

# Medicolegal Considerations in the Psychiatric Management of Pregnancy and Postpartum Disorders

Allison R. Horan, MD, MSc, Dale E. McNiel, PhD, and Renée L. Binder, MD

Psychiatrists who treat mental disorders in pregnancy must navigate the risks associated with prescribing medication to pregnant and breastfeeding people alongside the risks associated with untreated mental illness. This article examines how U.S. courts have engaged with this complex landscape when tasked with evaluating allegations of clinician and pharmaceutical negligence in cases involving pharmacological management of perinatal mental health disorders (PMHDs). We begin first with a review of the legal theories that form the basis of negligence lawsuits related to PMHDs. We then explore cases of both pharmaceutical negligence (which are usually pursued under product liability claims) and professional negligence (i.e., malpractice), distinguishing how the courts' interpretation of liability has varied for errors of omission and errors of commission. We then provide an analysis of relevant themes in this area of case law with the goal of informing expert witnesses of considerations when called to opine upon questions related to negligence in the treatment of PMHDs.

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Perinatal mental health disorders (PMHD) refer to mental disorders that develop or are exacerbated during pregnancy or the postpartum period. They encompass conditions such as depression, anxiety, bipolar disorders, psychosis, and substance-use disorders. PMHD are highly prevalent, affecting approximately 20 percent of pregnancies in the United States annually, which translates to about 800,000 families affected each year.<sup>1,2</sup> In fact, PMHD are the most common complication of pregnancy in the United States.<sup>3</sup> In addition to their prevalence, morbidity and mortality associated with undertreated PMHD can be significant. Indeed, they are the most reported cause of preventable pregnancy-related deaths in the United States, typically as a result of suicide or sequelae of substance-use disorders.<sup>4</sup> The field of reproductive psychiatry was born out of the reality that

this population, despite its vastness, often has complex and nuanced treatment needs, which when unaddressed can have devastating consequences.

Management of PMHD by the medical community has evolved. The introduction of chlorpromazine, an antipsychotic, and lithium, a mood-stabilizer, in the mid-20th century revolutionized the treatment of severe mental health disorders. It was not until the 1980s and 1990s that research began to specifically focus on examining the use of psychiatric medications for the treatment and prevention of PMHD.

Research remains a challenge in this area, given the ethics concerns involved in conducting randomized controlled trials on pregnant people. Thus, the psychiatric community's understanding of the risks and benefits of prescribing pharmaceutical agents for PMHD is largely based on animal models, long-term observational studies (often based on registries), and clinical expertise. Evidence-based recommendations from professional organizations, such as the American Psychiatric Association (APA),<sup>5</sup> American College of Obstetricians and Gynecologists (ACOG),<sup>6</sup> and American Academy of Psychiatry and the Law (AAPL),<sup>7</sup> provide practice guidelines for providers

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Dr. Horan is a forensic psychiatrist, Dr. McNiel is a professor emeritus of clinical psychology, and Dr. Binder is a professor of psychiatry and Director, Psychiatry and the Law Program, University of California, San Francisco, San Francisco, CA. Address correspondence to: Allison R. Horan, MD, MSc. E-mail: allison@doctorhoran.com.

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who evaluate and treat people with PMHD. These guidelines emphasize the importance of routine screening, individualized treatment plans that incorporate psychotherapy and pharmacotherapy as appropriate, and thorough risk discussions to inform patient care.<sup>5-7</sup> Because of the complexity of balancing the risks of PMHD and their associated treatments, recent literature in this journal and similar scientific journals have emphasized the central importance of informed consent when treating people with PMHD.<sup>8-11</sup>

Professional guidelines related to the diagnosis and treatment of PMHD have influenced legislative policy at both national and state levels. For instance, at the national level, the Bringing Postpartum Depression Out of the Shadows Act was enacted as part of the 21st Century Cures Act in 2016 and authorized grants to states to develop programs for maternal depression screening and treatment.<sup>12</sup> At the state level, for example, California Assembly Bill 1936 was signed by the governor in 2024 and required insurers to cover maternal mental health screenings to improve identification of PMHD and linkage to appropriate treatment.<sup>13</sup>

Apprehension still exists for many, however, when prescribing psychiatric medications to pregnant and lactating people. Indeed, as recently as July 2025, the U.S. Food and Drug Administration (FDA) convened a public expert panel to review the use and safety of selective serotonin reuptake inhibitors (SSRIs) during pregnancy, which drew attention and scrutiny from the medical community.<sup>14-16</sup> Prescribing psychiatric medication during pregnancy presents a complex risk situation that requires careful consideration: on the one hand, there can be significant risks associated with the use of psychotropic medications during pregnancy and lactation that increase the risk of developmental defects in offspring. Thalidomide, a sedative medication that was marketed as safe for pregnant people with morning sickness in the late 1950s and early 1960s is a salient example of the high stakes involved with prescribing in pregnancy. It is estimated that somewhere between 10,000 and 20,000 newborns who were exposed to thalidomide *in utero* were born with serious birth defects.<sup>17</sup> On the other hand, failing to prescribe necessary psychiatric medications can lead to mental health deterioration in the mother, with dire maternal and neonatal consequences, including maternal suicide and infanticide. The cases of Andrea Yates and Lindsay Clancy highlight the media attention and public scrutiny associated with negative outcomes related to PMHDs. Ms. Yates,

who drowned her five children in Texas in 2001 while experiencing postpartum psychosis, had been advised by her psychiatrist to discontinue her anti-psychotic medication shortly before the death of her children.<sup>18</sup> Although malpractice was not formally litigated, the defense argued that Ms. Yates's psychiatrist had failed to adequately manage her illness.<sup>18</sup> More recently, Ms. Clancy, a Massachusetts nurse who is alleged to have killed her three children before attempting suicide in early 2023, has pled not guilty by reason of insanity (NGRI) to murder charges based on the assertion that she was experiencing postpartum mental illness at the time of the alleged murders.<sup>19</sup> Her upcoming trial has garnered much public scrutiny over whether the multiple providers who prescribed her psychiatric medications in the months leading to the incident were negligent in their prescribing practices.<sup>19</sup>

The reality is there is no escaping risk when treating PMHD. There are often significant risks associated with intervention and significant risks associated with nonintervention, although patients may overestimate the risks of intervention with medication and underestimate the risks of nonintervention.<sup>20</sup> This article focuses on how U.S. courts have engaged with this complex landscape when tasked with evaluating allegations of clinician and pharmaceutical negligence in cases involving pharmacological management of PMHD.

We begin first with a review of the legal theories that form the basis of negligence lawsuits related to PMHD. We then explore cases of both pharmaceutical negligence (which are usually pursued under the legal umbrella of product liability claims) and professional negligence (i.e., malpractice), distinguishing how the courts' interpretation of liability varies for errors of omission and errors of commission. We selected cases based on a legal literature review, utilizing LexisNexis to identify and analyze relevant case law. Key terms (such as psychiatrist, malpractice, postpartum depression, and postpartum psychosis) were used in Boolean searches to capture judicial opinions pertaining to negligence in psychiatric treatment of PMHD. Using this literature review, we then provide an analysis of relevant themes in this area of case law with the goal of informing expert witnesses of relevant considerations when called upon to opine on questions related to negligence in the treatment of PMHD.

### Medicolegal Foundations of Negligence

Negligence is a foundational concept in tort law, defined as the failure to exercise the level of care a

reasonably prudent person would exercise under similar circumstances, resulting in harm to another.<sup>21</sup> It underpins both medical malpractice and product liability claims, but its application varies depending on context. In cases involving PMHD, negligence may arise from the actions of a health care provider or from pharmaceutical companies responsible for the development and distribution of medications used to treat PMHD.

Medical malpractice occurs when health care providers fail to meet their professional duty of care, resulting in harm to patients. It is defined, legally, based on four variables: a duty of care; a dereliction of that duty; damages resulting from dereliction of duty; and direct causation between the dereliction and the damages.<sup>22</sup> For pregnant or postpartum people with PMHD, malpractice can theoretically result from prescribing contraindicated treatment, failing to recommend indicated treatment, neglecting to monitor treatment adequately, neglecting to perform an adequate risk assessment, or failing to address the risks of untreated mental illness. Health care providers are required to obtain informed consent by discussing the potential risks and benefits of treatments. This is particularly important during pregnancy, where the risks of untreated mental illness must be weighed against the potential effects of medication on the patient and fetus. A failure to adequately inform a patient of such risks can lead to allegations of malpractice if harm does occur. In malpractice cases, the burden of proof is on the plaintiff, who is tasked with demonstrating that a provider's actions deviated from the standard of care and directly caused harm.<sup>22</sup>

Negligence claims against pharmaceutical companies, on the other hand, typically occur under product liability law, which focuses on the safety of medications and the adequacy of warnings about their risks.<sup>23</sup> Such claims often center around allegations of a pharmaceutical company's failure of duty to warn or the strict liability doctrine.

Duty to warn refers to the obligation pharmaceutical companies have to disclose known or reasonably knowable risks associated with their products to consumers.<sup>24</sup> This duty is generally discharged *via* the learned intermediary doctrine, which plays a pivotal role in shaping the interpretation of duty and dereliction of duty for pharmaceutical manufacturers.<sup>24</sup> This doctrine holds that a manufacturer fulfills its duty to warn by providing prescribers with adequate information

about the risks of its products. If manufacturers do this, then they have discharged their duty, and it becomes the prescriber's responsibility to relay the risk information to patients. A pharmaceutical company's failure to warn about legitimate and scientifically known risks on its packet inserts, such as teratogenicity of a medication, can open the company to liability if harm occurs. Multidistrict litigation cases (MDL) can be brought against manufacturers of psychiatric medications, alleging a failure of duty to warn with resulting congenital defects in newborns.

The legal doctrine of strict liability, on the other hand, holds that manufacturers are responsible for harm caused by their products, regardless of whether the manufacturer was negligent in warning about known risk or not.<sup>24</sup> This principle shifts the focus from the conduct of the manufacturer to the condition of the product itself. In cases that employ this doctrine, plaintiffs must demonstrate that a medication was defective in design, manufacturing, or labeling and that this defect caused harm.<sup>25</sup> Similar to malpractice lawsuits, product liability cases are constrained by the legal requirement of establishing causation. Plaintiffs must demonstrate that their harm would not have occurred but for the provider's actions or the pharmaceutical company's negligence in strict liability or duty to warn (see Table 1 for summary).

## Pharmaceutical Negligence

There are ample cases brought against pharmaceutical companies alleging negligence related to psychiatric medications prescribed for PMHD. The majority of these cases involve allegations that manufacturers failed to adequately warn about the teratogenic risks associated with a psychiatric medication; often, these cases involve MDL. The outcomes of these cases have varied, with some resulting in settlements and others resulting in judgements for the defendants.

### Examples of Settlements

An example of a failure to warn case that resulted in settlement is *Kiker v. SmithKline Beecham Corp.*<sup>26</sup> In this case, the plaintiff, Katheryn Kiker, took the antidepressant Paxil (paroxetine) while pregnant and gave birth to a child in 2001 with congenital abnormalities, including severe heart defects.<sup>26</sup> Paxil is manufactured by SmithKline Beecham Corporation, also known as GlaxoSmithKline (GSK).<sup>27</sup> Ms. Kiker alleged that GSK failed to adequately warn prescribers

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**Table 1** Establishing Negligence in Medical Malpractice and Product Liability

	Medical Malpractice	Product Liability
<b>Duty of Care</b>	Was there a physician-patient relationship? Did the physician have a professional obligation to provide care?	Did the manufacturer owe a duty to warn? Was the medication used as intended?
<b>Dereliction of Duty</b>	Did the physician's actions (or inactions) deviate from the standard of care? Were clinical guidelines or best practices followed? Was informed consent obtained and documented?	Did the manufacturer provide sufficient warnings about the medication's known risks at the time of prescribing to discharge its duty to warn? Was there a defect in design, production, or marketing?
<b>Direct Causation</b>	Did the physician's actions or inactions directly cause harm? Could other factors (e.g., patient comorbidities, external events) have contributed to the harm?	Did the medication's defect or the company's failure to warn directly cause harm? Were there intervening factors that might have led to the harm?
<b>Damages</b>	What specific physical, emotional, and financial harms resulted from the alleged negligence? Are the damages clearly linked to the negligent actions or omissions?	
<b>Defense Strategies</b>	Emphasizing adherence to standard of care Disputing causation Citing shared decision-making with the patient	Invoking the learned intermediary doctrine Disputing causation Asserting compliance with industry standards
<b>Standard of Proof</b>	Preponderance of evidence	

about teratogenic risks associated with Paxil. In a jury trial, GSK was found to have been negligent in their failure to warn, resulting in a reported \$2.5 million award to the family.<sup>26,27</sup> GSK subsequently agreed to pay over \$1 billion to settle more than 800 additional cases.<sup>28</sup> Ms. Kiker's counsel demonstrated that GSK's internal pregnancy adverse event reporting system had received "hundreds of adverse events related to Paxil exposure during pregnancy," which led to GSK issuing a warning label regarding teratogenicity in 2006 (Ref. 26, p 18). Ms. Kiker additionally alleged that, despite this finding, GSK had not conducted follow-up testing to further explore the teratogenic potential of Paxil.<sup>26</sup> GSK argued that it had added teratogenic information to the Paxil warning label as soon as it could. Subsequent research failed to robustly support cardiac teratogenicity with paroxetine use in pregnancy.<sup>29,30</sup> Nonetheless, during a jury trial in 2015, the jury concluded that GSK had been negligent in carrying out its duty to warn prescribers.<sup>26,31</sup>

Similarly, in *B.F. v. Abbott Labs., Inc.*,<sup>32</sup> the plaintiffs, two parents and their minor son B.F., brought a product liability action against Abbott Labs after their son was born with a number of congenital abnormalities, including a neural tube defect (spina bifida).<sup>32</sup> The parents alleged that the child's neural tube defect was caused by his mother's use of the mood-stabilizer, Depakote (valproic acid), during her pregnancy, which was prescribed to treat bipolar disorder, and that Abbott Labs, which manufactures Depakote, failed to adequately warn the mother's

prescriber of the risk of birth defects from Depakote.<sup>32</sup> Although Abbott's warning label for Depakote at the time included information on the risk of neural tube defects, the plaintiff's expert opined the label was inadequate for a number of reasons, including: the lack of advisement on the importance of contraceptive use while taking Depakote; that Depakote should only be used as a "last line" treatment in women of childbearing age; and the misleading risk of neural tube defects cited in the advisement as one to two percent, when studies had reported the rates of neural tube defects were as high as 3.8 percent.<sup>32</sup> The court, agreeing that Abbott had failed to adequately warn prescribers, denied the defense's motion for summary judgment. The case was allowed to proceed to trial and was reportedly settled out of court.<sup>33</sup>

### Examples of Defenses

Conversely, there are ample cases where pharmaceutical companies have successfully defended against negligence claims, usually by invoking either the learned intermediary doctrine or relying on the inherent challenges involved in establishing causation. For example, in *Swanson v. Abbott Laboratories*,<sup>34</sup> the plaintiff, Sharon Swanson, alleged that her son's birth defects were caused by her ingestion of Depakote during pregnancy.<sup>34</sup> Similar to *B.F. v. Abbott Laboratories*, this case also centered around a plaintiff who took Depakote to treat bipolar disorder, in this case, during the second and third trimesters of her pregnancy.

Ms. Swanson's son was later diagnosed with developmental delays, including autism spectrum disorder (ASD). Ms. Swanson alleged Abbott's warning label in 1996 was insufficient because it did not include a warning that the risk from *in utero* exposure to Depakote could extend beyond the first trimester and did not include that Depakote could increase the risk of developmental delay, including ASD. The defense countered that the warning label was in line with the scientific literature available at the time. The defense argued that insufficient scientific evidence existed to demonstrate direct causation between Depakote use and developmental disorders like ASD. The court agreed, concluding there was no clear evidence the Food and Drug Administration (FDA) would have approved a change to the Depakote warning label based on available scientific research. The court granted the defendant's motion for summary judgment.<sup>34</sup>

Another example of successful defense can be seen in the MDL *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*,<sup>35</sup> where plaintiffs claimed Pfizer did not adequately warn about teratogenic risks associated with the antidepressant Zoloft.<sup>35</sup> The court ruled in favor of the manufacturer here too, citing insufficient evidence to establish causation between the drug and alleged birth defects.

A final example of a successful defense mounted by a pharmaceutical company is seen in the case of *Fisher v. Abbott Labs*.<sup>36</sup> In this failure to warn case, the plaintiff alleged that Abbott Labs failed to warn a prescriber about teratogenicity. Jinna Miller took Depakote prescribed by her psychiatrist while pregnant. She gave birth to a newborn, Julian Fisher, with birth defects allegedly caused by *in utero* Depakote exposure. The psychiatrist in this case testified that he was aware of the teratogenic risks of Depakote exposure in pregnancy, warned Ms. Miller of these risks, and had tried other medication options to treat her bipolar disorder before prescribing Depakote as a "last resort."<sup>36</sup> Importantly, the psychiatrist testified that he stood by his decision to prescribe Depakote and was aware of the risks as listed on the manufacturer's label. The psychiatrist's testimony in this case allowed the defense to invoke the learned intermediary doctrine. The court here reviewed California's failure to warn legal standard, which dictates that evidence must be presented that a stronger or altered warning label would have changed the prescribing physician's conduct. In this case, the court concluded that the plaintiff produced no evidence that

stronger warnings about Depakote's risk of birth defects would have altered the psychiatrist's recommendation to prescribe the medication. The court granted Abbott Lab's motion for summary judgment and dismissed the plaintiff's claims.<sup>36</sup>

## Prescriber Negligence

Although pharmaceutical negligence lawsuits are a well established area of law, with defined strategies that both plaintiffs and defendants tend to rely on, malpractice suits targeting prescribing decisions in the treatment of PMHD remain rare, at least at the level of published appellate decisions. The scarcity of these cases may reflect inherent challenges with pursuing malpractice complaints in this area, including difficulties in establishing causation and the shared responsibility between prescribers and pharmaceutical companies, with much more precedence for lawsuits targeting pharmaceutical companies. In this section, we explore the limited case law related to cases alleging negligence in prescribing for PMHD. We will do this by distinguishing lawsuits related to acts of omission versus lawsuits related to acts of commission.

## Acts of Omission

Acts of omission refer to failures to act when a duty exists. In the context of treating PMHDs, omissions often involve failures to prescribe medication or failure to continue treatment without adequate justification. These lapses can have catastrophic consequences for both the mother and her child.

One case in which a psychiatrist's act of omission has been evaluated by the courts is *Walsh v. Borczon*.<sup>37</sup> In this case, Catherine Walsh, a patient in a voluntary outpatient clinic, learned that she was pregnant while her psychiatrist was out of town. She claimed she was advised by a covering physician to discontinue her psychiatric medication until she could consult with her primary psychiatrist. After discontinuing her medication in the context of her pregnancy, her mental disorder worsened, and she developed delusions "that there was something alien in her body that focused on her fetus" (Ref. 37, p 2). Ms. Walsh alleged that the abrupt cessation of her psychiatric medication led to psychiatric decompensation and her decision to have an abortion. She claimed to have suffered significant psychological harm because of this decision, based in part on her religious views. The court dismissed the case, ruling that the physician's act of omission did

not rise to the level of gross negligence. The Superior Court of Pennsylvania agreed with the trial court that the facts alleged by Ms. Walsh did not allege “a form of negligence where the facts support substantially more than ordinary carelessness, inadvertence, laxity, or indifference” (Ref. 37, p 20).

The court’s dismissal in *Walsh* reflects the high threshold for proving negligence in acts of omission, particularly in psychiatric care during pregnancy. The court determined that the covering physician’s advice to discontinue psychiatric medication until consultation with the primary psychiatrist did not rise to the level of gross negligence. It is worth noting that this legal standard contrasts sharply with professional guidelines for managing PMHD, which underscore the significant risks associated with abrupt discontinuation of psychiatric medications. For instance, clinical guidelines from the APA emphasize the potential for significant decompensation in pregnant individuals with abrupt cessation of treatment, including heightened risks of relapse, self-harm, harm to others, and adverse neonatal outcomes.<sup>5,38</sup>

### Acts of Commission

Acts of commission involve active decisions that result in harm. In the treatment of PMHD, these can include cases in which a provider prescribes teratogenic medications without proper risk assessment or without obtaining informed consent. To the best of our knowledge, cases have not been published on Lexis Nexus regarding malpractice lawsuits against individual prescribers or the health care systems seeking damages for acts of commission in PMHD prescribing. This absence is notable.

There are, however, lawsuits against pharmaceutical companies that have alluded to litigation against psychiatrists alleging negligence. For instance, *Muhammad v. Abbott Lab’s, Inc.*<sup>39</sup> references a prior case brought against prescribers at Northwestern Memorial Hospital (*Muhammad v. Northwestern Memorial Hospital*<sup>40</sup>). In this earlier case, the plaintiffs, Charles and Angie Muhammad, filed a medical malpractice claim alleging Mrs. Muhammad’s psychiatrists, despite having knowledge of the teratogenic risks of Depakote use during pregnancy, deviated from the standard of care by prescribing her this medication to treat schizoaffective disorder (SAD) after there was evidence she might become pregnant.<sup>39,40</sup> Based on court documents, prior to prescribing Depakote, the psychiatrists reviewed the risk of birth defects with Mrs. Muhammad, who was

taking birth control at the time and had indicated no desire to conceive. She subsequently became pregnant while taking Depakote and gave birth to a child with spina bifida. Both treating psychiatrists testified they were aware of the teratogenic risks of Depakote, including the risk of spina bifida, and that they had evaluated these risks against the risks of decompensation of Mrs. Muhammad’s SAD. They also described weighing these risks against the effectiveness of Depakote in controlling her symptoms as compared with other medications she had tried. Nonetheless, a jury found in favor of the Muhammads, awarding them an \$18.5 million verdict.<sup>40</sup> The jury’s verdict suggests that they felt either the prescribers had not adequately justified their recommendation to continue Depakote or insufficiently explained this risk scenario to the patient.

The *Muhammad* case gives reproductive psychiatrists rare insight into how the legal system evaluates medical negligence based on alleged acts of commission, particularly when it comes to prescribing medications during pregnancy. It highlights the need for psychiatrists to carefully document their clinical reasoning, not only regarding the medications they recommend, but especially when prescribing medications with well known teratogenic risks, including their reasoning behind why other medications were considered, but not recommended. *Muhammad* also underscores the importance of informed consent and continual reevaluation of treatment decisions as clinical contexts evolve.

### Trends in Negligence Interpretation

The cases discussed in this article reveal key trends in how courts have interpreted negligence in the pharmaceutical management of PMHD. These trends, which span pharmaceutical liability and prescriber malpractice, provide insights for both forensic psychiatrists, who may find themselves involved in similar cases as expert witnesses, and clinical psychiatrists, who care for patients with PMHD and wish to avoid malpractice allegations.

One such theme is the complexity of establishing causation. Of the four criteria involved in legally establishing negligence, establishing direct causation is perhaps most challenging in cases involving psychiatric care during the peripartum and postpartum periods. Courts require a clear demonstration that the harm would not have occurred but for the defendant’s actions or omissions, whether those involve a

prescriber's decisions or a pharmaceutical company's failure to warn. The nature of both fetal development and negative outcomes involving PMHD is that they are inherently multifactorial, shaped by biological, psychological, epigenetic, environmental, and social variables, which makes direct causation an elusively high bar to reach. A clear example of this is the *Swanson* decision, where the court granted summary judgment for the defendant because of the plaintiff's inability to causally link maternal Depakote ingestion to her child's diagnosis of ASD. There are multiple examples of this pattern of courts' issuing summary judgments in cases involving pharmaceutical companies because of insufficient evidence of direct causation.<sup>41-43</sup> For forensic psychiatrists acting as experts, this trend underscores the importance of not only evaluating causation within the full context of relevant scientific certainty and competing contributory factors but also offering clear and direct testimony about the inherent risk and uncertainties involved in treating individuals with PMHD.

Another trend across both pharmaceutical and prescriber-focused litigation is that allegations of negligence related to acts of commission may be more often successful for plaintiffs (often seeming to result in out-of-court settlements) than allegations of negligent acts of omission. This may be because acts of commission are more tangible and easier to link to adverse outcomes, making them a more common focus of litigation. Conversely, acts of omission seem to face a higher bar for proving negligence. This is illustrated in comparing the outcomes in *Walsh* with the outcomes in *Muhammad*. In *Walsh*, where the focus was on a physician's recommendation to discontinue treatment in pregnancy (and, also importantly, where the alleged harm was psychological and not physical), the court dismissed the plaintiff's claims of gross negligence. In *Muhammad*, despite the prescribers' testimony of their awareness of the teratogenic risks involved in prescribing Depakote and communication of those risks to the plaintiff, the jury found the prescribers were negligent in their recommendation to continue this medication. In *Muhammad*, in contrast to *Walsh*, there was a clear action taken (writing a prescription) and a clear, physical result (a child with a major congenital malformation) with an evidence-based nexus between the two. For forensic psychiatrists asked to opine on alleged negligence, this trend highlights the distinction between errors of omission and errors of commission. Although

acts of commission may be more apparent, acts of omission can be equally harmful, particularly in the context of PMHD, where untreated mental illness can have devastating consequences, including suicide and infanticide. Expert testimony should address the relative risks of both action and inaction, ensuring that courts understand the full scope of potential negligence.

### Navigating Tension within the Legal System

The medicolegal landscape of psychopharmacological management of PMHD is complex. Pharmaceutical companies are obligated to adequately warn about risks of their medications and navigate how to convey such warnings when the scientific literature is limited. Clinicians are obligated to clearly and concisely convey both known risks to patients as well as assist them in navigating decision-making when scientific information is limited or the risks are high. Patients face the task of making medical decisions when their own health needs and the needs of their fetus or newborn are in tension. The legal system is tasked with assessing the locus of blame when things go awry. The above examination of case law illuminates that these four groups are under different pressures. Courts are responsible for using legal standards to assess whether a defendant's actions represented negligence, often assessed retrospectively with the benefit of hindsight. By contrast, clinical guidelines emphasize individualized, forward-looking decision-making, requiring prescribers to balance competing risks and benefits in real time. This divergence is further complicated by the differing ways in which pharmaceutical companies and clinicians discharge their duties, which highlight the unique challenges faced by prescribers in navigating these intersecting responsibilities. Forensic psychiatrist experts are, at times, asked to assist legal proceedings by providing opinions as to how these factors affect a particular allegation of negligence (see Table 2).

As discussed above, pharmaceutical companies primarily fulfill their duty to warn through standardized mechanisms, such as warning labels and prescribing information, which are designed to communicate risks broadly and systematically. Clinicians are tasked with translating these general warnings into nuanced, patient-specific conversations, often involving multiple variables: determining which risks to prioritize; how to present them in a way that fosters understanding; and how to strike a balance between overemphasizing risks that might dissuade necessary treatment

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**Table 2** Best Practices for Expert Witnesses Evaluating Psychiatric Malpractice

Key Area for Evaluation	Questions to Consider
<b>Diagnosis</b>	Was the diagnosis reasonable based on available information? Was the diagnosis supported by thorough assessment? Were appropriate attempts made to gather information required for diagnostic clarification?
<b>Informed Consent</b>	Did the patient have the capacity to consent to treatment? If not, were appropriate steps taken to utilize a surrogate decision-maker? Was the patient adequately informed of treatment risks and benefits?
<b>Rationale for Treatment</b>	Did the prescriber provide the rationale for the proposed treatment? Were treatment recommendations justified for the clinical situation?
<b>Causation</b>	Was the harm directly attributable to the prescriber's actions or inactions? Were there other variables or comorbidities that may have contributed to harm?
<b>Treatment Decisions</b>	Were there errors of omission (i.e., withholding treatment, stopping treatment, or failures to act) that contributed to alleged harm? Did active decisions (e.g., prescribing teratogenic medications) deviate from standard of care, and if they did, was this justified by the clinical scenario?
<b>Adherence to Standards of Care</b>	Were treatment decisions consistent with professional guidelines? Were deviations from standards of care justified by the patient's unique circumstances?
<b>Documentation</b>	Was the clinical decision-making process clearly recorded?

and underemphasizing risks that could lead to harm. This tension, codified legally *via* the learned intermediary doctrine, places significant responsibility on prescribers, who must integrate often dense and lengthy pharmaceutical warnings into clear, actionable guidance for their patients. Although pharmaceutical companies are scrutinized for the adequacy of their warnings, prescribers must navigate the additional layer of ensuring that these warnings are contextualized within the patient's clinical scenario and effectively communicated.

For forensic psychiatrists asked to opine on malpractice cases, the dual layer of responsibility underscores the importance of evaluating how prescribers operationalize risk information provided by pharmaceutical companies. They need to opine whether or not the prescriber engaged in a balanced, patient-centered discussion that addressed both the risks of treatment and the risks of nontreatment and if the decision-making process was adequately documented. These questions lie at the heart of bridging the gap between legal expectations, manufacturer duties, and the realities of clinical care.

### Conclusion

The cases discussed in this article illuminate the necessary components for attributing harm in negligence cases involving PMHD. Whether targeting pharmaceutical companies or prescribers, plaintiffs

must establish that harm resulted directly from the defendant's actions or omissions, a requirement that is particularly challenging in cases involving PMHD because of the multifactorial nature of outcomes. Establishing causation is often the most formidable hurdle, as both maternal and neonatal outcomes are shaped by a complex interplay of biological, psychological, environmental, and social factors. Successful cases often hinge on clear, undisputed causal links, where specific actions, such as prescribing a teratogenic medication, were demonstrably tied to a negative outcome. Logically, establishing causality becomes more challenging with less certain scientific literature and the more time that elapses between an alleged negligent decision and a purported harm, as was seen in *Swanson*.

For forensic psychiatrists evaluating such cases, it is crucial to avoid the logical pitfalls of overemphasizing acts of commission while underestimating the potential harm caused by omissions. The legal system often prioritizes tangible actions, such as prescribing medications, because they offer a more straightforward path to causation. As professional guidelines emphasize, failures to act, such as failure to diagnose or failure to adequately treat PMHDs, can lead to equally significant harm, including suicide, infanticide, and poor neonatal outcomes.

Expert evaluations must consider both types of errors, weighing the risks of action against inaction in light of the specific circumstances of each case.

Thorough analysis of causation requires not only assessing scientific evidence but also recognizing the limits of that evidence and clearly communicating these uncertainties to the court. Ultimately, expert witnesses play a pivotal role in bridging the gap between the intricacies of clinical decision-making, the incompleteness of the scientific literature on the risks involved in prescribing for PMHD, and the legal system’s search for accountability in the tragic cases in which outcomes are poor.

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