UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

RANDI L. KUNNEMANN, as Independent Administrator of the Estate of KARIN K. KUNNEMANN,	)	
Plaintiff,	)	Case No. 05 C 3211
v.	)	Magistrate Judge Arlander Keys
JANSSEN PHARMACEUTICA PRODUCTS, L.P., and ALZA CORPORATION,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

This diversity case involves claims by the mother of a woman who died while using a 100 mcg/hr Duragesic patch, a device used in the control of chronic pain. The case is before the Court on a motion for summary judgment filed by the defendants. For the reasons explained below, the motion is granted in part and denied in part.

Factual Background

Beginning in 1992, when she was 14 years old, Karin Kunnemann experienced persistent, almost daily abdominal pain and vomiting; at some point, she also began experiencing headaches and joint pain. Her doctors were never able to determine the exact cause of her afflictions; at one point she was diagnosed with Lupus, she was also diagnosed with "mixed connective tissue disorder" and fibromyalgia. Whatever the diagnosis, she suffered

from chronic pain and various neurological problems, including regular losses of consciousness and interrupted breathing. In August of 2003, Ms. Kunnemann underwent a sleep study, which revealed that she had "slow respirations during sleep" and brief episodes where she actually stopped breathing altogether.

Throughout her ordeal, Ms. Kunnemann saw a number of different physicians and specialists (including pain management specialists and psychiatric specialists), and she was prescribed a number of narcotics and pharmaceuticals to control her pain and alleviate her symptoms. By 1997 she had had a central line surgically implanted in her chest so that she could inject Demerol directly into her own body every few hours. Dr. Francine Long, who treated Ms. Kunnemann from February of 1997 to May of 2000, testified that she was surprised that a 19-year-old would have a central line; another treating physician, Dr. James Gruft, agreed that such a drastic measure was extremely rare in such a young person. Not only was Ms. Kunnemann taking an extraordinarily large number of drugs, but, for those she was taking, the dosages were extraordinarily high as well. Yet nothing seemed to work.

In November 1998, Ms. Kunnemann began seeing Dr. James Gruft, a pain management specialist. According to Dr. Gruft, by November of 1999, Ms. Kunnemann's medications had become "totally out of control" in that she was taking "very high doses of

narcotics." Deposition of James Gruft, p. 102. Ultimately, Dr. Gruft prescribed the Duragesic patch for Ms. Kunnemann. Although Dr. Gruft initially recommended that Ms. Kunnemann replace the patches every three days (which is what the manufacturer recommends), within a month of the initial prescription, he upped his recommendation, advising her to replace the patches every two days. Thus, by the end of 1999, Ms. Kunnemann was using the 100 mcg/hr patches and replacing them every 48 hours. It is undisputed that, from that point until June 2004, Ms. Kunnemann followed this regimen without incident or issue. In fact, according to Ms. Kunnemann's family, the Duragesic patches managed her pain better than the oral medications and narcotics she had used in the past.

In October of 2000, Ms. Kunnemann began seeing Dr. Michael Skaredoff for pain management; he continued the Duragesic regimen implemented by Dr. Gruft, and he also prescribed Oxycodone (another opioid) for breakthrough pain. Along with the pain medication, Ms. Kunnemann was prescribed Xanax (a tranquilizer) and Seroquel or Lexapro (antidepressants). Ms. Kunnemann worked with Dr. Skaredoff until May 28, 2004, when he advised her that he was moving his practice to Wisconsin. Ms. Kunnemann was upset about Dr. Skaredoff's move. Although it is unclear whether it was related to her being upset, the same day she learned of Dr. Skaredoff's departure, she went to the emergency room at Central

DuPage Hospital, complaining of migraine headaches, nausea, vomiting, blurred vision, sweating, passing out and soreness; she was diagnosed with dehydration and was later admitted, on June 2, 2004, for evaluation and pain control. While at the hospital, Ms. Kunnemann received her regular pain medications (the Duragesic patch and oxycodone); she also received Dilaudid, another opioid.

On June 6, 2004, after having her Duragesic patch replaced, Ms. Kunnemann was discharged from Central DuPage Hospital. The next day, June 7, she went to bed in the early afternoon; her mother checked on her a couple of times that evening, and, in her view, she appeared to be fine. By the next morning, Ms. Kunnemann was dead. Her mother found her, unresponsive, in her bed; by the time the paramedics arrived, Ms. Kunnemann's body was cold to the touch. At the time of her death, Ms. Kunnemann was just 27.

On June 8, just a few hours after she was found dead in her bed, Dr. Jeffrey Harkey, the Medical Examiner for DuPage County, performed an autopsy on Ms. Kunnemann. The autopsy revealed that Ms. Kunnemann was wearing a single 100 mcg/hr Duragesic patch on her thigh; Dr. Harkey removed the patch and preserved it. Dr. Harkey drew blood from Ms. Kunnemann's aorta and sent it to AIT Laboratories in Indianapolis for toxicology testing; according to AIT, the fentanyl test was positive and quantitated at 5.82

ng/mL. Based upon this, and with virtually no information about Ms. Kunnemann's medical history or her history of using the Duragesic patch, Dr. Harkey concluded that Ms. Kunnemann died from fentanyl toxicity. In reaching this conclusion, Dr. Harkey relied primarily upon the Physician's Desk Reference, which lists the maximum fentanyl blood level after application of the 100 mcg/hr patch as 1.9-3.8 ng/mL. Dr. Harkey noted this cause of death on the autopsy report.

The product at issue in this lawsuit is Duragesic, a prescription pain patch designed to deliver medication through the user's skin; the active ingredient in the Duragesic patch is fentanyl, an opioid analgesic; it is contained in a gel mixture inside each patch and then released via the patch through the user's skin. According to the package insert, Duragesic carries a risk of "serious or life-threatening hypoventilation" or respiratory depression. Therefore, the Duragesic patch is indicated for patients who require continuous treatment for chronic pain that is moderate to severe in intensity and that cannot be managed with lesser means. Duragesic is manufactured by ALZA Corporation and distributed by Janssen Pharmaceutica Products, LP; it was approved by the United States Food & Drug Administration in 1990. Duragesic is available in five dosage strengths, with the lowest delivering 12.5 micrograms of fentanyl per hour, and the strongest delivering 100 micrograms of fentanyl

per hour. It is undisputed that Karin Kunnemann was using the strongest dosage patch at the time of her death. It is also undisputed that Ms. Kunnemann was, at the direction of her pain management physician, replacing her patches every 48 hours, rather than the 72 hours typically ordered on the prescriptions.

The particular patch at issue in this case - the one Ms. Kunnemann was wearing when she died - has been inspected three times; it was first inspected the day of the autopsy by Dr. Harkey, the Medical Examiner, and then by representatives of both parties. Dr. Harkey testified that he examined the patch and saw nothing that appeared to be abnormal; in particular, he detected no leakage from the patch. *See* Deposition of Jeffrey Harkey, p. 66.

On May 31, 2005, Ms. Kunnemann's mother (and the administrator of her estate) filed suit against Janssen and Alza; as amended, her complaint alleged claims of product liability (based upon both strict liability and negligence theories), breach of warranty (express and implied), violation of the Illinois Consumer Fraud & Deceptive Business Practices Act, and unjust enrichment. Discovery proceeded for the next few years, and, on June 13, 2008, the defendants moved for summary judgment. Along with their summary judgment motion, the defendants filed several motions to strike. All of these motions are now fully briefed.

Discussion

A. Motions Regarding Expert Testimony

Before turning to the merits of the defendants' summary judgment motion, the Court will consider the defendants' objections concerning the plaintiff's expert testimony. The defendants have asked the Court to strike portions of Dr. Cheryl Blume's declaration, as well as portions of Dr. Michael Baden's declaration. They also filed an objection to the expert testimony offered by the plaintiff in response to the summary judgment motion.

1. Defendants' Motion to Strike Portions of Dr. Blume's Declaration

The defendants first seek to strike portions of Dr. Cheryl Blume's declaration. Dr. Blume holds Ph.Ds in medical pharmacology and toxicology; she is the president of Pharmaceutical Development Group, Inc., a consulting firm specializing in pharmaceutical development and registration activities. The plaintiff supplied the defendants with Dr. Blume's original expert report on April 27, 2007; she was deposed on October 17, 2007 and again on June 10, 2008. Her current declaration, executed June 26, 2008, consists of 31 pages. The defendants ask the Court to strike paragraphs 30-33, 38, 43, 45, 46 and 49 of that declaration, arguing that the opinions contained in these paragraphs are new and untimely.

In challenged paragraphs 30, 31 and 32, Dr. Blume opines

that Ms. Kunnemann's postmortem fentanyl level was toxic and lethal; in paragraph 33, she opines that the level demonstrates that the patch malfunctioned and failed to perform as intended. At her deposition, Dr. Blume testified similarly. She testified that, in her opinion, a level of 5.82 was not intended, and that her opinion was based upon the data contained in the Duragesic package insert and on the FDA's position that anything above 5 is a "dose dump." Blume Dep., p. 154-55. Accordingly, the Court finds that the opinions stated in paragraphs 30, 31, 32 and 33 are consistent with what Dr. Blume said at her deposition; there is nothing new or particularly surprising in these paragraphs and the Court denies the motion to strike them.

Paragraph 38 provides information concerning Dr. Blume's review of other autopsies in which the cause of death was listed as fentanyl toxicity; based upon these, Dr. Blume opines that the medical examiner's conclusion concerning cause of death in Ms. Kunnemann's case was reasonable. The defendants argue that, if Dr. Blume had rendered this opinion in a timely manner, they would have explored her analysis in detail during her deposition. First, it is not clear that this information is new; Dr. Blume discussed the fentanyl literature and adverse event studies in her original report and at her deposition. But, even if this information is new, the defendants are free to challenge it at trial. The defendants had ample opportunity to explore Dr.

Blume's beliefs and opinions during discovery and this paragraph is not so novel that they should be prejudiced, or even surprised, by it.

In paragraph 43, Dr. Blume addresses drugs that might affect the body's metabolism of fentanyl, and she concludes that Ms. Kunnemann was not using any drugs that might have inhibited her metabolism of fentanyl. In paragraph 45, she discusses postmortem redistribution and concludes that fentanyl is not subject to high levels of postmortem redistribution. The defendants suggest that this is a new opinion. But Dr. Blume specifically addressed the issue of post-mortem redistribution at her deposition. In fact, she testified that she did not think it was possible that postmortem redistribution had played any role with respect to Karin Kunnemann. Blume Dep., p. 155-56. The defendants had an opportunity to explore this opinion, and they should not be surprised that it has now come up in her declaration. The Court finds that Dr. Blume's opinions concerning postmortem redistribution are consistent with the testimony she gave at her deposition and with the opinions included in her initial expert report. Accordingly, the Court declines to strike them.

In paragraph 46, Dr. Blume opines that the defendants should have warned that Duragesic, even when properly used, could cause death; she also opines that the labels should have contained

warnings concerning the "very narrow therapeutic index (small difference between what is therapeutic and toxic) associated with fentanyl." The defendants seek to strike this paragraph.

The first part of this paragraph is not new. In her original expert report, Dr. Blume stated as follows:

> Despite meeting all criteria for appropriate, and presumed safe, use of the product, Ms. Kunnemann ultimately received a toxic dose of Duragesic resulting in her death. Similar reports of unexplained deaths in opioid-tolerant patients using the patch appropriately were available to Alza/Janssen prior to Ms. Kunnemann's death. These reports should have alerted the company to enhance the warnings provided to physicians and their patients using Duragesic to specify that death or other serious adverse events may occur even if the product is used as indicated. Unfortunately, the Duragesic product label did not sufficiently warn patients that appropriate use of the patch could result in respiratory depression or death. Alza/Janssen chose only to dilute the label language by noting that misuse of the product (i.e., abuse), or use by non-opioid tolerant patients, could result in respiratory depression or death.

Original Expert Report of Dr. Cheryl D. Blume, p. 47. But the second part, where Dr. Blume opines that the package insert should have included a warning concerning the "very narrow therapeutic index" is new, and, accordingly, this part of Dr. Blume's warnings opinion is stricken.

In paragraph 49, Dr. Blume opines that Ms. Kunnemann's cause of death was a "toxic level of fentanyl delivered from a Duragesic patch," and she lists the reasons for her opinion. The defendants contend that this is the first time Dr. Blume is offering an opinion that the patch Ms. Kunnemann was using

malfunctioned. Not true. At her deposition, she specifically testified that, in her view, the patch malfunctioned; she testified that she didn't know why, but that she knew it did. See Blume Dep., 154. Thus, the Court declines to strike her opinion that the patch malfunctioned.

2. Defendants' Motion to Strike Portions of Dr. Baden's Declaration

The defendants also ask the Court to strike certain portions of the declaration submitted by Dr. Michael Baden, a board-certified pathologist and the former medical examiner for the City of New York. Specifically, the defendants seek to strike ¶¶7(f), 7(k), 7(n), 7(o), 8, 10, 11, 16, 18, 20, 21, 22, 23, and 24. Initially, the defendants ask the Court to strike any mention of the records from Ms. Kunnemann's stay at Central DuPage Hospital right before her death on the ground that Dr. Baden testified at his deposition that he had not reviewed those records. It is true that Dr. Baden initially testified at his deposition that he hadn't reviewed the records from Ms. Kunnemann's last hospital stay. *See* Deposition of Michael Baden, p. 30). But, as the deposition was winding up, counsel flipped through the documents Dr. Baden had in his file, and, she specifically noted that the records from Central DuPage Hospital were, in fact, included there. Baden Dep., p. 148. Thus, knowing they were in his file, the defendants can hardly be surprised if Dr. Baden reviewed them. For the same reason, the

Court declines to strike paragraph 10.

The defendants next ask the Court to strike Dr. Baden's opinions concerning any defect in the patch Ms. Kunnemann was wearing when she died. At his deposition, Dr. Baden testified that he would not be offering an opinion concerning whether the patch Ms. Kunnemann was wearing at the time of her death was defective; he testified that he had "no knowledge one way or the other." Baden Dep., p. 50. Dr. Baden testified that he didn't know how Ms. Kunnemann's overdose occurred, only that it did; he testified that it could have occurred by defect in the patch, but that he had "no way of knowing how it occurred." Baden Dep., pp. 145. Specifically, he said,"[a]ll I'm saying is, it did occur, but I have no opinion as to how it occurred." Baden Dep., p. 145.

But Dr. Baden also testified that he agreed with Dr. Harkey's concluding opinion that Karin Kunnemann died from "fentanyl toxicity due to delivery of Fentanyl by means of a Duragesic 100 microgram patch." Baden Dep., p. 97-98. Paragraph 8 of Dr. Baden's declaration, which states that "Karin Kunnemann died from fentanyl toxicity because too much fentanyl was delivered by the Duragesic 100 mcg patch that she was wearing when she died," is consistent with this testimony. The Court sees no reason to strike it. Similarly, paragraphs 11, 18, 20, 22 and 23 would seem to be consistent with Dr. Baden's deposition testimony.

The same is not true of paragraph 21. At his deposition, Dr. Baden testified that tolerance plays a significant role with narcotics such as fentanyl; his testimony would seem, in other words, to be contrary to what is stated in paragraph 21. Accordingly, the Court will strike this paragraph. So too with paragraph 24, which states that, "[i]n my opinion, the most reasonable explanation for [Ms. Kunnemann's death] is a malfunction of the patch that she was wearing that delivered too much fentanyl in too short a time to her blood stream and caused her death." This is squarely at odds with what he said at his deposition, and, accordingly, the Court will strike it. Dr. Baden specifically said he wasn't going to offer an opinion on the issue of how the overdose occurred or as to the existence of any defect in the patch, and for him to do so now is improper and patently unfair to the defendants.

3. Defendants' Objections to Plaintiff's Expert Testimony

In addition to the two motions to strike, the defendants filed objections to plaintiff's expert testimony; specifically, defendants challenge the testimony of Dr. Blume, Dr. Baden and Dr. Anisfield. Some of the arguments raised have already been addressed in connection with the motions to strike. But the defendants also raise a general objection to these experts; specifically, they argue that they are not qualified to render many of the opinions they assert in the declarations they

submitted in response to the defendants' summary judgment motion. The defendants argue that Dr. Blume is not qualified to render an opinion concerning cause of death, postmortem redistribution, the lethal nature of Ms. Kunnemann's postmortem fentanyl level, or the defectiveness of the Duragesic patch Ms. Kunnemann was wearing when she died; they also argue that her opinions about the Duragesic label are irrelevant and inadmissible. With respect to Dr. Baden, the defendants argue that he is not qualified to render an opinion concerning the defectiveness of the patch, postmortem redistribution, or the lethalness of Ms. Kunnemann's fentanyl level. They argue that Dr. Anisfield is not qualified to render an opinion concerning the safety of the Duragesic patch or Ms. Kunnemann's cause of death; they also argue that his testimony about patches other than the 100 mcg/hr patch is irrelevant; finally, they argue that Dr. Anisfield's opinions are inadmissible because they are not based on sound reasoning or methodology reliably applied to the facts of the case.

Some of the challenges to the testimony of Dr. Blume and Dr. Baden have been resolved in connection with the motions to strike. But, for the most part, the defendants' objections seem more like motions *in limine*, and the Court will, accordingly, deal with the bulk of these issues at the pretrial conference and at trial. Specifically with regard to Michael Anisfield, an

industrial pharmacist and a consultant regarding the application of good manufacturing practices in the pharmaceutical industry, the Court notes that his testimony played no role in the Court's decision today. But, as a preliminary matter, the Court is inclined to believe that, under the circumstances of this case, his testimony is irrelevant. The Court will save any definitive ruling on the issue for the motion *in limine* that will no doubt be coming down the pike.

B. Defendants' Motion for Summary Judgment

With these rulings in mind, the Court turns now to the parties' summary judgment arguments. Summary judgment is proper when the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A genuine issue of material fact exists if the "evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). To survive summary judgment, the non-moving party must offer more than "mere conclusory" allegations. *Nowak v. St. Rita High School*, 142 F.3d 999, 1002 (7th Cir. 1998). *See also Matsushita Elec. Indus., Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986) (the non-moving party must

offer more than a "metaphysical doubt as to the material facts"). The non-moving party will lose on summary judgment if he cannot present sufficient evidence to support each element of his case for which he will bear the burden of proof at trial. *Celotex*, 477 U.S. at 322. And the Court will disregard all facts not properly supported by the record. *Brasic v. Heinemann's Inc.*, 121 F.3d 281, 284 (7th Cir. 1997).

1. Non-Product Liability Claims

Initially, Janssen and Alza contend that they are entitled to summary judgment on plaintiff's breach of warranty, consumer fraud, unjust enrichment and punitive damages claims. Ms. Kunnemmann does not appear to oppose the motion as to these claims, and the Court will, therefore enter summary judgment in the defendants' favor on them. This leaves the plaintiff's product liability claims.

2. Product Liability Claims

In Count I of her amended complaint, the plaintiff alleges a product liability claim based upon a theory of strict liability; she alleges here that the particular Duragesic patch involved in this case was, when it left the defendants' possession, unreasonably dangerous and defective, and that, as a result of that condition, the patch caused Karin Kunnemann to suffer a fatal overdose of fentanyl. In Count II, she alleges a product liability claim based upon a theory of negligence; she alleges

that, by reason of *res ipsa loquitur*, the defendants were negligent in supplying the defective Duragesic patch, and that, as a result of defendants' negligence, Karin Kunnemann received a fatal overdose of fentanyl from the patch.

a. Strict Liability

Under Illinois law, to recover in a product liability action, a plaintiff must prove that the injury resulted from a condition of the product, that the condition was an unreasonably dangerous one, and that the condition existed at the time the product left the manufacturer's control. *Kelso v. Bayer Corp.*, 398 F.3d 640, 642 (7th Cir. 2005)(citing *Sollami v. Eaton*, 772 N.E.2d 215, 219 (Ill. 2002)). The defendants argue that they are entitled to summary judgment because the plaintiff cannot establish that Ms. Kunnemann's death "resulted from" a condition of the Duragesic patch or that the condition was an unreasonably dangerous one that existed when the patch left the defendants' control.

(1) Causation

With regard to the element of causation, the plaintiff must show that a defect in the product was the proximate cause of the injury; defectiveness may not be inferred merely from the evidence that an injury occurred. *E.g., Malen v. MTD Products, Inc.*, No. 05 C 6478, 2008 WL 4610295, at *5 (N.D. Ill. Oct. 10, 2008). In opposition to the motion for summary judgment, counsel

for Ms. Kunnemann argues that the best evidence of a defect is the fact that Ms. Kunnemann died. But, as just explained, that fact alone is not enough to establish causation; something more is required.

To be sure, there is evidence in the record suggesting that Ms. Kunnemann's death was caused by a toxic level of fentanyl, and that the level present in her blood at the time of her death necessarily means that the patch delivered more fentanyl than it was intended to deliver - that is, the patch malfunctioned. But these facts are far from firmly established.

Initially, although it is undisputed that the level of fentanyl in Ms. Kunnemann's blood at the time of the autopsy was 5.82, there is some dispute about whether that level existed in her blood at the time of her death. Dr. Yale Caplan, a forensic toxicologist and defense expert, testified that, because of a phenomenon known as "postmortem redistribution," a well-established scientific process in which drugs release from body tissue back into the blood as tissue breaks down after death, it is difficult to say exactly how much fentanyl Ms. Kunnemann had in her blood when she died, but that the level would have been lower than the level recorded at the autopsy. Deposition of Yale Caplan, p. 42-43, 55-56. Graham Jones, a forensic toxicologist and another defense expert, similarly opined that the level of fentanyl found in Ms. Kunnemann's body postmortem, likely was not

the level that existed immediately prior to her death. *See* Deposition of Graham Jones, p. 161. On the other hand, both Dr. Harkey and Dr. Blume testified that they did not believe postmortem redistribution would have had any effect on the fentanyl concentration level.

Additionally, there is some question about whether, if the 5.82 level was present at the time of Ms. Kunnemann's death, it was toxic to her. Dr. Harkey testified that, after the toxicology report came back, he reached a conclusion as to the cause of death: he determined that Ms. Kunnemann died of fentanyl toxicity due to delivery of fentanyl by means of a Duragesic 100 microgram per hour patch. Harkey Dep., p. 80. He testified that he reached his conclusion based upon the fact that Ms. Kunnemann's fentanyl concentration came back as 5.82, which was higher than 3.8, the number he believed was the high end of the range for maximum concentration of fentanyl within 25 to 72 hours after application of such a patch. Harkey Dep., p. 81. Dr. Cheryl Blume opined that Ms. Kunnemann's postmorten fentanyl level was "approximately twice the upper limit of therapuetic range," that it was "above the upper limit of the generally accepted therapeutic range," and that "[t]his elevated fentanyl level caused respiratory depression and ultimately her death, as noted by the medical examiner." Blume Declaration, ¶¶19, 26.

On the other hand, Dr. Caplan testified that it was

impossible and improper to simply look at the level of fentanyl in Ms. Kunnemann's blood and, without more information, conclude that the level was toxic and lethal; he testified that many other variables would factor into that determination - including her tolerance to opiates, how long she had been taking the medication and in what dosage. Caplan Dep., pp. 44-45, 51-52, 54. For Ms. Kunnemann in particular, Dr. Caplan testified, you'd have to consider that she was a chronic user of Duragesic, replacing the patch every two days, which was, in his view, on the high side of the spectrum of use. Caplan Dep., p. 54. When asked at his deposition about what level of fentanyl would cause death, Dr. Caplan testified that the numbers alone are fairly meaningless when it comes to cause of death; he testified that, just because a particular medical examiner ruled in a particular case that fentanyl toxicity was the cause of death and that person's level happened to be 3, that does not mean that a level of 3 causes death. Caplan Dep., p. 126-128.

Concerning the 2003 Duragesic package insert, which showed that, for the 100 mcg/hr patch, the mean maximal concentration of fentanyl following the first 72-hour application was 2.5 ng/mL, with a standard deviation of 1.2, Dr. Caplan testified that this means that 66% of the population using the patch would have concentrations within the range of 1.3 ng/mL and 3.7 ng/mL. Caplan Dep., pp. 136-137. Dr. Caplan testified that, even given

this information, Ms. Kunnemann's concentration, even forgetting about postmortem distribution, was within three standard deviations of the mean of the population that was studied in the clinical trials documented in the package insert, which means that she was within the expected bell curve covering 97.5% of the population. Caplan Dep., p. 139-140. Dr. Caplan testified that a fentanyl concentration that is within three standard deviations of the mean maximal concentration reflected in the package insert - a level of 6.1, in other words - would be consistent with, according to the data in the package insert, therapeutic dosing. Caplan Dep., p. 148. He also testified that, because Ms. Kunnemann was replacing the patches every two days instead of every three (as the package insert instructs), he would expect her concentration to be higher than that population anyway. Caplan Dep., p. 140-141.

Additionally, although the package insert provides data concerning acceptable fentanyl concentrations, that data would presumably relate to a 72-hour-use model; it is undisputed that Ms. Kunnemann was replacing her patches every 48 hours, and there is some evidence that this would have made a difference in terms of the expected fentanyl concentration. For example, Dr. Charles Laurito, an anesthesiologist specializing in pain medicine who was retained by the defendants as an expert, testified that using a patch every two days would produce a higher fentanyl level than

using a patch every three days. See Deposition of Charles Laurito, p. 143.

Dr. Gerhard Levy, a pharmaceutical scientist, pharmacokineticist and expert in biopharmaceuticals and pharmacodynamics with a specific research interest in pharmacodynamics of analgesics, similarly testified that 5.82 would not have been a lethal dose for Ms. Kunnemann; he testified that, during her June 2004 stay at Central DuPage Hospital, Ms. Kunnemann was administered a level of opiates that was three times higher per day than what she was getting at home, and she didn't die, suggesting that her tolerance for opiates was extraordinarily high and that the level of fentanyl in her blood would not have been fatal. Deposition of Gerhard Levy, p. 90.

Finally, there is some question about whether "fentanyl toxicity" was really the cause of death for Ms. Kunnemann. Dr. Harkey, who performed the autopsy on Ms. Kunnemann, testified that, in his opinion, she died from "fentanyl toxicity due to delivery of fentanyl by means of a Duragesic 100 microgram patch." Harkey Dep., pp. 98-99. Indeed, he listed this cause of death on the death certificate. And certainly, the experts retained by the plaintiff agree with this conclusion.

On the other hand, there is an abundance of evidence suggesting that Dr. Harkey's conclusion may have been flawed. Dr. Charles Laurito, testified that, in his view, Dr. Harkey's

cause of death finding was an overly simplistic answer to a very complicated question. He testified that he didn't know why Ms. Kunnemann died, but that it was multi-factorial and a combination of the vast quantities of medications she was taking, pre-existing EKG abnormalities, hypokalemia with an acute episode of dehydration and diarrhea; he testified that his "best bet is that it's a death from a sudden arrythmia. Deposition of Charles Laurito, p. 32; *see also, id.*, at p. 54-55, 168. He testified that, in his view, "poly-pharmacy was a contributor to her death. Laurito Dep., pp. 44, 48. After reviewing the myriad medications Ms. Kunnemann was taking at the time of her death, he testified that "all of these medicine[s] have side affects and they can do a variety of things, not the least of which is depress respirations and make her somewhat acidotic, change the membrane permeability of potassium and sodium. They all contribute to different kinds of arrythmia. *Id.* at 87. Dr. Laurito testified that, in his opinion, the exact cause of Karin Kunnemann's death cannot be determined to a reasonable degree of medical certainty. Laurito Dep., p. 167. He also testified that he examined the list of medications found in Ms. Kunnemann's room and that, using the prescription labels and analyzing the number of pills in each container, he determined that there were 21 Roxicodone pills that were unaccounted for and there were at least 30 Alprazolam that were unaccounted for; in his view, these findings were evidence

that Karin Kunnemann did not take her medicine as prescribed. Laurito Dep., pp. 193-195.

Dr. Gerhard Levy similarly testified that the Duragesic patch did not cause Ms. Kunnemann's death; specifically, he testified, "I can say with a fairly substantial level of confidence that fentanyl did not kill this lady . . . ." Deposition of Gerhard Levy, p. 90; *see also* Levy Dep., p. 92. And Dr. Francine Long, who treated Ms. Kunnemann from February 1997 through May of 2000 - a period during which Ms. Kunnemann was not regularly using the Duragesic patch - testified that, in her opinion, Ms. Kunnemann was addicted to narcotics, that she exhibited "drug seeking" behaviors, and that she may have been - consciously or subconsciously - doing things to make herself sick or to exacerbate her symptoms; she also testified concerning issues Karin was facing at home and how the dysfunction in her home life may have contributed to her illness. *See* Deposition of Francine Long, pp. 90-91, 113-114, 124, 126-27, 130, 137, 138-139. All of this evidence supports the idea that something other than fentanyl toxicity may have caused Ms. Kunnemann's death.

There is also some evidence to suggest that the cause of death conclusion listed in the autopsy may have been based on incomplete information. Dr. Caplan testified that, in his view, the toxicology testing that was done in connection with Ms. Kunnemann's autopsy was incomplete; he testified, for example,

that he identified four other drugs that, based upon her prescriptions, should have been present in her system but did not show up on the toxicology report. Caplan Dep., pp. 74-76. Specifically, he testified that Ms. Kunnemann was taking Alprazolam and Roxicodone - two very potent drugs; yet these did not show up in the toxicology report (whether because the testing did not have the requisite level of sensitivity or because of some other reason). Caplan Dep., pp. 77-78. He testified that she was also taking Seroquel and Lexapro, yet these were not even included in the testing protocol. Caplan Dep., p. 78.

Dr. Jones similarly opined that it would have been inappropriate, from a toxicologist's perspective, to conclude solely based on the fentanyl concentration that the cause of death was fentanyl toxicity; he testified that this is so for a couple of reasons: first, in his view, the level wasn't that high under the circumstances, and, second, the toxicology results were incomplete; there were other medications that she was prescribed and that should have been in her system that the lab either did not test for or did not have the capability to detect - namely, Roxicodone, which is an opiate, Alprazolam, Lexapro, which is an antidepressant, and Seroquel, which is an antipsychotic. Jones Dep., pp. 56-58.

Even Dr. Harkey, who initiated the fentanyl toxicity cause of death, identified other issues that may have caused Ms.

Kunnemann's death or at least substantially contributed to her death. Dr. Harkey testified that, upon examination, he noted that Ms. Kunnemann had a tunneling artery, which he acknowledge is a condition that can cause death or be a contributing factor in the cause of death. Harkey Dep., pp. 69-71. He also testified that, when he did a microscopic examination of a representative section of Ms. Kunnemann's heart, he saw increased interstitial and perivascualar fibrosis, which was consistent with myocardial ischemia or tissue death; he testified that this condition is not normally seen in people Ms. Kunnemann's age and that, indeed, the condition is rare at this age, absent some other medical background that might explain its presence. Harkey Dep., pp. 71-72. He also testified he has seen this condition - tissue death in the heart - in people who have used narcotics for many years. Harkey Dep., p. 73. Dr. Harkey also testified that a documented prolonged QT interval puts a patient at risk for a cardiac arrythmia and sudden death, and that there are certain prescription drugs, including Seroquel, which Ms. Kunnemann was taking, that put a person at risk for a prolonged QT interval. Harkey Dep. Pp. 74-75.

In fact, Dr. Harkey testified that oxycodone and alprazolam are, like fentanyl, central nervous system depressants that can cause respiratory depression; he also testified that such depressants, when combined, can have an additive and even a

synergistic effect. He testified that, if the toxicology report had come back showing that Karin Kunnemann had oxycodone and alprazolam in her system - and there is some evidence that it should have, given that she was supposed to be taking both at the time - he probably would have listed the cause of death as "something like central nervous system depression due to multiple drugs." Harkey Dep., pp. 89-91.

In short, significant issues of material fact exist on causation. In particular, questions of fact exist concerning whether the level of fentanyl in Ms. Kunnemann's blood at the time of the autopsy is indicative of the level of fentanyl in her blood at the time of her death; whether that level was, in her case, toxic; and whether other conditions might also have contributed to or caused her death. These issues must be resolved by a jury.

(2) The Condition of the Patch

As explained above, to prevail on her claims, Ms. Kunnemann must prove that the patch was "unreasonably dangerous" and that this was so when the product left the defendants' control. Under Illinois law, a product may be "unreasonably dangerous" because of a design defect, or because of a failure to warn of a particular danger, or because of a failure to instruct on the proper use of the product as to which the average consumer would not be aware. *Kelso*, 398 F.3d at 642 (citing *Sollami*, 772 N.E.2d

at 219). Based upon the arguments in the briefs, it appears that the plaintiff is claiming that the patch was unreasonably dangerous both because of a design defect and because of a failure to warn of a particular danger - namely, the danger that the patch could cause respiratory depression even when used properly and that it could release its medication in a manner that could lead to a fatal overdose.

It is undisputed that everyone who inspected the patch Ms. Kunnemann was wearing when she died found no visible defect. Even Dr. Harkey testified that his conclusion about cause of death cannot be read to say anything about whether the patch was somehow defective. *See* Harkey Dep., p. 80. Indeed, the plaintiff admits that she has no evidence of any specific defect in the patch; rather, she states that she will offer the testimony of several experts - namely, Dr. Cheryl Blume, Dr. Michael Baden and Michael Anisfield - who will testify that the patch suffered from a non-specific manufacturing or design defect. And these witnesses seem to agree that the lethal dose of fentanyl was released unintentionally, through some malfunctioning of the patch. They also agree, however, that they can't explain exactly what happened or what the defect was.

The mere fact that a product causes injury does not mean, in and of itself, that it was defective. Illinois has adopted comment k to the Restatement (Second) of Torts §402A, which

provides, in pertinent part, as follows:

> there are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified notwithstanding the unavoidable high degree of risk which they involve.

Restatement (Second) of Torts, §402A, comment k at 353-54 (1965). According to comment k, a product is defectively designed if it presents an "unreasonable danger" - that is, when the risks carried by using the product outweigh its benefits. *Id.* If, on the other hand, the benefits outweigh the risks, the product is not unreasonably dangerous, and the manufacturer is not subject to strict liability. *Id. See also Woodbury v. Janssen Pharmaceutica, Inc.*, No. 93 C 7118, 1997 WL 201571, at *5 (N.D. Ill. April 10, 1997).

Although comment k specifically mentions drugs, not all drugs fall within the purview of comment k; rather, the application of comment k must be decided on a case-by-case basis. *E.g., Woodbury*, 1997 WL 201571, at *5 (citing *Glassman v. Wyeth Laboratories, Inc.*, 606 N.E.2d 338, 342 (Ill. App. Ct. 1992). To come within the purview of comment k, a drug must be unavoidably unsafe, be properly prepared and have adequate warnings. *Woodbury* (citing *Glassman*, 606 N.E.2d at 539). Here, the parties

seem to agree that Duragesic was unavoidably unsafe; indeed, no one has argued that the risks associated with using the patch outweigh its benefits; nor has anyone questioned whether the patch is a desirable and useful product.

Ms. Kunnemann has argued, however, that the issue is not whether the medication in the patch was unavoidably unsafe - she concedes that it is - but whether the patch, which is supposed to deliver a steady, reliable stream of potent opioid, but, because of a design defect, instead is likely to deliver sudden toxic bursts of that opioid, is unavoidably unsafe. Framing the question this way, according to the plaintiff, saves the claim from summary judgment. The Court disagrees. Regardless of how the issue is framed, the evidence still shows that Duragesic was not unreasonably dangerous: Dr. Skaredoff testified that he had read all of the literature associated with Duragesic, that he had attended seminars concerning its use and that he was familiar with the risks associated with it; yet, he testified, he regularly prescribed it for his patients. And every expert involved in this case agrees that Duragesic is a useful and desirable drug for dealing with chronic pain; no one disputes Duragesic's beneficial use. Thus, based upon the evidence presented, the Court is persuaded that Duragesic is unavoidably unsafe, but not unreasonably dangerous.

That does not end the inquiry, however. As the plaintiff

correctly notes, comment k does not shield a manufacturer from liability unless the evidence demonstrates that the drug was manufactured properly (in other words, there was no manufacturing defect) and that the drug was accompanied by appropriate warnings. Here, issues of fact exist as to both.

First, although there is no evidence of any kind of obvious defect in the particular patch involved here, there is evidence in the record suggesting that the Duragesic patch was designed to deliver a level of fentanyl and that the level present in Ms. Kunnemann at the time of her death was significantly higher than that level. Saying that the patch was defective because it delivered more fentanyl than intended is not the same as saying the patch was defective because Ms. Kunnemann died; the latter would clearly run contrary to Illinois law providing that injury alone is not sufficient to establish a defect, while the former does not. It is a subtle distinction, but it is enough to get the plaintiff to a jury on the issue.

Second, with regard to the warnings, it is undisputed that the FDA-approved Duragesic label stated that "deaths from hypoventilation due to inappropriate use of Duragesic . . . have been reported"; that the label warned that use of the patch was contraindicated in certain circumstances due to the possibility of "life-threatening hypoventilation"; and that the label warned that hypoventilation and coma could occur in patients who use the

patch simultaneously with other central nervous system depressants, including other opioids. And, to be sure, the medical doctors who addressed the issue here agree that the Duragesic package insert contained adequate warnings. For example, Dr. Skaredoff testified that the package insert for Duragesic "tells me what I need to know about handling this drug." Skaredoff Dep., pp. 97-98. He testified that the information in the insert was adequate for him to make a prescribing decision for his patients. Skaredoff Dep., p. 98. And Dr. Gruft testified that the Duragesic package insert "addresses the major problems that [he had] encountered in [his] clinical practice" and that the insert contained adequate information to allow him to make a prescribing decision. *See* Gruft Dep., p. 54, 56.

But Dr. Blume testified that the warnings were not adequate. She testified that the package insert did not adequately warn physicians and their patients that death or other serious adverse events may occur even if the product was used as indicated; she testified that the Duragesic product label did not sufficiently warn patients that appropriate use of the patch - not just misuse or abuse - could result in sufficient respiratory depression to cause death. *See* Blume Declaration, ¶49. And there is evidence in the record to suggest that such events occurred - though there is really no question that Ms. Kunnemann was not using the patch

as indicated. In fact, the record shows that a medical officer, in connection with the defendants' New Drug Application, expressed concern that, with the 75 and 100 ug/hr patches, a toxic dose of fentanyl could be delivered to a significant fraction of the clinical population. At this stage, the Court is persuaded that there is enough evidence to create an issue of fact as to the adequacy of the warnings.

In sum, issues of fact remain as to whether the plaintiff can prove that Ms. Kunnemann's death resulted from some defect in the patch and that the patch was somehow defective - whether because of an actual design or manufacturing defect or because of inadequate warnings. Accordingly, summary judgment in defendants' favor is inappropriate on the plaintiff's strict product liability claim.

b. Negligence

To prove her product liability negligence claim, Ms. Kunnemann must establish the existence of a duty of care owed by the defendants, a breach of that duty, an injury that was proximately caused by that breach, and damages. *Malen v. MTD Products, Inc.*, No. 05 C 6478, 2008 WL 4610295, at *8 (N.D. Ill. Oct. 10, 2008). The big issue here, as above, is causation - was Karin Kunnemann's death proximately caused by some breach on the part of the defendants? And just as above, the Court finds that, although the evidence is certainly mixed on the point, the

plaintiff has offered enough evidence to get to a jury on this issue.

3. Preemption

Finally, the defendants argue that plaintiff's product liability claims are preempted by federal law. In January of this year, the Supreme Court granted certiorari in *Levine v. Wyeth*, No. 2004-384, --- A.2d ----, 2006 WL 3041078 (Vt., Oct.27, 2006), cert. granted, 552 U.S. ----, 128 S.Ct. 1118, 169 L.Ed.2d 845, 2008 WL 161474 (2008), to address the question of "whether the prescription drug labeling judgments imposed on manufacturers by the Food and Drug Administration pursuant to FDA's comprehensive safety and efficacy authority under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use." Absent specific guidance on the issue, this Court declines to foreclose the plaintiff's claims on the basis of preemption, especially where the defendants have failed to persuade the Court that Illinois law concerning the adequacy of warnings conflicts with the federal regulations governing the issue. *See, e.g., Orso v. Bayer Corp.*, No. 04 C 0114, 2006 WL 2794975, at *4-5 (N.D. Ill. Sept. 27, 2006); *Caraker v. Sandoz Pharmaceuticals Corp.*, 172 F.supp.2d 1018, 1032-1044 (S.D. Ill. 2001). The Court rejects the defendants' preemption argument.

Conclusion

For the reasons set forth above, the Court finds that summary judgment in the defendants' favor is appropriate on plaintiffs breach of warranty, consumer fraud, unjust enrichment and punitive damages claims. With regard to the remaining claims, the Court finds that issues of fact remain that preclude the entry of summary judgment in defendants' favor. Accordingly, the defendants' motion for summary judgment is denied as to plaintiffs' strict liability and negligence claims. The defendants' motions to strike are granted in part and denied in part, and ruling on the remainder of the defendants' objections concerning expert testimony is reserved.

Date: December 2, 2008

ENTER:

Arlander Keys

ARLANDER KEYS
United States Magistrate Judge