IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

Robbie Booker, Plaintiff, vs. General Electric Company; GE Healthcare a/k/a General Electric Company d/b/a GE Healthcare; GE Healthcare, Inc. d/b/a GE Healthcare Medical Diagnostics; and GE Healthcare AS, Defendants.	)	Case No. 2008 L 6214 *Consolidated with* Case No. 2008 L 6209 *In re Gadolinium Dye*

ORDER

This case comes on the call on Plaintiff Robbie Booker's ["Booker"] Motion for Leave to Assert a Claim for Punitive Damages against the General Electric Defendants ["GEHC"]. Booker and GEHC both filed briefs and exhibits in support of their respective positions. On March 22, 2010, this court heard extensive oral arguments on the motion. This court allowed both parties the opportunity to present witnesses, however the parties declined to do so. Therefore, based on the parties' briefs, exhibits, and oral arguments, it is hereby ordered that Booker's Motion for Leave to Assert a Claim for Punitive Damages against GEHC is granted, as more fully set forth below.

Background

Robbie Booker is a 57 year old woman who has suffered from end stage renal disease since approximately November 1999. Omniscan, a prescription drug manufactured by GEHC, is a gadolinium-based contrast agent ["GBCA"] used in magnetic resonance imaging ["MRI"] procedures. Omniscan has been approved by the U.S. Food and Drug Administration ["FDA"] since 1993. Booker alleges that she was injected with Omniscan eleven times from 2001 through 2007 during MRI procedures. In October 2007, Booker was diagnosed with Nephrogenic Systemic Fibrosis ["NSF"]. NSF is a rare disease that causes severe scarring and tissue growth in the skin, joints, and other organs. Booker alleges that there is a definitive link between the development of NSF in renally impaired patients and exposure to GBCAs like Omniscan. Booker states that she is almost completely disabled as a result of her NSF. She claims that she is profoundly disfigured, and suffers severe leg, arm, and shoulder pain due to skin changes and restriction of motion caused by the NSF.

Booker brought this product liability case against GEHC alleging claims of design defect and failure to warn. Booker now seeks to amend her complaint to add a claim for punitive damages, alleging that there is evidence showing that GEHC acted with conscious disregard or indifference to the consequences of administering Omniscan to renally-impaired patients. Booker argues that the facts in this case show that GEHC acted with wanton disregard for patient safety. In support of her motion, Booker has submitted five volumes of exhibits to the court. The volumes contain medical literature, expert witness disclosures, expert witness affidavits, medical studies, abstracts, and reports from GEHC about Omniscan.

GEHC argues in response that Booker's request to add a count for punitive damages should be denied for four main reasons. First, GEHC claims that the cellular and biochemical processes that cause NSF still remain unknown. Second, GEHC argues that the preclinical and clinical studies upon which Booker relies did not show that Omniscan is unreasonably dangerous or that any injury would likely result from its use. Third, GEHC states that the four Adverse Event Reports that Booker highlights fail to substantiate her claim that GEHC knew Omniscan could cause "skin toxicities" because the reports described only vague and generalized symptoms that were not consistent with each other or with NSF. Finally, GEHC maintains that it took immediate action to gather information, distribute comprehensive warnings, and initiate labeling revisions with the FDA and European Union regulators following the discovery of a potential association between NSF and GBCAs. GEHC also submitted numerous volumes of exhibits with the same types of medical studies and supporting materials.

Analysis

"'It has long been established in this State that punitive or exemplary damages may be awarded when torts are committed with fraud, actual malice, deliberate violence or oppression, or when the defendant acts willfully, or with such gross negligence as to indicate a wanton disregard of the rights of others.'" *Barton v. Chicago & N. W Transp. Co.*, 325 Ill. App. 3d 1005, 1030 (1st Dist. 2001), quoting *Kelsay v. Motorola, Inc.*, 74 Ill. 2d 172, 186 (1978), see also *Proctor v. Davis*, 291 Ill. App. 3d 265, 285 (1st Dist. 1997). The trial court will allow the plaintiff leave to amend her complaint to add a prayer for relief seeking punitive damages if the plaintiff establishes a reasonable likelihood of proving facts at trial sufficient to support an award of punitive damages. *Stojkovich v. Monadnock Bldg.*, 281 Ill. App. 3d 733, 741 (1st Dist. 1996), citing 735 ILCS 5/2-604.1 (West 1994). The initial decision to allow the plaintiff leave to amend her complaint to add punitive damages is a question of law for the trial judge to decide. *Loitz v. Remington Arms Co.*, 138 Ill. 2d 404, 414 (1990).

"'In a products liability case, the goal of awarding punitive damages is to deter manufacturers from placing dangerously defective products into the stream of commerce by making it unprofitable to an unpredictable degree.'" *Jablonski v. Ford Motor Co.*, 2010 Ill. App. LEXIS 65, 117 (5th Dist. 2010), quoting *Baier v. Bostitch*, 243 Ill. App. 3d 195, 205 (1st Dist. 1993). "In the context of a punitive damages claim, willful and wanton conduct 'approaches the degree of moral blame attached to intentional harm, since the defendant deliberately inflicts a highly unreasonable risk of harm upon others in conscious disregard of it.'" *Jablonski*, 2010 Ill. App. LEXIS at 117, quoting *Loitz*, 138 Ill. 2d at 416. '"The essential elements of willful and wanton conduct in a product liability case include knowledge of the defect, knowledge or notice that the defect was likely to cause injury[,] and failure to warn of or remedy a known defect or take some other affirmative action to avoid the injury.'" *Jablonski*, 2010 Ill. App. LEXIS at 117-18, quoting *Collins v. Interroyal Corp.*, 126 Ill. App. 3d 244, 256 (1st Dist. 1984).

This court is not deciding whether the evidence Booker relies upon in support of her motion will be admitted at trial, nor is this court deciding whether there is sufficient evidence to entitle Booker to have the jury instructed on punitive damages. Those decisions will be made by the court at a later stage in the litigation based on the testimony and exhibits that are admitted into evidence at trial. Instead, this court must decide based on the evidentiary submissions alone whether Booker has a reasonable likelihood of proving facts at trial sufficient to support an award of punitive damages.

To support Booker's claim that she is entitled to plead punitive damages, Booker must submit evidentiary material that GEHC's conduct was willful and wanton. *Illinois Pattern Jury Instruction 35.01.* The question then becomes whether the evidentiary material submitted by Booker supports the reasonable likelihood that she can prove that GEHC engaged in a course of action that showed an utter indifference or conscious disregard for the safety of Booker and others. *Illinois Pattern Jury Instruction 14.01.* Booker argues that the evidentiary material she submitted, when viewed in its entirety, entitles her to add a count for punitive damages to her complaint.

Booker submits the following assertions in support of her claim for punitive damages. Gadodiamide was first synthetized by Salutar in 1987. *Booker Exhibit 25.* When Nycomed bought Salutar in 1989, Omniscan (internally called S-041) was Salutar's most developed and promising contrast medium. *Id.* Omniscan is also referred to as Gd-DTPA-BMA. *Id.* As early as 1989, scientists at GEHC's predecessor, Nycomed, were studying the toxicity of gadolinium in the livers and kidneys of mice. *Booker Exhibit 20.* A draft project report dated March 13, 1989, indicates that Omniscan (not yet approved by the FDA) was retained in the livers and kidneys of mice at a higher level than Magnevist (already approved by the FDA). *Id.* The draft report concluded that Omniscan caused the highest retention of gadolinium in the liver as compared to the other GBCAs tested, which "could be taken as an indication for the relative instability of [Omniscan] in vivo compared to [the other GBCAs]." *Id.* Booker asserted at the hearing, and GEHC did not dispute, that this draft report was never submitted to the FDA. GEHC responded, however, that the final version of the Nycomed Project Report, dated May 28, 1991, was submitted to the FDA with complete findings and conclusions. *Booker Exhibit 22.* Booker disputes that the complete findings and conclusions from the draft report were in the final report submitted to the FDA. Although Booker's Exhibits 20 and 22 are designated by GEHC as study FT-PAH 2/89, the 1991 report does not reference the 1989 report.

In Booker's exhibits 12a, 13, and 14, Booker indicates that scientists at GEHC recognized the toxicity of free gadolinium as early as 1990. The submissions also indicate that in the early 1990s, GEHC knew it was necessary to bind gadolinium to a chelate in order to render the free gadolinium inert and prevent toxic exposure in the human body. *Karen Saebo Project Report, Booker Exhibits 13, 15-19.* Booker submitted exhibits concerning GEHC's knowledge in 1991 that the longer that a GBCA remains in the body, the greater the risk of dissociation of the chelate, significantly increasing the toxicity of the gadolinium. *Booker Exhibits 14, 16-18.* GEHC answers that in her discovery deposition, Ms. Saebo makes clear that these were draft findings, they were not finalized, and they were not indicative of what happens in humans.

Some of Booker's exhibits indicate that GEHC had knowledge in the early 1990s that Omniscan was less stable than other GBCAs on the market, having a greater tendency to break down and expose the patient to toxic free gadolinium. *Booker Exhibits 20-28.* Booker also asserts by way of documentary exhibits that GEHC knew in 1996 that patients with impaired renal function were at a higher risk of being exposed to free gadolinium because a large amount of the Omniscan was not being cleared from their bodies. *Booker Exhibits 31-33.* In response, GEHC presented a report from Benjamin Newton, Ph.D., one of its experts, who explains that Booker's free gadolinium theory is just that, a theory. *GEHC Exhibit 30.*

Furthermore, Booker included exhibits demonstrating that from 2002 through 2006, GEHC received four FDA Adverse Event Reports ["AERs"] documenting four patients with renal impairment who developed severe skin problems and joint pain symptoms following administration of Onmiscan. First, in 2002, GEHC learned of a man in Copenhagen, Denmark, who suffered from renal failure, had

been injected with Omniscan, and experienced several after-effects, including persistent leg pain, which resulted in a diagnosis of NSF. *Booker Exhibit 40.* Second, in 2003, GEHC learned of a female dialysis patient in Copenhagen who had been admitted to the hospital soon after an MRA was performed with Omniscan because she was suffering from "violent muscle and joint pains, reduced energy, heart palpitations, hair loss and nausea [which was] with high probability a consequence of the use of the contrast agent Omniscan 300 in connection with MR angiography..." *Booker Exhibits 41-45.* Third, GEHC had knowledge in late 2004 of a female patient in Texas who suffered from end- stage renal disease and developed skin lesions and contractures following administration of Omniscan. *Booker Exhibit 47.* Both the patient and her doctor connected her symptoms with the Omniscan injection she received. *Id.* Finally, Booker asserts that GEHC had knowledge of a fourth case in 2005 where a German man with end-stage renal disease was injected with Omniscan and immediately suffered from reddened skin, burning skin, muscle pain, and reduced mobility of joints. *Booker Exhibits 49-51.* Booker asserts that after receiving these four reports, GEHC should have been on notice of the dangerousness of Omniscan in renally impaired patients because of the similarity of their reported symptoms to NSF. GEHC responds that none of the AERs specifically cited NSF and that the symptoms described in all four AERs were different, non-specific symptoms with no discernable pattern that could have put them on notice of a connection between Omniscan and NSF.

In January 2006, Dr. Thomas Grobner, an Austrian nephrologist, published an article describing his hypothesis that Bayer's GBCA, Magnevist, "possibly play[ed] a triggering role" in the development of NSF in five of his patients with end-stage renal disease. *GEHC Exhibit 4.* In April 2006, Dr. Grobner published an erratum stating that his patients had received Omniscan, not Magnevist. *GEHC Exhibit 13.* GEHC conceded in its brief and at the hearing that on April 19, 2006, Herlev Hospital in Denmark reported a cluster of 20-25 additional cases of NSF associated with the administration of Omniscan to renally impaired patients. *GEHC Exhibit 61.*

Booker presented exhibits indicating that on May 10, 2006, Hugo Flaten, Vice President of Global Pharmacovigilance at GEHC, called an internal meeting to discuss the possible measures to be taken to protect patients in connection with the reports of NSF and Omniscan in Austria and Denmark. *Booker Exhibit 52.* The meeting minutes report that "the group felt that precautionary measures should be taken, e.g., a temporary stop of use in patients with severely impaired renal function." *Id.* The "Action" items that closed the minutes stated, "We should proactively propose to restrict the use of Omniscan in patients with severely impaired renal function." *Id.* However, instead of directly warning about the risks of Omniscan in renally impaired patients, GEHC sent a "dear doctor" letter on June 6, 2006, which "inform[ed]" the healthcare professionals of the 25 European cases of NSF in four years and concluded, "[t]o date, a causal relationship between NFD/NSF and [gadolinium-based contrast] agents has not been established." *Booker Exhibit 53.* GEHC argues that there is no evidence to support a claim that it acted with conscious disregard for patient safety because it cooperated with the FDA and other world-wide health authorities.

In September 2007, GEHC revised the Omniscan label to include a "black box" warning, the most serious kind of warning a drug label can contain. The warning is set off in a black-bordered box at the top of the label and is headed, in bold letters: "Warning: Nephrogenic Systemic Fibrosis." The warning goes on to inform doctors that, "[g]adolinium-based contrast agents increase the risk for Nephrogenic Systemic Fibrosis (NSF)" in patients with renal insufficiency. Booker asserts that prior to September 2007, no similar warning alerted doctors to this information. Booker presented exhibits showing there have been no new cases of NSF associated with Omniscan since the black box warning in September 2007. *Booker Exhibit 55.*

Booker was injected with Omniscan on April 24, 2001; July 18, 2002; March 5, 2003; July 31, 2003; October 29, 2003; November 3, 2003; December 7, 2004; December 27, 2005; February 23, 2006; May 4, 2006; and March 6, 2007. All of the injections took place before the black-box warning was issued in September 2007. All but the last injection took place before the issuance of the "dear doctor" letter in June 2006.

Booker and GEHC have presented contradictory evidentiary submissions on these points, which leave questions of fact for the jury at trial. However, after a thorough review of the briefs and exhibits submitted by the parties, this court finds that the information in Booker's evidentiary exhibits, if proven at trial, could persuade the jury that in GEHC's effort to obtain FDA approval and desire to market Omniscan, it ignored mounting evidence from 1989 through 2007 that Omniscan was dangerous to renally impaired patients. The evidentiary material, if proven at trial, could also convince the jury that in spite of the evidence indicating Omniscan was dangerous to renally impaired patients and contrary to the May 2006 advice of Hugo Flaten, Vice President of GEHC's own Pharmacovigilance department, GEHC failed to order a temporary halt to the use of Omniscan in renally impaired patients. If proven at trial, the evidentiary material could persuade the jury that GEHC failed to timely revise the label to include a black box warning explicitly stating that Omniscan increases the risk for NSF in patients with renal insufficiency. If proven, the evidentiary material could convince the jury that GEHC had knowledge of the danger of Omniscan in the renally impaired in April 2006, a year before Booker's last Omniscan injection, but failed to properly warn of the risk until September 2007, six months after her last injection. If Booker is able to prove the above, the jury could properly conclude that GEHC engaged in a course of action that showed an utter indifference to or conscious disregard for the safety of Booker and other renally impaired patients.

Conclusion

Based on the foregoing analysis, Booker's Motion for Leave to Assert a Claim for Punitive Damages against GEHC is granted.

ENTERED: April 2, 2010

Deborah Mary Dooling
Circuit Court Judge Law
Division