Products Liability Law Daily Wrap Up, TOP STORY—DRUGS—Pa. Cmmw: $1.75M jury award against makers of Risperdal® reduced to $680K, (Mar. 21, 2016)

Products Liability Law Daily Wrap Up

Click to open document in a browser

By Pamela C. Maloney, J.D.

Although a Pennsylvania trial court refused to set aside a jury verdict entered against the makers of Risperdal®, an antipsychotic medication, it did reduce an award of $1,750,000 to $680,000 in accordance with the statutory cap imposed by Maryland law on the amount of "noneconomic damages" available in personal injury cases. In reducing the award, the Pennsylvania Court of Common Pleas ruled that Maryland, not Pennsylvania law applied to this case because the cap was part of Maryland's substantive law (*Murray v. Janssen Pharmaceuticals, Inc.*, March 10, 2016, DiNubile, V.).

The patient, who had been diagnosed with autism, took Risperdal in 2002. According to the patient's complaint against Janssen Pharmaceuticals, a division of Johnson & Johnson, his use of the drug caused him to develop serious side effects including abnormal breast growth (gynecomastia), tardive dyskinesia (TD), involuntary movement disorders, and weight gain. The jury awarded the patient $1,750,000, finding that the drug manufacturer negligently failed to provide adequate warnings to physicians and health care providers of the extent of the risk of abnormal breast growth stemming from the use of the drug by adolescents [see *Products Liability Law Daily's* November 10, 2015 analysis]. The drug maker moved for judgment notwithstanding the verdict (JNOV) on several grounds, including that (1) there was insufficient evidence that the patient had gynecomastia or, if he did, that it was caused by Risperdal; (2) the learned intermediary doctrine absolved it from liability; (3) testimony by the patient's expert was insufficient to establish negligence, particularly after the issuance of the 2006 label by the FDA approving the drug for use in treating children and adolescents with autism; and (4) the manufacturer was not liable for off-label use of the drug.

Learned intermediary defense. The court first explained that the question of whether Maryland had adopted the learned intermediary doctrine was moot because the jury had been correctly instructed that if the drug maker negligently failed to advise physicians/health care providers of a known risk, it would be liable to the general public. The court concluded that the patient had presented ample evidence that the drug maker's duty to warn his treating physician had been breached.

The court also found that testimony by the patient's pediatrician and psychologist, who stated that they stood by their medical decision to prescribe the drug, was sufficient to create a jury question on this issue because it was unclear whether they would have prescribed Risperdal had a different warning about the risk of gynecomastia been given. Because the jury answered the question in favor of the patient, the manufacturer's JNOV claim must fail.

Expert testimony. The patient's expert testimony, which was based on a number of studies showing that the drug maker knew about the risk of gynecomastia in male children and adolescents who took the drug but failed to warn health care providers was clear-cut and was sufficient to raise a jury issue which was resolved in favor of the patient. Thus, the JNOV motion on this ground also failed.

Furthermore, the expert's testimony clearly established that the drug maker knew of the risk of gynecomastia during the three year period prior to the 2006 FDA-approved label change. The fact that the drug maker failed to inform the FDA of that risk as well as its failure to warn physicians and health care providers of the risk supported the jury's finding of negligence.

Liability for off-label use. The court rejected the drug maker's argument that it could not be liable for off-label use of the drug for two reasons. First, the drug maker clearly knew that off-label use of the drug to treat children and adolescents was extensive. Second, the drug maker sought to have Risperdal approved by the FDA for children and adolescents; thus, how could it claim that they couldn't be held liable if they failed to warn of the risk of gynecomastia merely because it was prescribed to the patient off-label?

The court also rejected the drug maker's argument that because this use of Risperdal was off-label, federal law precluded the state law negligence claims. Under *Wyeth v. Levine*, original manufacturers cannot assert that they are immune from state causes of action merely because they complied with FDA requirements. They have a duty to inform physicians and health care providers of all significant known/knowable risks and failure to do so opened them up to state court claims. The facts presented by the patient and accepted by the jury were that that the drug maker knew of the off-label use of Risperdal, encouraged it, and sought FDA approval while negligently failing to advise physicians and health care providers of the risk of gynecomastia. Under these circumstances, the drug maker's JNOV preemption argument also failed.

Remittitur. Under Maryland law, damages for pain and suffering cannot exceed $500,000 for causes of action arising on or after October 1, 1994, with an additional $15,000 added to the cap each year beginning on October 1, 1995, depending on when the cause of action arose. The patient began taking the drug in 2003, and it was assumed for purposes of calculating the patient's damages that the cause of action arose at that time. The verdict was rendered in November 2015; therefore, the sum of $180,000 ($15,000 times 12 years) was added to the $500,000 base amount, for a total of $680,000.

The patient's argument that the Maryland cap was a procedural law and thus, did not apply to an action brought in Pennsylvania was rejected. Damages and the issues arising from them are the very heart of a tort action and are part of the substantive, not procedural law of Maryland. Furthermore, the basic Pennsylvania conflict of law principles dictated the application of Maryland law to this issue. There was no wording in the Maryland statute confining its application only to lawsuits brought in Maryland. In addition, Maryland clearly had the most significant contacts to the issues arising in this litigation. The patient was a resident of Maryland. The drug was recommended and prescribed by health care providers located in Maryland, the patient purchased and ingested the drug in Maryland, and the patient was injured and treated there. Pennsylvania was merely the forum state the patient chose for his lawsuit. As such, the law of the state with the most significant ties to the case cannot be ignored and remittitur under Maryland law was warranted.

The case is No. 1990.

Attorneys: Brian J. McCormick Jr. (Ross Feller Casey, LLP) for Nicholas Murray. Melissa A. Graff (Drinker Biddle & Reath LLP) for Johnson & Johnson, Janssen Pharmaceuticals, Inc. and Janssen Research & Development, LLC.

Companies: Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Janssen Research & Development, LLC

MainStory: TopStory JuryVerdictsNewsStory DamagesNews DrugsNews PennsylvaniaNews