avoid causing further harm. Physicians who are treating or are in the position of reviewing cases for forensic purposes should be familiar with contemporary terminology, language, and policy. Forensic experts should also be aware of the medical standard of care as it changes. This case also raises the point that, as court rulings and claims for medically necessary treatments align with advancing medical science, public dollars for appropriate care may need to be identified if not readily available.

Disclosures of financial or other potential conflicts of interest: None.

Determining Liability When a Patient Develops Tardive Dyskinesia

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Despite Concerns about Negligent Misrepresentation in the Manufacturer's Marketing, an Antipsychotic's FDA Class Label Warning Regarding Tardive Dyskinesia Was Adequate

DOI:10.29158/JAAPL.3899L2-19

In *Johnson & Johnson, Inc. v. Fortenberry*, 234 So.3d 381 (Miss. 2017), the Supreme Court of Mississippi examined a trial court's ruling in a product liability suit. Action was brought against the manufacturer of the second-generation antipsychotic Risperdal after a patient developed tardive dyskinesia. The trial court's jury awarded the patient $1.95 million for failure to provide an adequate warning as well as negligent misrepresentation of tardive dyskinesia risk. On appeal, the court reversed and found that the class label warning provided an adequate warning. At the same time, the court was also in support of $650,000 in economic damages. The court also noted that the negligent misrepresentation claim was outside of the scope of the state's product liability law and that jury instructions for this claim were improper. The trial court's ruling was reversed and remanded.

Facts of the Case

Louise Taylor was psychiatrically hospitalized for a psychotic episode in 1998. Her outpatient psychiatrist, Dr. Richard Rhoden, initially continued her hospital-initiated, first-generation antipsychotic, haloperidol. Dr. Rhoden later prescribed quetiapine, a second-generation antipsychotic. After a suicide attempt by an overdose with quetiapine, Dr. Rhoden prescribed Risperdal, another second-generation antipsychotic. Per Dr. Rhoden, Ms. Taylor and her daughter received information regarding possible side effects of Risperdal, including tardive dyskinesia (TD), which is a potentially irreversible, involuntary movement disorder linked to antipsychotic use. Like all other antipsychotic medications on the market, Risperdal had a Food and Drug Administration (FDA) class label warning for tardive dyskinesia.

Ms. Taylor was prescribed Risperdal from March 1999 until January 2001. At a January 2001 visit with Dr. Rhoden, Ms. Taylor was noted to have developed oral dyskinesia. Dr. Rhoden consequently decreased Risperdal and restarted quetiapine. In February 2001, Ms. Taylor was reported to have developed tardive dyskinesia.

Ms. Taylor filed a complaint (through her conservator and niece, Brenda Fortenberry) against Ortho-McNeil Janssen Pharmaceuticals, the manufacturer and distributor of Risperdal, as well as its parent company, Johnson & Johnson, Inc., claiming that the medication resulted in the development of tardive dyskinesia. (Ms. Taylor named Dr. Rhoden in the lawsuit, but that claim settled out of court.) The trial court jury found in Ms. Taylor's favor, noting Janssen's "failure to provide adequate warnings/instructions" and Janssen's "negligent marketing/misrepresentation" (*Fortenberry*, p 386). Ms. Taylor was awarded $650,000 in economic damages and $1.3 million in noneconomic damages.

Janssen appealed the decision on several grounds. Janssen argued that Ms. Taylor's failure-to-warn claim did not present evidence suggesting that the Risperdal warning was inadequate. Janssen also argued that they were entitled to judgment due to insufficient evidence on Ms. Taylor's negligent misrepresentation claim. Janssen argued that there was no proof that Dr. Rhoden, in prescribing Risperdal to

Ms. Taylor, received or relied on misrepresentation from Janssen. Janssen further argued that the jury instructions regarding the claim of negligent misrepresentation were improper.

Ruling and Reasoning

As to Ms. Taylor's failure-to-warn claim, the Supreme Court of Mississippi reversed and rendered judgment in favor of Janssen. The court stated that Ms. Taylor's attempt to prove her failure to warn claim through Janssen's marketing materials went beyond the statutory scope of the 1993 Mississippi Products Liability Act (MPLA), in which the "only pertinent question is whether the prescription drug label contained adequate warnings or instructions" (Miss. Code Ann § 11-1-63(c)(i)-(ii) (2014)). The court found that Dr. Rhoden, the learned intermediary, was warned of the danger of tardive dyskinesia "in no uncertain terms" via the Risperdal package label and that the warning was sufficiently adequate (*Fortenberry*, p 393).

The court found that a jury question did exist, however, as to whether there was a "material misrepresentation or omission" in the marketing materials provided to Dr. Rhoden (*Fortenberry*, p 399). The court considered whether the Janssen marketing materials misrepresented Risperdal as having a lower tardive dyskinesia risk than other medications. The court reviewed expert testimony from an academic psychiatrist and a neurologist specializing in movement disorders. Testimony reflected that the meaning of "atypical" had shifted over time with the marketing of second-generation antipsychotics to a point where there was "no consensus definition of the term" (*Fortenberry*, p 396). The court held that a jury question did exist as to whether Dr. Rhoden relied on Janssen's alleged misrepresentation in prescribing Risperdal, and whether this reliance resulted in Ms. Taylor's damages. The court reversed and remanded for a new trial on grounds raised by Janssen regarding improper jury instructions on several matters, including a claim of negligent marketing. Regardless, the court held that negligent marketing and negligent advertising were both outside the scope of a misrepresentation claim.

Dissent

In contrast to the court's decision, the dissent, while concurring in part regarding the reversal and remand of the negligent misrepresentation claim, argued against the central holding of the majority opinion. The dissent stated that Risperdal's FDA class label was inadequate to warn Dr. Rhoden of the severity of the risk of tardive dyskinesia. The dissent cited "substantial evidence" of the inadequacy of the FDA warning label laid out at trial, including a psychiatrist's expert testimony that the class warning was "cookie cutter" and "meaningless." The dissent also noted that if adequate warnings were provided to the physician, the learned intermediary doctrine could insulate the pharmaceutical company from liability.

The dissent said that the FDA warning's adequacy should be determined by a jury, and that "reasonable and fair-minded jurors" had heard the psychiatrist's expert testimony and concluded that the warning was inadequate to warn Dr. Rhoden of Risperdal's risk of tardive dyskinesia (*Fortenberry*, p 410). In addition, the dissent stated that a jury could have concluded that Janssen's "aggressive marketing and overpromotion" could have rendered the FDA warning inadequate by failing to adequately inform Dr. Rhoden (*Fortenberry*, p 410). The dissent argued that the jury's verdict should stand.

Discussion

This case illustrates differing legal analyses of two theories of liability against the manufacturer of a second-generation antipsychotic related to tardive dyskinesia. While the precedent in this case is only applicable in Mississippi, the court's holding that the class label warning regarding tardive dyskinesia was an adequate warning could potentially preclude liability against the manufacturers of antipsychotics under a similar theory of liability. The court interpreted the applicable state statute as limiting the scope of the claim to the product label despite the label's lack of information regarding the risk of tardive dyskinesia in Risperdal relative to other antipsychotic medications.

In contrast, the court's holding that a valid jury question existed regarding the negligent misrepresentation of the risk of tardive dyskinesia in the marketing of Risperdal leaves open the possibility of liability for the manufacturers of second-generation antipsychotics. In its analysis, the court highlighted guidance from the FDA that cautioned against presenting Risperdal as superior to other antipsychotic medication in terms of safety or efficacy. Despite this, the court also ruled that the economic damages initially awarded by the trial court were appropriate.

Because Dr. Rhoden settled the action against him out of court, it is still an open question to what extent and under what circumstances the prescribing psychiatrist is liable when a patient develops tardive dyskinesia. Psychiatrists should be aware that, via the learned intermediary doctrine, the duty to warn patients about the risks, benefits, and side effects of medications still falls to the prescribing physician in obtaining informed consent. Psychiatrists should be mindful of how they explain the risks and benefits of a medication to a patient and attempt to avoid a general approach when explaining the risks and benefits of antipsychotics. The prescribing psychiatrist remains in the position to give warnings and provide an informed opinion as to whether a specific drug is appropriate.

Disclosures of financial or other potential conflicts of interest: None.

Community Supervision of Probationer

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Department of Corrections' Supervision of a Probationer Who Committed Murder After Prison Release Did Not Constitute Gross Negligence

DOI:10.29158/JAAPL.003900-19

In *Harper v. State,* 429 P.3d 1071 (Wash. 2018), the Washington Supreme Court considered whether the Washington Department of Corrections' (DOC) supervision of probationer Scottye Miller constituted gross negligence and whether the DOC was liable in failing to prevent Mr. Miller from murdering his girlfriend, Tricia Patricelli. Specifically, the court explored if the appeals court had erred in focusing too narrowly on what the DOC had neglected to do without considering what the DOC had done to prevent Mr. Miller and Ms. Patricelli from reestablishing contact while Mr. Miller was on supervised probation.

Facts of the Case

On October 30, 2012, Mr. Miller murdered his girlfriend, Ms. Patricelli, 15 days after being released from prison. During that time, Mr. Miller was being actively supervised by the DOC. Prior to his release, it was also known by Ms. Patricelli, her family, her friends, and the DOC that Ms. Patricelli was physically abused by Mr. Miller in the past and that he would "likely do so again if they resumed their relationship" (*Harper*, p 1071). Nonetheless, after his release from prison, Mr. Miller and Ms. Patricelli resumed their previous relationship.

Ms. Patricelli had lied to the DOC, telling them that she was not in a relationship with Mr. Miller and that she would be moving to a new location unknown to him. Mr. Miller's mother was aware that her son and Ms. Patricelli were in contact, and she signed documents stating Mr. Miller was sleeping at her home, when in fact he was living with Ms. Patricelli. Ms. Patricelli also did not tell her mother, Cathy Harper, that Mr. Miller was living with her. At the time of the murder, the DOC was monitoring Mr. Miller for a 2010 misdemeanor probation and a 2012 misdemeanor probation for assault of Ms. Patricelli that included an order of no contact with her among his other probation conditions.

A DOC victim services advocate communicated with Ms. Patricelli to notify her of Mr. Miller's impending release and to develop a safety plan. A day after his release on October 16, Mr. Miller reported to his DOC supervisor that he was living with relatives rather than at his release address at the Sober Solutions Program. Mr. Miller was not disciplined by the DOC for not seeking approval before changing addresses. The DOC verified that Mr. Miller had begun the process of seeking domestic violence treatment, including scheduling a psychological evaluation. On October 23, Mr. Miller tested negative for drugs and alcohol for a second time and submitted a shelter log stating he stayed with his mother each night. On October 29, the day before Mr. Miller was to report to his DOC supervisor for the third time, the DOC supervisor called Mr. Miller's mother to verify his living arrangements. The next morning, Mr. Miller stabbed Ms. Patricelli at her home over accusations of infidelity.

Ms. Harper sued the DOC in the Superior Court for King County, alleging gross negligence in its supervision of Mr. Miller. She alleged that the DOC should have monitored Mr. Miller using GPS (global positioning monitoring system), conducted home visits, moni-