA; if not, they are claims of general negligence.

[14] In the brief in support of the PCF’s summary judgment motion filed in Elkhart Superior Court, it characterized Plaintiffs’ arguments as follows:

Instead, the gravamen of plaintiffs’ underlying complaints is that OSMC [was] negligent in procuring preservative-free [MPA] from NECC.

Based on a review of the underlying complaints and the deposition testimony of [OSMC]’s representatives, the PCF anticipates that plaintiffs’ arguments related to whether the MMA applies to their claims will fall into two broad categories - namely, (1) the decision to use a preservative-free [MPA], and (2) the decision to purchase that product from NECC.

Appellant’s App. p. 277.

[15] In the PCF’s motion in St. Joseph Superior Court, it characterizes the Plaintiffs’ claims as follows:

Instead, the gravamen of plaintiffs’ underlying complaints is that [Anonymous Clinic was] negligent in procuring preservative-free [MPA] from NECC. The “question of whether a given course of treatment was medically proper and within the appropriate, standard” is the “quintessence of a malpractice case.” *Howard Reg’l Health Sys. v. Gordon*, 952 N.E.2d 182, 185 (Ind. 2011). But, noticeably absent in this case is any allegation that the “course of treatment” was improper or improperly administered. Instead, plaintiffs allege that the course of treatment was tainted by a third party who allowed the medications to become contaminated.

This factual scenario is fundamentally different from the allegations that state a claim for medical malpractice.

The complaint allegations relevant to [Anonymous Clinic] fall into two broad categories - namely, (1) the decision to use a preservative-free [MPA], and (2) the decision to purchase that product from NECC.

Appellant’s App. pp. 996-97. So, the question is whether deciding to use preservative-free MPA and deciding to purchase it from NECC constitute “health care” under the MMA. If so, the alleged negligence in those areas would be subject to the MMA. If not, such claims would be claims of general negligence.

A. Legal Arguments

[16] The PCF contends that the general procurement of products that will eventually be used in the course of treatment does not qualify as “health care” under the MMA. The OSMC and Anonymous Clinic argue that Plaintiffs’ allegations are covered by the MMA. *Amici* point out that the U.S. District Court for the District of Massachusetts, which is hearing hundreds of similar cases in federal multidistrict litigation (“the MDL Court”), has determined similar claims to be claims of professional negligence, and urges this court to do the same.

[17] “The [MMA] is not all-inclusive as to claims against medical providers, and a claim against a medical provider sounding in general negligence or premises liability rather than medical malpractice is outside the [MMA].” *Peters v. Cummins Mental Health, Inc.*, 790 N.E.2d 572, 576 (Ind. Ct. App. 2003), *trans. denied*.

The Act covers “curative or salutary conduct of a health care provider acting within his or her professional capacity, but not conduct *unrelated* to the promotion of a patient’s health or the provider’s exercise of professional expertise, skill, or judgment.” *Howard Reg’l Health Sys. v. Gordon*, 952 N.E.2d 182, 185 (Ind. 2011) (emphasis added) (citation and quotation marks omitted).

When deciding whether a claim falls under the provisions of the Act, “we are guided by the substance of a claim to determine the applicability of the Act.” *Doe by Roe v. Madison Ctr. Hosp.*, 652 N.E.2d 101, 104 (Ind. Ct. App. 1995).... [W]e reiterate that the “fact that the alleged misconduct occurs in a healthcare facility” or that “the injured party was a patient at the facility,” is not dispositive in determining whether the claim sounds in medical malpractice. *Madison Ctr., Inc. v. R.R.K.*, 853 N.E.2d 1286, 1288 (Ind. Ct. App. 2006), *trans. denied*. “[T]he test is whether the claim is based on the provider’s behavior or practices while acting in his professional capacity as a provider of medical services.” *Id.* (quotation marks omitted). We also noted more recently that:

A case sounds in ordinary negligence [rather than medical negligence] where the factual issues are capable of resolution by a jury without application of the standard of care prevalent in the local medical community. By contrast, a claim falls under the Medical Malpractice Act where there is a causal connection between the conduct complained of and the nature of the patient-health care provider relationship.

B.R. ex rel. Todd v. State, 1 N.E.3d 708, 714-15 (Ind. Ct. App. 2013) (citations omitted), *trans. denied*.

Terry v. Cmty. Health Network, Inc., 17 N.E.3d 389, 393 (Ind. Ct. App. 2014).

Indiana courts understand the Malpractice Act to cover “curative or salutary conduct of a health care provider acting within his or her professional capacity,” *Murphy v. Mortell*, 684 N.E.2d 1185, 1188 (Ind. Ct. App. 1997), but not conduct “unrelated to the promotion of a patient’s health or the provider’s exercise of professional expertise, skill, or judgment.” *Collins v. Thakkar*, 552 N.E.2d 507, 510 (Ind. Ct. App. 1990). To determine whether the

Act is applicable, the court looks to the substance of a claim. *Van Sice v. Sentany*, 595 N.E.2d 264 (Ind. Ct. App. 1992).

Thus, regardless of what label a plaintiff uses, claims that boil down to a “question of whether a given course of treatment was medically proper and within the appropriate standard” are the “quintessence of a malpractice case.” *Id.* at 267 (plaintiff’s claims of fraud and battery fell within the Malpractice Act because the first was essentially a claim that the defendant failed to adhere to a standard of care and the second was a claim that the defendant did not obtain informed consent for a procedure); *Popovich v. Danielson*, 896 N.E.2d 1196, 1202-04 (Ind. Ct. App. 2008) (though styled as assault and battery, fraud, breach of contract, and defamation, all plaintiff’s claims involved defendant’s exercise of professional judgment and involved actions taken while providing medical care and thus the requirements of the Act applied).

By contrast, to fall outside the Malpractice Act a health care provider’s actions must be demonstrably unrelated to the promotion of the plaintiff’s health or an exercise of the provider’s professional expertise, skill, or judgment. *Kuester v. Inman*, 758 N.E.2d 96 (Ind. Ct. App. 2001); *Collins*, 552 N.E.2d at 510 (Ind. Ct. App. 1990) (Act held inapplicable in cases where the conduct involved was “unrelated to the promotion of a patient’s health or the provider’s exercise of professional expertise, skill or judgment”).

Howard Reg’l Health Sys. v. Gordon, 952 N.E.2d 182, 185-86 (Ind. 2011).

1. Harts and Pluard

[18] The PCF relies primarily on two Indiana cases to support its argument that alleged negligence in this case is not governed by the MMA. The first of these cases is *Harts v. Caylor-Nickel Hosp., Inc.*, 553 N.E.2d 874 (Ind. Ct. App. 1990), *trans. denied*, in which the elderly plaintiff was injured when the railing allegedly

collapsed on his hospital bed, causing him to fall out. *Id.* at 875-76. Harts argued, and the court agreed, that his claim against the hospital was not subject to the MMA. *Id.* at 879. In so doing, the *Harts* court relied on our earlier decision in *Winona Memorial Found. of Indianapolis v. Lomax*, 465 N.E.2d 731 (Ind. Ct. App. 1984):

“*Such matters as the maintenance of reasonably safe premises are within the common knowledge and experience of the average person. Health care providers, who must make up the medical review panel..., are no more qualified as experts on such matters than the average juror. And as we have stated: ‘When ... the matters at issue are within the common knowledge and experience of the jury, expert testimony regarding the exercise of reasonable care is improper and should be excluded.’ Emig v. Physicians’ Physical Therapy Service, Inc., 432 N.E.2d [52, 53 (Ind. Ct. App. 1982)] (citing Rosenbalm v. Winski, (1975) 165 Ind. App. 378, 332 N.E.2d 249).”*

Harts, 553 N.E.2d at 879-80 (quoting *Lomax*, 465 N.E.2d at 740) (emphasis in *Harts*, first ellipsis added).

[19] Noting that Harts’s allegations were limited to a claim that the hospital’s employees failed to properly restrain or secure the guardrail on his bed, we concluded that

[t]he tenor of Harts’ complaint taken as a whole clearly supports an allegation of ordinary negligence. We cannot say that these allegations were part and parcel of diagnosis and treatment which would subject his claim to coverage under the Act. He did not allege any breach of duty directly associated with medical negligence that was integral to the rendering of medical treatment that would subject his claim to the Medical Malpractice Act.

Harts, 553 N.E.2d at 879.

[20] The PCF also relies on our decision in *Pluard ex rel. Pluard v. Patients Compensation Fund*, 705 N.E.2d 1035 (Ind. Ct. App. 1999), *trans. denied*. Infant Pluard was injured when a surgical lamp detached from a wall and fell on him, striking him in the head. *Id.* at 1036. After settling with the hospital, Pluard sought to recover excess damages from the PCF, which countered that the tort that caused Pluard's injuries was not governed by the MMA. *Id.* We ruled in favor of the PCF, concluding that

[t]he nurses' assistant's manipulation of the light, while very close in time to the light's falling on Pluard, has not been alleged to have caused his injury. Pluard was injured because the light fell on him; the light fell on him because it was not properly attached to the wall. Put another way, the duty to secure the light, and even the nurses' assistant's duty to position it, did not involve a health care decision involving the exercise of professional skill or judgment. Instead, it involved the general duty to maintain safe premises and equipment. As such, it involves issues capable of resolution without application of the standard of care prevalent in the local medical community, and thus, is outside the purview of the Act, which requires convening a panel of medical experts for the purpose of judging a completely different kind of question. Even when we view the evidence in the light most favorable to Pluard, and accept the proposition that the light fixture's fall was sufficiently proximate in time as to make it part of the ongoing care of Pluard, the nurses' assistant being under the direction of the surgeon, it still was not an event that required the exercise of professional skill and judgment.

Id. at 1038.

[21] The PCF contends that the court's focus in *Harts* and *Pluard* was on whether the product was defective or misused during treatment. Specifically, the PCF asserts that the decisions stand for the proposition that if the product is defective, the claim falls outside the MMA, and, if the product is misused, the claims are governed by the MMA. It would follow, then, that because there have been no allegations that the Defendants misused the MPA, Plaintiffs' claims fall outside the MMA. We are not persuaded, however, that the PCF's position is a reasonable reading of *Harts* and *Pluard*.

[22] A fair reading of both decisions indicates that the court's true focus in both cases was on whether the issues were capable of resolution without referring to the medical standard of care; if so, the claims would not be subject to the MMA. The *Harts* court stated that "[w]hen ... the matters at issue are within the common knowledge and experience of the jury, expert testimony regarding the exercise of reasonable care is improper and should be excluded." *Harts*, 553 N.E.2d at 879 (quoting *Lomax*, 465 N.E.2d at 740). The *Pluard* court also based its conclusion on this distinction, determining that the case involved "issues capable of resolution without application of the standard of care prevalent in the local medical community, and thus, is outside the purview of the Act, which requires convening a panel of medical experts for the purpose of judging a completely different kind of question." *Pluard*, 705 N.E.2d at 1038. Contrary to the PCF's assertion, *Harts* and *Pluard* stand for the proposition that matters are not subject to the MMA when they can be resolved without reference to the local medical standard of care.

[23] With this in mind, we turn to Plaintiffs' specific allegations. Plaintiffs have alleged that Defendants negligently decided to purchase preservative-free MPA from NECC and also negligently failed to properly investigate and evaluate NECC's manufacturing procedures. The PCF asserts that these allegations are not covered by the MMA. We have little trouble concluding that the selection of preservative-free MPA—in particular, preservative-free MPA made by NECC—in favor of MPA with preservatives from other suppliers, were actions that involved the exercise of professional medical skill and judgment, *i.e.*, they qualify as the practice of medicine.

[24] We have observed that “[t]he practice of medicine may be said to consist in three things: First, in judging the nature, character, and symptoms of the disease; second, in determining the proper remedy for the disease; third, in giving or prescribing the application of the remedy to the disease.” *Fowler v. Norways Sanitorium*, 112 Ind. App. 347, 42 N.E.2d 415, 420 (Ind. Ct. App. 1942) (quoting *Underwood v. Scott*, 23 P. 942, 943 (Kan. 1890)) (superseded by statute on other grounds as recognized by *Sloan v. Metro. Health Council of Indpls., Inc.*, 516 N.E.2d 1104, 1106 (Ind. Ct. App. 1987)). We conclude that the allegations in this case clearly fall under the second aspect of the practice of medicine—selection of the proper remedy.

[25] As mentioned, MPA is injected into the lumbar spinal region of patients to relieve lower back pain. In Anonymous Clinic's case, the decision to administer preservative-free MPA was made by a physician, Dr. Kathryn Park, on the basis that preservatives can be neurotoxic. In OSMC's case, the decision

to purchase preservative-free MPA from NECC was made by its medical board, which consisted of Dr. Gene Grove and other physicians on OSMC's board. Physicians at SMC determined that the preservatives in question could cause arachnoiditis and damage the spinal cord. Selection of preservative-free MPA clearly involved the practice of medicine.

[26] We also conclude that the decision to purchase preservative-free MPA from NECC was an integral part of the remedy-selection process. For Anonymous Clinic, the decision to purchase from NECC was made by Dr. Park because NECC was, as far as she knew, the only supplier of preservative-free MPA; Anonymous Clinic had used other NECC products for years without problems; and NECC had a good reputation among other physicians. Put another way, Anonymous Clinic's medical decision to administer preservative-free MPA necessarily involved an evaluation of NECC's suitability as a supplier because it represented the only source known to the clinic. It is reasonable to assume that Dr. Park evaluated NECC's suitability in light of Anonymous Clinic's long-standing relationship with NECC and its reputation.

[27] In the case of OSMC, the decision to source the MPA from NECC was also the result of a long-standing relationship. In 2005, OSMC began purchasing betamethasone and hyaluronidase from NECC after Elkhart General Hospital began ordering compounded pharmaceuticals from NECC. As it happens, in addition to being on the medical board of OSMC, Dr. Grove was chairman of the pharmacy and therapeutics board at Elkhart General and had become aware that the Elkhart General medical staff had authorized NECC as a

supplier. The record reflects that OSMC's trust in Elkhart General's vetting process for pharmaceutical suppliers played a role in OSMC's subsequent authorization of NECC as a supplier. It is reasonable to assume that OSMC weighed the potential benefits of using preservative-free MPA from NECC against the potential risks and determined that purchasing the medication from NECC was a reasonable approach. This decision is obviously one that was made using professional judgment. In summary, pursuant to this court's holdings in *Harts* and *Pluard*, the line between MMA claims and non-MMA claims divides them into situations that can be understood without the assistance of expert testimony and those that cannot be, and the claims in this case fall into the latter category.⁴

⁴ Plaintiffs and OSMC bring our attention to two Indiana cases in which the court concluded that claims involving allegedly defective products provided by medical providers to patients were nonetheless subject to the MMA. See *St. Mary Med. Ctr., Inc. v. Casco*, 639 N.E.2d 312, 315 (Ind. Ct. App. 1994); and *Dove by Dove v. Ruff*, 558 N.E.2d 836 (Ind. Ct. App. 1990), *trans. denied*. It is worth noting, however, that in *Casco* and *Dove*, the plaintiffs were attempting to have their cases treated as products liability claims, while the PCF is attempting to have the claims here treated as general negligence. In the first situation, the question is whether the product was used as part of medical treatment and in the second, whether the actions of the health care providers cannot be understood by laypersons without expert testimony. While the holdings in *Casco* and *Dove* are certainly not inconsistent with our conclusion in this case, the issues resolved are different and the reasoning is not particularly helpful here.

Amici, who are health care providers and defendants in several cases involving defective MPA, note that the U.S. District Court for the District of Massachusetts ("the MDL Court") is currently overseeing multi-district litigation ("MDL") from jurisdictions nationwide involving steroids made by NECC in *In re: New England Compounding Pharmacy, Inc., Products Liability Litigation*, No. 1:13-md-02419 (D. Mass.). The MDL Court has dismissed claims regarding defective MPA under other states' laws. As with *Casco* and *Dove*, however, the plaintiffs' claims in those cases are all claims of products liability, unlike the negligence claims brought in this case. Consequently, the MDL Court's reasoning is no more helpful in this case than the courts' reasoning in *Casco* and *Dove*.

Finally, the *Amici* have compiled a table of cases in their brief from other jurisdictions addressing the question of whether the delivery of a product in the context of medical treatment can support a products liability claim or whether the claim is one of medical malpractice. The *Amici* note that twenty-three of twenty-five jurisdictions to consider the question have determined the claim before it to be one of

2. *Lack of Causal Connection*

[28] The PCF also contends that there is no causal connection shown in this case between the treatment of any individual patient and the exercise of medical judgment by any Defendants. The PCF’s argument is apparently that the decisions by Defendants to purchase preservative-free MPA from NECC, even if they did involve the exercise of medical judgment, occurred years before any of Plaintiffs received their treatments and were therefore made outside the provider-patient relationship. This position would seem to be based on the proposition that only decisions made by providers with specific patients in mind can be subject to the MMA. The language of the MMA is not so restrictive. “‘Health care’ means an act or treatment performed or furnished, or that should have been performed or furnished, by a health care provider for, to, or on behalf of a patient during the patient’s medical care, treatment, or confinement.” Ind. Code § 34-18-2-13. Nothing in the statutory language exempts decisions made by a health care provider regarding a general course of treatment for a particular class of patient. We conclude that general decisions that later affect particular patients are not exempt from the provisions of the MMA for an alleged lack of causal connection.

medical malpractice and not products liability. Suffice it to say that, as with *Casko, Dove*, and the decisions rendered by the MDL Court, all of the holdings rely on the concept that medical treatment is primarily a service and not a sale of products and do not address negligence theories of the type brought in this case.

B. Policy Arguments

[29] The PCF points out that, pursuant to the MMA, the total recovery in any malpractice action is \$1,250,000 per injury or death. Ind. Code § 34-18-14-3(a)(3). Moreover, the MMA caps the health care provider’s malpractice liability at \$250,000 per occurrence. Ind. Code § 34-18-14-3(b). Amounts in excess of this are payable from the PCF upon petition. Ind. Code §§ 34-18-14-3(c), -15-3. Also, subject to certain terms and conditions,

[i]f an annual aggregate [of \$750,000⁵] for a health care provider qualified under this article has been paid by or on behalf of the health care provider, all amounts that may subsequently become due and payable to a claimant arising out of an act of malpractice of the health care provider occurring during the year in which the annual aggregate was exhausted shall be paid from the patient’s compensation fund[.]

Ind. Code § 34-18-6-6(a).

[30] The PCF notes that OSMC faces approximately 100 individual claims while Anonymous Clinic faces approximately twelve individual claims. Assuming that Defendants are found liable for negligence following trial in all or many of these cases, the potential exposure could be significant. The PCF asserts that the General Assembly did not contemplate making the PCF the insurer of the safety of practically all products used in health care and suggests that a decision

⁵ It does not seem to be disputed that all Defendants have annual aggregates of \$750,000 each pursuant to Indiana Code section 34-18-4-1(1)(C)(i), which provides that “[i]f the health care provider is a health facility, the minimum annual aggregate insurance amount is as follows:… For health facilities with not more than one hundred (100) beds, three (3) times [\$250,000.]”

against it would subject it to strict liability in this and similar cases. The PCF further argues, essentially, that the allegedly increased potential liability it would face due to cases such as this would result in increased surcharges from healthcare providers to fund the PCF and jeopardize their ability to obtain affordable medical malpractice insurance.

[31] Defendants counter that a determination that this case is governed by the MMA does not thwart but, rather, furthers the legislative intent. Defendants argue that the MMA was designed as a comprehensive medical liability insurance arrangement that struck a balance between ensuring both that (1) the patients injured by professional negligence receive at least some compensation and (2) health care providers can continue to provide affordable health care.

Anonymous Clinic also argues that the PCF mischaracterizes Plaintiffs' claims as product liability and that the PCF would not be subject to strict liability for defective products used in medical care. OSMC also points out that a statutory mechanism, *i.e.*, Indiana Code section 34-18-5-4, already exists for increasing the surcharge on health care providers to maintain the PCF's liquidity in the event of large payouts. In a nutshell, Defendants argue that even if the claims at issue in this case were to drain the PCF entirely, it is not this court's place to ensure the PCF's liquidity; this court's only job is to decide if the claims before it are governed by the MMA. To the extent that there may be a public policy question with the MMA and the PCF, it is the General Assembly's decision to address the question.

[32] The Defendants and Plaintiffs have the much more defensible position here, namely that ensuring the PCF's continued liquidity is not this court's job. If, pursuant to the MMA's plain language and under current precedent, the Plaintiff's claims *should* be governed by the MMA, we should rule as such, whatever the consequences. *See, e.g., Ind. Dep't of Env'tl. Mgmt. v. Chem. Waste Mgmt., Inc.*, 643 N.E.2d 331, 338 (Ind. 1994) ("The General Assembly has decided to concentrate the State's energies on regulating commercial waste disposal facilities and it is not our job to second guess such decisions."). Even if we assume that the claims in this case will result in payouts sufficient to threaten the viability of the PCF (which is by no means a foregone conclusion), we are not free to ignore the law in an attempt to save it.

Conclusion

[33] There is really only one issue before the court in this case, whether alleged negligence by a medical provider in selecting a certain drug from a particular supplier are claims subject to the MMA or sound in general negligence. Indiana law stands for the proposition that if allegations cannot be understood by laypersons without resort to expert testimony, the claims are governed by the MMA. We conclude the claims in this case, *i.e.*, that Defendants were allegedly negligent in choosing to purchase and administer preservative-free MPA and in choosing NECC without proper vetting, are allegations that claim negligence in decisions that were made using professional expertise. Because we conclude that Plaintiffs' claims are governed by the provisions of the MMA,

we affirm the judgment of the trial courts and remand for further proceedings consistent with this opinion.

[34] We affirm and remand for further proceedings.

Pyle, J., and Altice, J., concur.