PUBLISHED

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
BIG STONE GAP DIVISION

A.F. MCCAULEY, Plaintiff, v. **PURDUE PHARMA L.P., ET AL.,** Defendants.	Case No. 2:01CV00080 Case No. 2:02CV00054
CHARLES C. BRUMMETT, ET AL., Plaintiffs, v. **PURDUE PHARMA, L.P., ET AL.,** Defendants.	**OPINION** By: James P. Jones Chief United States District Judge

Neil L. Henrichsen, Henrichsen Siegel, P.L.L.C., Washington, D.C., Douglas J. McNamara, Cohen Milstein Hausfeld & Toll, P.L.L.C., Washington, D.C., and Emmitt F. Yeary, Yeary & Associates, P.C., Abingdon, Virginia, for Plaintiffs; William W. Eskridge, Wade W. Massie, and Mark E. Frye, Penn, Stuart & Eskridge, Abingdon, Virginia, and Chilton D. Varner, King & Spalding, Atlanta, Georgia, for Defendants.

In this products liability action, governed by Virginia law, the plaintiffs seek to recover damages for harms allegedly caused by their use of OxyContin, a prescription pain medication. Before me are the defendants' motions for summary judgment, which I resolve in their favor.

I

These cases arise out of the misuse of prescription drugs that has ravaged many rural communities, particularly in the Appalachian South.[1] The latest and most devastating player in this epidemic has been OxyContin® Tablets ("OxyContin"), a pain management drug whose only active ingredient is the opioid oxycodone.[2] In bringing these actions, the plaintiffs claim that they have been injured as consumers of OxyContin. The defendants are the affiliated pharmaceutical companies that manufacture and sell OxyContin.

The procedural history of these actions is somewhat prolonged. Plaintiff A.F. McCauley originally filed suit in state court together with four other persons ("the

---

[1] For a history and description of the problem, see U.S. Gen. Accounting Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem* (2003).

[2] Technically, an "opioid" is a synthetic drug with the properties of an opiate, but not directly derived from opium. *Merriam Webster's Collegiate Dictionary* 815 (10th ed. 1996). For the purposes of this opinion, "opioid" and "opiate" will be considered synonymous.

McCauley plaintiffs") on June 15, 2001, against Purdue Pharma, L.P., Purdue Pharma, Inc., and The Purdue Frederick Company (collectively "Purdue"); Abbott Laboratories and Abbott Laboratories, Inc. (collectively "Abbott Labs"); and Drs. Richard Norton and Shireen Brohi, physicians who had allegedly treated certain of the plaintiffs and prescribed OxyContin. The plaintiffs sued on behalf of themselves and a class of other OxyContin users. The defendants removed the case to this court pursuant to its diversity jurisdiction.[3] Thereafter, the McCauley plaintiffs voluntarily dismissed Drs. Norton and Brohi from the action.[4]

The McCauley plaintiffs were subsequently permitted to withdraw their class action allegations and file an amended complaint.[5] On April 2, 2002, McCauley refiled his complaint as the sole plaintiff. On the same date, plaintiffs Charles C. Brummett, Joseph D. Deckard, Charles G. Ewing, and William C. Matney filed a separate complaint making identical claims. Due to their similarity, the two actions were consolidated for pretrial proceedings and discovery. Thereafter, plaintiff

---

[3] *See* 28 U.S.C.A. § 1332(a) (West 1993 & Supp. 2004).

[4] Before the action against Dr. Norton was withdrawn, I denied the plaintiffs' request to add Dr. Norton's professional corporation as a party, on the ground that the addition was sought solely for the purpose of destroying diversity jurisdiction. *McCaulley v. Purdue Pharma, L.P.*, 172 F. Supp. 2d 803, 810 (W.D. Va. 2001).

[5] *See McCaulley v. Purdue Pharma, L.P.*, No. 2:01CV00080, 2002 WL 398715 (W.D. Va. Mar. 14, 2002) (setting forth reasons for allowing class action claims to be withdrawn).

Ewing's case was severed, and the claims against Abbott Labs were voluntarily dismissed in both cases. Finally, after Purdue's present motion for summary judgment, Matney sought to voluntarily dismiss his action with prejudice, which motion was granted, leaving presently before me in both cases McCauley, Brummett, and Deckard as the plaintiffs and Purdue as the defendant.

In their complaints, the plaintiffs list a variety of legal claims premised on the factual allegations that OxyContin was a defective product, that the warnings Purdue issued on the drug's package insert failed to warn physicians of its true potency and of its dangers, and that Purdue's marketing staff falsely represented the risks of the drug.[6] Having completed discovery, the plaintiffs now concede that the only factual theory upon which they are prepared to move forward is that Purdue marketed the drug to the plaintiffs' physicians by falsely representing in written promotional materials and in oral claims made by its sales representatives that OxyContin was safer, less addictive, and less prone to abuse than other oxycodone-based pain medications. Purdue, in turn, has moved for summary judgment against each of the plaintiffs, asserting that they have failed to create a genuine issue of material fact as

[6] Specifically, the plaintiffs allege the following: violation of the Virginia Consumer Protection Act ("VCPA") (Count I); false advertising (Count II); products liability for failure to warn (Count III); products liability for design defect (Count IV); breach of warranty (Count V); negligence (Count VI); negligence per se (Count VII); conspiracy (Count VIII); and unjust enrichment (Count IX).

to any of their claims.[7] The principal argument made by Purdue is that the plaintiffs have failed to show that OxyContin caused their claimed injuries, in light of their prior and concurrent use of other pain medications. The motions have been briefed and argued and are ripe for decision.

II

The evidence in the record is voluminous. For purposes of resolving the present motions, only the relevant facts of the case, either undisputed or, where disputed, taken in the light most favorable to the non-movants on the summary judgment record, are detailed.

---

[7] In particular, Purdue contends that summary judgment against one or more of the plaintiffs is proper for one or more of the following reasons: (1) none of the plaintiffs has met his burden of showing specific causation because the evidence does not show and no expert will testify that OxyContin specifically caused the individual plaintiff's damages; (2) the plaintiffs, as a matter of public policy, cannot recover for alleged injuries arising from their own unlawful conduct; (3) Purdue's duty to warn extends only to physicians under the learned intermediary doctrine, and there is no genuine issue of material fact that Purdue did not fulfill this duty; (4) Purdue's duty to warn is supplanted by the treating physicians' independent knowledge of the risks of OxyContin; (5) Purdue's warnings were adequate as a matter of law because they were approved by the United States Food and Drug Administration; (6) the plaintiffs' claims under the VCPA fail as a matter of law because Purdue's representations were to physicians, not to their patients; (7) the warnings in question are regulated by the federal Food, Drug, and Cosmetic Act ("FDCA") and are therefore exempt from any regulations under the VCPA; (8) the FDCA preempts any state regulations of prescription drug warnings; and (9) Brummett's and Deckard's claims are barred by the applicable Virginia two-year statute of limitations. Because I decide the motions on the basis of lack of evidence of causation, it is unnecessary for me to decide the other grounds.

OxyContin is a prescription-strength pain relief medication manufactured and sold by Purdue and approved by the United States Food and Drug Administration for treatment of moderate-to-severe pain. Its single active ingredient is oxycodone, which is also an ingredient in other prescription pain medications, including Percocet, Endocet, and Tylox.[8] Like other opioids, including morphine, codeine, and hydrocodone, oxycodone interacts with the so-called mu receptor in the human central nervous system to provide pain relief. It is significant that all these opioid analgesics function in the same pharmacokinetic manner. They can all induce euphoria and intense feelings of well-being, making them highly addictive and prone to illicit use.

OxyContin's primary distinctiveness from other oxycodone-based analgesics is that its oxycodone is delivered via a controlled-release formulation, leading each tablet to provide pain relief for more hours than traditional immediate-release formulations and allowing patients to thus take fewer doses per day. A corollary to this feature is that each tablet of OxyContin contains more milligrams of active oxycodone than does a single tablet of other opiate pain medications. For example, whereas the typically-prescribed tablet of Percocet or Endocet contains two and a half or five milligrams of oxycodone, the lowest dose of OxyContin contains ten

[8] All three of these drugs' active ingredients are acetaminophen and oxycodone.

milligrams of oxycodone. In addition, the controlled-release feature of OxyContin functions only if the tablet is taken whole. It is easily destroyed by chewing or otherwise crushing the tablet, thereby releasing the entire larger dose of oxycodone at once.

Each of the plaintiffs in this case was prescribed opioid prescription drugs by his physicians for relief of intense, chronic pain. All were placed on other opioids prior to ever being given OxyContin, and each was also continued on one or more of these other opioids while taking OxyContin. They each claim that they became dependent upon or addicted to opioids only after they started their treatment with OxyContin and suffered personal harm and financial loss as a result.

A. Plaintiff McCauley.

Plaintiff A.F. McCauley is a seventy-year-old former coal miner who has an extensive history of drug dependence and detoxification. The record indicates that he sustained a back injury while working in the coal industry and received pain treatment with opioids sporadically between 1984 and 1990. In 1990, McCauley began to see multiple physicians for pain treatment, including Drs. Fred Litton and Kelly Taylor, and received multiple prescriptions for Tylenol III and Tylenol IV.[9]

[9] The active ingredients of both Tylenol III and Tylenol IV are acetaminophen and codeine.

Although the time periods of these prescriptions overlapped, McCauley did not notify either doctor that he was receiving pain medication from the other.

In September 1990, McCauley also began to frequent Dr. Patrick Molony for pain in his knees, arms, and shoulders, visits that have continued through earlier this year. During these initial years, Dr. Molony prescribed Tylenol III and Tylenol IV at different times, not knowing that McCauley continued to see other physicians and receive multiple prescriptions of opioid pain medications. With this limited knowledge, Dr. Molony did not believe McCauley needed "drug rehab of any kind" during this time period. (Molony Dep. 89.) He maintains, in hindsight, that had he known that McCauley was obtaining opioid medications from multiple physicians, he would not have issued the prescriptions he did.

In early 2000, McCauley began to receive treatment from Dr. Richard Norton, at a clinic named Physician Access, for severe, unrelieved shoulder pain. Dr. Norton prescribed several short-release opioid medications, including Endocet and Percocet, and additionally first prescribed OxyContin for McCauley on January 31, 2000. Dr. Norton did not believe McCauley to have a "drug abuse problem" at this time and did not caution him that OxyContin tablets were to be taken whole or that the medication might be habit-forming, addictive, or might lead to drug dependence. (Norton Dep.

82.) Nonetheless, McCauley maintains that he always took the tablets at the times prescribed and did not chew, crush, snort, or inject them.

While being treated by Dr. Norton, McCauley continued to receive treatment and pain medications, including Percocet, Lortab,[10] Tylenol III, and hydrocodone from other physicians, although he did not share this information with Dr. Norton. After a few months of this treatment, McCauley signed the written pain management contract that was regularly used by Dr. Norton's clinic. This agreement warned of the hazards of opioid medications and obligated the patient to list all medications recently taken, to affirm that opioid pain medication was not being obtained from another physician at the same time, and to commit to using one pharmacy to fill the prescriptions. The evidence indicates that even after signing this agreement, McCauley continued to frequent multiple physicians to obtain opioid pain medications. In defense of his continued violations, McCauley claims that he signed the agreement without reading it and thus was not aware of the commitments he was making. Dr. Norton avows that he would have discontinued McCauley from pain management treatment had he known.

Dr. Norton typically prescribed McCauley two forty-milligram OxyContin tablets per day. After utilizing this dosage for some ten months, in November 2000,

[10] Lortab's active ingredients are acetaminophen and hydrocodone.

Dr. Norton lowered McCauley's dose to two twenty-milligram tablets per day, apparently as a normal precaution designed to minimize the risk of dependence. Dr. Norton did "not see [any] evidence of abuse" in his patient at this time. (*Id*. at 78.) This first prescription of the lower dosage was McCauley's last prescription of OxyContin. McCauley continued to take the medication as prescribed for the following two to three weeks but experienced significant withdrawal symptoms. Thus, during this time period, McCauley resorted to purchasing OxyContin from friends without a prescription. These "street" purchases primarily consisted of twenty milligram tablets and continued through December 2002. McCauley indicated that he has also purchased eighty milligram tablets at times and would take only half of such a tablet by breaking it.

In July 2000, while still receiving OxyContin and other pain medications from Dr. Norton, McCauley entered a methadone treatment program at a drug treatment clinic named DRD Knoxville Medical Clinic. He participated in this outpatient program through December 2000. Throughout this period, McCauley also continued to visit Dr. Molony and received prescriptions for acetaminophen with codeine and hydrocodone. McCauley explains that he continued to seek medication for pain relief because he did not understand that the medications defeated the effect of the methadone. He further admits that he did not disclose his methadone treatment to Dr.

Molony because he intended to terminate the methadone treatment due to the expense and would not have received needed pain medication if he had divulged the truth.

Upon leaving the methadone treatment program, McCauley continued to rely on Dr. Molony's prescriptions, as well as prescriptions for Tylenol from Dr. Deborah Barton, a physician who had taken over Dr. Norton's patients after he was no longer able to practice.[11] These physicians did not prescribe OxyContin, and McCauley continued to purchase "street" OxyContin at this time. In January 2001, he again entered a detoxification program, this time at Woodridge Hospital in Johnson City, Tennessee, where, according to Dr. Rodney Houghton, a physician at the hospital, McCauley's records indicate that he suffered from "an opioid addiction." (Houghton Aff. ¶ 3.) McCauley remained at this facility for approximately eleven days and continued concurrently to take the medications prescribed by Dr. Molony as well as "street" OxyContin. Upon his release, McCauley continued treatment with Dr. Molony but again concealed from him any information about his recent detoxification program, purportedly for the same reasons as the previous time.

McCauley again entered a detoxification program in August 2002 and remained there for only three to four days. Upon his discharge, he once again

[11] Unrelated to these cases, Dr. Norton was convicted by a jury in this court of federal offenses arising from a kickback scheme with a local hospital administrator. He is now serving a prison sentence.

continued pain treatment with Dr. Molony and did not disclose that he had undergone detoxification. McCauley also continued to purchase "street" OxyContin, taking it twice a day until it became "really, really hard and expensive to get" (McCauley Jan. 2003 Dep. 64), which was in approximately September of 2002. From then on, he used "street" OxyContin approximately ten times per week and last took it in early December 2002. During this time period, McCauley additionally saw Dr. Wayne VanZee for treatment on five separate occasions. Upon his initial interview and examination of McCauley, "it was clear to [Dr. VanZee] that [his patient] had developed profound opioid addiction during the course of his treatment with OxyContin." (VanZee Aff. ¶ 2.)

On December 5, 2002, McCauley entered a detoxification center yet again, where he remained for twenty-nine days. He again visited Dr. Molony approximately three to four days after his release from this program and received a prescription for Tylenol IV, which he took once a day, but not regularly. In line with his past conduct, McCauley did not tell Dr. Molony of his drug rehabilitation treatment.

At this point, the record indicates that McCauley's reliance on opioids diminished significantly. In 2004 he testified that he continued to experience pain in his back and knees and had been prescribed Darvocet, which he took only when needed, and otherwise relied on non-prescription-strength Tylenol as needed.

McCauley regularly used two different pharmacies to fill his prescriptions, in an effort to thwart the pain medication tracking systems that pharmacies utilize. He also paid for some prescriptions in cash instead of allowing his health insurance to cover them, again to avoid detection. McCauley also maintains that he did not read any drug information he may have received from the pharmacies and has never seen an OxyContin advertisement. Finally, he professes that, before he began his OxyContin regimen, he was able to stop taking his pain medications for two or three days at a time before experiencing pain again. He was unable to similarly withhold the medications once he started on OxyContin.

B. Plaintiff Brummett.

Plaintiff Charles C. Brummett is a fifty-one-year-old former self-employed masonry and concrete contractor. Brummett's relevant medical history starts in March 1996, when he began receiving pain treatment from Dr. Norton and other physicians at Physician Access for long-standing back problems. In addition to referring him to several specialists, Dr. Norton prescribed opioids, including Percocet, Lorcet,[12] Lortab, and Endocet, over the course of the ensuing two years. Dr. Norton treated Brummett without securing a pain management contract from him or similar

[12] Lorcet's active ingredients are acetaminophen and hydrocodone.

commitments in any other form until December 2000, when Brummett signed the clinic's standard pain management agreement.

In March 1998, Dr. Norton, not believing his patient to have a "drug abuse problem" at the time, first prescribed OxyContin for Brummett, to be taken along with Endocet. (Norton Dep. 82.) Brummett had not heard of OxyContin prior to this time. He claims that Dr. Norton may have mentioned the risk of dependency on opioids but did not issue any other significant warnings. Brummett generally took the OxyContin tablets as prescribed, at least for the first few months. His prescription records indicate that he began to accelerate his doses and refill his prescriptions sooner than scheduled starting in August 1998. In about 1999, Brummett expressed concern to Dr. Norton that he might be acquiring dependency on one of his pain medications and was reassured by the physician that "OxyContin had been designed so as not to be as addictive as the normal pain medications." (Brummett Sept. 2002 Dep. 109.)

In late 1999 or early 2000, Brummett realized he had a problem with his use of OxyContin. He regularly had trouble complying with the dosing schedule and would take the tablets a few hours earlier than scheduled. Brummett did not bring his problem to the attention of Dr. Norton, out of fear that a confession would lead the doctor to terminate him as a patient, thereby leaving him without the medication

altogether. Instead, Brummett continued OxyContin treatment with Dr. Norton until November 2000, when Dr. Norton left his practice.

During his last few visits with Dr. Norton, Brummett also consulted with Deidra Taylor, a counselor at Physician Access. At her initial consultation with him, in April 2000, Taylor did not observe any "red flags" in Brummett's history that would indicate an increased risk for addiction or abuse. (Taylor Dep. 30.) She explained to him the distinction between dependence and addiction and told him that OxyContin presented the risk of opioid dependence. However, at the time of this conversation, Brummett knew it was "a little late in the game" and that it would be "very difficult" for him to discontinue the medication. (Brummett Sept. 2002 Dep. 57, 59.) He also maintains that he realized in approximately May 2001 that he had a "pretty strong dependency" and would depend on OxyContin to supply him with the needed energy to go to work. (*Id*. at 39.)

Through the end of 2001, Brummett obtained the bulk of OxyContin he used from prescriptions. There were occasional times when he borrowed one or two tablets from a friend or an acquaintance to sustain him until his prescription could be refilled. Brummett obtained these tablets by trading them for other medication or purchasing them with cash. From 2002 on, Brummett's access to OxyContin was affected by Dr. Norton's departure from practice. Although he received some pain

treatment in the form of OxyContin from Drs. Barton and Ali Sawaf and even attempted to discontinue OxyContin altogether, he increasingly began to rely on purchases of "street" OxyContin. Brummett also received treatment and OxyContin from Drs. Robert Hayes, Harold Schultz, and Catherine Page. Before long, Dr. Hayes refused to prescribe any more OxyContin because of his concern that Brummett was seeing multiple doctors for pain management at the same time. Dr. Schultz likewise stopped prescribing the drug after becoming aware that Brummett had been charged with conspiracy to possess OxyContin, even though the charge had been dismissed. During this time of scarcity, Brummett would secure OxyContin from "pretty much anywhere [he] could find it." (*Id*. at 30.)

In October 2001, Brummett entered an outpatient methadone clinic in Knoxville, Tennessee, for treatment of his opioid dependence. He transferred to a different facility, Life Center of Galax, in April 2002, where, according to Dr. Maria Encarnacion, Brummett's treatment records indicate "he had an opioid addiction." (Encarnacion Aff. ¶ 3.) His treatment at the clinic was quite successful and he earned his way from having to go to the clinic seven days a week when he first started to going only twice a week and being given five days of take-home treatments. Brummett remained under methadone treatment until October 2002.

Brummett maintained at his last deposition, in April 2004, that he had not taken any OxyContin since October 2001. He continued pain treatment with Dr. Schultz and took oxycodone and Percocet as prescribed, and denied taking any pain medications outside of a prescription. He admitted to occasionally taking a pill earlier than prescribed but maintained that it was not an everyday practice. The prescription records in evidence indicate that Brummett may have accelerated his dosages again between January 2003 and October 2003.

It is further undisputed that, during this relevant medical history, Brummett regularly used more than one pharmacy to fill his prescriptions. He testified to having chewed OxyContin tablets one or two times but said he did not repeat that conduct after learning from his pharmacist that the drug was to be taken only whole. He maintained that he has never otherwise crushed or injected the medication, but has attempted to snort it once, without much success. Finally, Brummett testified at his deposition that although he had taken other pain medications both before and after his spell with OxyContin, he found it more difficult to control his need for and reliance on pain medications after his exposure to OxyContin.

C. Plaintiff Deckard.

Plaintiff Joseph D. Deckard is a forty-two-year-old factory worker. His relevant medical history relates to his nearly continuous treatment by Dr. Steven Adkins for fifteen years.

Deckard first began receiving medical care from Dr. Adkins in 1997 due to a back injury incurred by lifting weights. Upon X-ray diagnosis, it was determined that Deckard suffered from a bulging disc, and Dr. Adkins treated him for the pain by prescribing short-release opioids, specifically Lorcet and Lortab. Deckard maintained at his deposition that he did not recall Dr. Adkins having discussed any risk of dependence with him during this treatment. Deckard continued on this regimen for more than eighteen months and almost singularly received his medications by means of the prescriptions, although there may have been a time or two that he suffered unexpected pain and accepted a tablet from a co-worker. Deckard also admitted sometimes depleting his supply of the medication before the next prescription was scheduled to be filled, suggesting he accelerated his dosage at certain times. The prescription records submitted into evidence corroborate that Dr. Adkins began to refill Deckard's prescriptions of Lorcet and Lortab earlier than scheduled starting in April 1998.

After a period of treatment with short-release opioids, Deckard began to express to Dr. Adkins that he was having to take increasing amounts of the medications in order to remain pain free. Dr. Adkins substantiates that Deckard had developed a tolerance to hydrocodone, the active ingredient in Lortab and Lorcet, by this time. In response, in April 1999, Dr. Adkins first prescribed OxyContin for Deckard, saying it "would work better" and would eliminate the injurious effects of acetaminophen, an ingredient of Lortab, on the liver. (Deckard Aug. 2002 Dep. 44.) Dr. Adkins believed at the time that OxyContin "was a safer alternative to immediate release opioid medication." (Adkins Dec. ¶ 2.) Deckard testified that he had not heard of OxyContin before being prescribed it by Dr. Adkins and that Dr. Adkins did not discuss with him any risks of dependence or addiction at this time. Dr. Adkins supplemented the OxyContin with Percocet, and Deckard maintains that during the course of this treatment he relied only on these prescriptions from Dr. Adkins and did not obtain these medications from any other sources.

The record indicates that, as early as the second prescription, in May 1999, Deckard took OxyContin more frequently than prescribed and, at some point, gradually increased to as many as eight twenty-milligram tablets a day. Dr. Adkins was well aware of the speed with which Deckard was taking the medication and often remarked on the patient's "opioid dependence" in his notes. (Adkins Dep. 77.)

Deckard would at times call the clinic claiming he had flushed the tablets down the toilet in an attempt to prevent himself from relying on them but could not tolerate the withdrawal and needed the medication again. At other times, he would relate different accounts of losing medication and of his resulting need for an early prescription. Dr. Adkins did at times discuss with his patient the problems of dependence and addiction. He also cautioned Deckard more than once that his treatment at that clinic would be terminated if he continued to take his medications more frequently than prescribed.

Dr. Adkins continued to write prescriptions for Deckard, even though they never lasted as long as they were supposed to and he noted that Deckard was at times taking "dangerous level[s]" of OxyContin. (*Id*. at 89.) Dr. Adkins believed instead that Deckard was not taking the medication for "any secondary gain" but just "to feel normal." (*Id*. at 45.) Nevertheless, Dr. Adkins asserts that, after prescribing OxyContin, he observed Deckard "develop an increasing chemical dependency upon and tolerance of OxyContin." (Adkins Dec. ¶ 3.) He has additionally acknowledged his role and the lapses in his monitoring leading to Deckard's state of dependence on pain medications.

Dr. Adkins finally stopped prescribing OxyContin for Deckard in March 2001, at Deckard's request. In April 2001, after having taken his last OxyContin tablet the

very same day, Deckard entered the detoxification center at Indian Path Pavilion. He remained at the inpatient program for four to five days and thereafter continued to refrain from OxyContin on his own. Deckard maintains that he entered this program because he knew he "needed to get off the OxyContin" and because he "didn't want to die." (Deckard Aug. 2002 Dep. 70, 71.) He described his withdrawal symptoms during these days like describing an "elephant to [a] blind man," suggesting that they were unimaginably excruciating. (*Id*. at 110.) At his April 2004 deposition, Deckard maintained that he had not taken any OxyContin from any source since completing that last prescription from Dr. Adkins.

Upon release from Indian Path Pavilion, Deckard returned to Dr. Adkins for pain treatment, specifying that he did not want OxyContin. Dr. Adkins thereafter treated him with short-release opioids, primarily hydrocodone and Lortab. Deckard took these medications according to the prescription schedule but admits that Dr. Adkins warned him again at times that he would not continue treating Deckard if he could not abide by the schedule. These prescriptions continued until June 2002, and it is undisputed that Dr. Adkins knew throughout the treatment that Deckard had recently been released from a detoxification center.

In June 2002, Deckard again entered a recovery center, Corner Stone of Recovery in Louisville, Tennessee. He claims that his reason for doing so was that

he had primarily detoxed from OxyContin under his own supervision and was therefore no longer physically dependent but remained mentally dependent. He described this treatment as much less agonizing, marked by a general discomfort. Deckard remained in this program for almost one month and was released in mid-July 2002. Between this discharge and April 2004, Deckard had not seen Dr. Adkins and had neither received nor taken prescription pain medication from any source. He maintained that he then relied occasionally on non-prescription strength Tylenol.

During this relevant medical history, Deckard regularly used more than one pharmacy to fill his prescriptions. He also testified that he sometimes chewed the OxyContin tablets, that he started to do so approximately twelve to eighteen months after his first prescription, and that he concealed this information from Dr. Adkins. Deckard admitted having once attempted to snort the medication but denied injecting it. He also testified that he may have given one tablet to his brother on one occasion but otherwise did not distribute them in any manner. Deckard maintained that he had never seen an advertisement for OxyContin prior to or during his use of the medication and never received any written information from the pharmacies. Finally, Deckard declared that if Dr. Adkins had warned him of all the consequences he would suffer after taking OxyContin, he would never have taken it.

One of Deckard's primary claims for damages is the impact of OxyContin on his employment. Deckard worked for AFG, a glass manufacturing company, during most of the pertinent time. In March 2001, during the height of his OxyContin use, he was cautioned by his employer that his performance was no longer up to par but was not offered any information about the specific deficiencies. Stimulated partly by this, Deckard entered his first detoxification center. After completing the program, he returned to work, but claims he was never again able to perform his job at the quality that he did before his struggle with OxyContin. Nevertheless, the evidence indicates that he received a favorable evaluation from his employer in November 2001, but was ultimately terminated in February 2002.

D. Purdue's Expert Submissions.

In support of its argument that the plaintiffs have failed to carry their burden of proving specific causation, Purdue has submitted declarations from three experts, each of whom has reviewed the plaintiffs' medical records. In essence, these physicians opine that OxyContin is not the cause of the plaintiffs' injuries because the plaintiffs had engaged in using other opioids, both prior to and concurrent with their use of OxyContin.

Kathleen T. Brady, M.D., Ph.D., is a pharmacologist and psychiatrist. She explains that any opioid, including OxyContin, "if taken repeatedly over an extended

period of time at a sufficiently high dose, causes physical dependence[,]" and that the severity of this dependence depends on various factors, including the duration of opioid intake, the dosage, and the co-utilization of other drugs. (Brady Dec. Concerning McCauley ¶ 24; Brady Dec. Concerning Brummett ¶ 24; Brady Dec. Concerning Deckard ¶ 24.) She further relates that, in her professional experience, patients who used opioid analgesics for pain relief as prescribed developed addiction only if they had a prior history of substance abuse.

Dr. Brady specifically notes that each plaintiff used opioid prescription medications for several years prior to first taking OxyContin. It is her opinion that if any of the plaintiffs "has had a substance use disorder with regard to opioids, he had that substance use disorder long before he was prescribed" OxyContin, and that "any consequences [he] experienced [were] not caused by [OxyContin], but by a history of opioid use." (Brady Dec. Concerning McCauley ¶ 39; Brady Dec. Concerning Brummett ¶ 38; Brady Dec. Concerning Deckard ¶ 37.) Dr. Brady also notes that the plaintiffs continued to treat with other opioid medications along with OxyContin and expresses that any physical dependence they suffered would have been the same even if they had never taken OxyContin. She summarizes that "in no way was the [OxyContin] responsible for causing [the plaintiffs'] dependence on opioids or its consequences." (*Id.*)

In addition, as to plaintiff Deckard, Dr. Brady observes that he was terminated from his employment approximately eleven months after he discontinued his use of OxyContin. She maintains that several factors, including depression, anxiety, and reliance on multiple medications, could have impacted Deckard's workplace performance, and that "his termination cannot be attributed to OxyContin." (Brady Dec. Concerning Deckard ¶ 38.)

John Albert Hagy, Sr., M.D., is a practicing physician and a medical educator with over forty-three years of experience in pain treatment. He has been retained by Purdue as an expert to testify about the under-treatment of pain and the role of opioids in pain management. As an expert, Dr. Hagy maintains, as to McCauley and Deckard, that any consequences suffered by them because of their opioid use was a result of their lengthy histories of opioid use and their simultaneous use of "other psychoactive drugs" and cannot be ascribed to OxyContin. (Hagy Dec. Concerning McCauley ¶ 10; Hagy Dec. Concerning Deckard ¶ 10.) As to Brummett, he similarly opines that any harm suffered by him is attributed to his "long-standing opioid use" and not to OxyContin. (Hagy Dec. Concerning Brummett ¶ 10.)

Marc A. Swanson, M.D., is a practicing physician who is board certified in pain management. He would testify as an expert about the under-treatment of pain, the risks of addiction, and the role of opioids in pain management. He maintains that

"it is rare for a patient without a prior history of abuse to become addicted to opioids prescribed for pain when that patient is properly monitored by the physician." (Swanson Dec. Concerning McCauley ¶ 10.) However, he notes that, although all opioids are comparable in their effects, patients are dissimilar, meaning that metabolism of, tolerance of, and side effects from various opioids will vary amongst individuals. Like the other experts, Dr. Swanson also believes that the plaintiffs' patterns of opioid use were "well established prior to [their] treatment with" OxyContin and for that reason, any consequences suffered by their "opioid use cannot be attributed to" OxyContin. (*Id*. ¶ 30.)

The plaintiffs have not identified any retained experts in the case.

III

Summary judgment is appropriate when there is "no genuine issue of material fact," given the parties' burdens of proof at trial. *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248 (1986); *see* Fed. R. Civ. P. 56(c). In determining whether the moving party has shown that there is no genuine issue of material fact, a court must assess the factual evidence and all inferences to be drawn therefrom in the light most favorable to the non-moving party. *See Ross v. Communications Satellite Corp.,* 759 F.2d 355, 364 (4th Cir. 1985).

Rule 56 "mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Summary judgment is not "a disfavored procedural shortcut," but an important mechanism for weeding out "claims and defenses [that] have no factual basis." *Id.* at 327. It is the "affirmative obligation of the trial judge to prevent factually unsupported claims and defenses from proceeding to trial." *Drewitt v. Pratt*, 999 F.2d 774, 778-79 (4th Cir. 1993) (internal quotation marks omitted).

Although the moving party must provide more than a conclusory statement that there are no genuine issues of material fact to support a motion for summary judgment, it "'need not produce evidence, but simply can argue that there is an absence of evidence by which the nonmovant can prove his case.'" *Cray Communications, Inc. v. Novatel Computer Sys., Inc.,* 33 F.3d 390, 393-94 (4th Cir. 1994) (quoting 10A Charles Alan Wright, et al., *Federal Practice and Procedure* § 2720, at 10 (2d ed. Supp. 1994)); *see also Celotex,* 477 U.S. at 325 ("[T]he burden on the moving party may be discharged by 'showing'—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party's case.").

Once the moving party has met its burden, "the nonmoving party must come forward with 'specific facts showing that there is a *genuine issue for trial.*'" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 587 (1986) (quoting Fed. R. Civ. P. 56(e)). The non-moving party's evidence must be probative, not merely colorable, *Anderson v. Liberty Lobby, Inc.,* 477 U.S. at 256, and cannot be "conclusory statements, without specific evidentiary support," *Causey v. Balog,* 162 F.3d 795, 801-02 (4th Cir. 1998).

IV

The parties agree that Virginia substantive law applies in this diversity case. *See Erie R.R. v. Tompkins*, 304 U.S. 64, 78 (1938).

The plaintiffs represent that their sole remaining claim is that Purdue made false written and oral claims as to OxyContin's abuse potential and that these misrepresentations resulted in the plaintiffs' injuries. Even accepting for the purposes of argument that there is evidence supporting a claim that Purdue is responsible for misrepresenting to the plaintiffs' physicians that OxyContin is less subject to risk of harm than other opioids, it is a settled principle of Virginia tort law that proof of the defendant's tortious conduct and of the plaintiff's injury is not sufficient to establish a cause of action. These elements alone do nothing more than place the dispute in

"the realm of speculation and conjecture." *Blacka v. James*, 139 S.E.2d 47, 50 (Va. 1964). Instead, a plaintiff seeking recovery bears the burden to produce evidence showing that the defendant was the proximate cause of the injury sustained. *Id.* "The proximate cause of an event is that act or omission which, in natural and continuous sequence, unbroken by an efficient intervening cause, produces the event, and without which that event would not have occurred." *Beale v. Jones*, 171 S.E.2d 851, 853 (Va. 1970). Although there may well be more than one proximate cause of an injury, *Panousos v. Allen*, 425 S.E.2d 496, 499 (Va.1993), Virginia courts follow the "but for" rule of proximate causation, under which a defendant is not liable unless the harm would not have occurred but for the defendant's act. *See Sugarland Run Homeowners Ass'n v. Halfmann*, 535 S.E.2d 469, 474 (Va. 2000). Proximate causation is ordinarily a question of fact for the jury but may be resolved by a court as a matter of law when reasonable persons could not differ as to its existence or absence. *See Atkinson v. Scheer*, 508 S.E.2d 68, 71 (Va. 1998).

The evidence is undisputed that McCauley, Brummett, and Deckard were all regular users of opioid pain medications prior to ever being prescribed OxyContin and that they continued to rely on other opioid medications even while taking OxyContin. Plaintiff McCauley had used Tylenol III, Percocet, Endocet, generic oxycodone, and generic hydrocodone for more than ten years prior to ever using

OxyContin. At times, his use of these drugs was quite heavy, as he received multiple prescriptions of the same medications from more than one physician, and the inference is reasonable that McCauley must have relied on a doubled supply of the medications during these times. In addition, even while taking OxyContin, McCauley continued to receive prescriptions for and use additional opioid medications, including Percocet, Lortab, generic oxycodone, Endocet, Tylenol III, Tylenol IV, methadone, and generic hydrocodone.

Plaintiff Brummett routinely relied on Lorcet, Percocet, Lortab, Endocet, and generic hydrocodone for approximately two years before taking OxyContin. He also continued to use Endocet, generic hydrocodone, generic oxycodone, Percocet, Tylox, and methadone while on OxyContin.

Plaintiff Deckard used Lortab, Lorcet, and generic hydrocodone for approximately eighteen months prior to using OxyContin, and the evidence suggests that he accelerated his doses of opioid medications during the pre-OxyContin time phase. Deckard additionally continued with Lortab, Percocet, and generic hydrocodone, while being treated with OxyContin.

Having thoroughly reviewed all the evidence presently in the summary judgment record and viewing all inferences in the light most favorable to the non-

movants, I find that the plaintiffs have failed to create a genuine issue of material fact that their use of OxyContin was the proximate cause of their alleged injuries because there is inadequate evidence to differentiate between the plaintiffs' use of OxyContin and the other medications taken by them.

The record contains unrefuted evidence that all the relevant opioid medications function in the same manner.[13] While the plaintiffs have submitted their physicians' opinions asserting that they suffered from opioid addiction or dependence, only Dr. VanZee's opinion[14] that McCauley "had developed profound opioid addiction during the course of his treatment with OxyContin" specifically invokes OxyContin.[15] (VanZee Aff. ¶ 2.) In contrast, the defendant has advanced three experts, all of whom assert that OxyContin was not the cause of any injuries sustained by the plaintiffs

---

[13] For example, counsel for the plaintiffs asserted in oral argument that "[f]rom a molecular standpoint they're not different [but] from a marketing standpoint the difference [with OxyContin] is amazing." (Summ. J. Hr'g Tr. 44.)

[14] Dr. VanZee has not been identified as a retained expert under Federal Rule of Civil Procedure 26(a)(2)(B). However, the plaintiffs represent that Dr. VanZee would be a "hybrid witness . . . who can testify both as [an] expert . . . and also in [his] capacity as a treating physician." (Summ. J. Hr'g Tr. 38.) *See NGO v. Standard Tools & Equip., Co.,* 197 F.R.D. 263, 265-67 (D. Md. 2000) (holding that treating physician may testify as to opinions based on information learned during course of treatment without Rule 26(a)(2)(B) expert disclosures).

[15] Dr. Adkins' statement in his affidavit that he "observed [McCauley] develop an increasing chemical dependency upon and tolerance of OxyContin" does not go to causation because Dr. Adkins has admitted that he believed McCauley to have been dependent on opioids before ever starting OxyContin. (Adkins Aff. ¶ 3.)

because each of them had been so extensively reliant on other opioids before or during their encounters with OxyContin.

Given the amount and variety of similar opioid drugs McCauley, Brummett, and Deckard were consuming in addition to OxyContin, I cannot infer that OxyContin was the proximate cause of the alleged injuries simply because OxyContin is an opioid and the plaintiffs allege that they suffered opioid addiction or dependence. The plaintiffs are unable to distinguish the oxycodone contained in OxyContin from all the other multiple opioids the plaintiffs utilized. Thus, without more, a jury presented with the facts of this case would be forced to speculate in determining whether OxyContin was a proximate cause of the plaintiffs' alleged injuries.

Dr. VanZee's opinion as to McCauley is also not sufficient to create a genuine issue of material fact as to whether OxyContin use was a proximate cause of McCauley's alleged injuries. As a preliminary matter, it is not clear that Dr. VanZee was familiar with McCauley's entire history and extent of opioid use. Dr. VanZee's treatment records indicate that his familiarity with McCauley's medical history came solely from the information McCauley related to the doctor upon his initial consultation. McCauley shared with Dr. VanZee information about his struggle with OxyContin, but these records contain absolutely no mention of any other drugs McCauley had taken. They also do not recount the intensity and the long duration of

McCauley's dependence on other opioid medications. Thus, Dr. VanZee's opinion is evidently not based on complete information.

In addition, Dr. VanZee's opinion states only his professional belief that McCauley's addictive condition began "during" his treatment with OxyContin. He does not say that OxyContin was the cause of McCauley's addiction. Dr. VanZee's opinion fails to make the issue of causation less speculative or conjectural because it fails to eliminate the possibility that other opioid drugs are to blame for McCauley's injuries. *See Logan v. Montgomery Ward & Co.*, 219 S.E.2d 685, 688 (Va. 1975) (holding that in products liability case the plaintiff's evidence must eliminate the liability of some other party). Moreover, because McCauley used other opioids concurrently with OxyContin, Dr. VanZee's lukewarm opinion actually sheds little light on what the proximate cause of the alleged opioid addiction may have been. The plaintiffs' failure to produce an expert who will opine that OxyContin was the proximate cause of the plaintiffs' alleged injuries is fatal to their case.

The plaintiffs emphasize in their argument opposing summary judgment that there may be more than one proximate cause of an injury and that, at the very least, OxyContin was a contributing factor to the plaintiffs' injuries. In support, they quote *Molchon v. Tyler*, 546 S.E.2d 691 (Va. 2001), for the proposition that "when the evidence does not wholly exclude a defendant's negligence as a contributing cause

of the plaintiff's injuries as a matter of law, proximate causation becomes a question of fact for the jury's determination." *Id.* at 696. *Molchon* dealt specifically with the issue of proof of proximate causation when there existed an independent intervening cause between the defendant's negligence and the plaintiff's injuries. The statement cited by the plaintiffs, when read in context, refers to the original act of negligence as a contributing cause rather than to the intervening act of negligence. Even if *Molchon* was analogized to the facts at hand, the plaintiffs would have to argue that OxyContin was an independent intervening cause, in which case *Molchon* sheds no additional light on the plaintiffs' burden because they would still need to show that OxyContin was a cause of their injuries. In addition, even where the facts of a case suggest that an injury was caused by more than one cause, a plaintiff must still link the defendant's act to the injury by proving specific causation and may not rely on mere speculation and conjecture:

> When there is substantial evidence introduced which tends to prove that plaintiff's injuries may have resulted from one of two causes, for one of which the defendant is responsible and for the other of which he is not responsible, . . . the plaintiff must fail if his evidence does not prove that his damages were produced by the negligence of the defendant; and he must also fail if it appears from the evidence just as probable that damages were caused by one as by the other because the plaintiff must make out his case by a preponderance of the evidence.

Boyle v. United Techs. Corp., 792 F.2d 413, 415-16 (4th Cir. 1986) (quoting *Cape Charles Flying Serv., Inc. v. Nottingham*, 47 S.E.2d 540, 544 (Va. 1948)). There is simply no evidence in the present record showing that OxyContin was a proximate cause of the plaintiffs' injuries or that no other party was responsible for the plaintiffs' injuries, and the facts of the case do not permit such inferences.

The plaintiffs explain that the lack of an expert to testify that OxyContin was a proximate cause of their alleged injuries is not critical to their case because the primary issues in the case "clearly [lie] in the range of the jury's common knowledge and experience." (Resp. to Mot. for Summ. J. 22.) In particular, the plaintiffs argue that the jury, after hearing the evidence at the trial, can rely on widely available "[c]ommonsense guideposts" to determine whether each of the plaintiffs exhibited a state of addiction, and can determine proximate causation based on whether these symptoms materialized before or after the plaintiffs commenced their treatment with OxyContin. (*Id.* at 23.) I find it difficult to accept that the facts of this case, particularly the plaintiffs' complex medical histories, are amenable to such clear-cut parsing. However, even as a matter of law, the plaintiffs' arguments are misplaced.

It is of course true that Virginia tort law does not mandate expert testimony to show proof of causation in every case. However, in a products liability action, proof of causation must ordinarily be supported by expert testimony because of the

complexity of the causation facts. *See Rohrbough v. Wyeth Labs., Inc.*, 916 F.2d 970, 972 (4th Cir. 1990) (holding that essential element of causation in products liability action involving medical vaccine must be proved by expert testimony under West Virginia law); *Hartwell v. Danek Med., Inc.*, 47 F. Supp. 2d 703, 707 (W.D. Va. 1999) (holding same as to products liability case involving medical device under Virginia law).[16] In the present case, pain, tolerance, dependence, abuse, and addiction are complex medical conditions whose symptoms may overlap and that are properly diagnosed by experienced professionals with appropriate medical knowledge. Likewise, the plaintiffs' reference to the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders*[17] counters their own point. The *Manual* qualifies in its "Introduction" that "there is no assumption that each category of mental disorder is a completely discrete entity with absolute boundaries dividing it from other mental disorders or from no mental disorder. There is also no

---

[16] The plaintiffs, in their brief in opposition to summary judgment, refer to no products liability actions in which experts have been deemed unnecessary. Instead, they rely on malpractice actions for their proposition. Not only are they distinguishable on that fact alone, these cases are also not persuasive because they do not address complex causation factors such as are present in this case. *See Beverly Enters.-Va., Inc.*, 441 S.E.2d 1, 3 (Va. 1994) (holding that in "rare instances" expert testimony is unnecessary in medical malpractice actions to prove negligence, where circumstances are "clearly" within the jury's "common knowledge and experience").

[17] Am. Psychiatric Ass'n, *Diagnosis & Statistical Manual of Mental Disorders, Text Revision* (4th ed. 2000).

assumption that all individuals described as having the same mental disorder are alike in all important ways." (Purdue Summ. J. Reply Mem. Ex. A.) In addition, the *Manual* acknowledges the complexity of the disorders it addresses and cautions that only "individuals with appropriate clinical training and experience in diagnosis[,]" and not "untrained individuals[,]" should apply the criteria to assess the existence of certain conditions. (*Id*.)

Moreover, the plaintiffs' argument proposes that the jury be allowed to apply the logical fallacy of *post hoc, ergo propter hoc*, or of confusing sequence with causation. The plaintiffs' burden is greater than merely showing a temporal link between their use of OxyContin and any injuries they sustained. Instead, it is evidence of the causal link between OxyContin and their injuries that the plaintiffs lack. *See Rohrbough*, 916 F.2d at 974 (holding that expert testimony showing a temporal link between administrations of vaccine and patients' symptoms was insufficient to prove causation).

Because the plaintiffs have failed to distinguish between the impact of OxyContin and other opioids used by them, they are essentially attempting in this case to recover from Purdue damages for injuries that have not been established to be directly attributable to Purdue. *See Roche v. Lincoln Prop. Co.*, 278 F. Supp. 2d 744, 750 (E.D. Va. 2003) (holding that expert testimony that failed to distinguish between

harm attributable to mold and to other common allergens was insufficient to prove causation). Based on the evidence produced, no reasonable juror could find that OxyContin was the proximate cause of the plaintiffs' injuries, and the plaintiffs have therefore failed to make a prima facie case of liability.

Because the plaintiffs are unable to prove their case as to the basic element of causation, it is not necessary for me to consider the other grounds presented by the defendants in support of summary judgment.

V

As a trial judge hearing criminal cases, I am unfortunately all too familiar with the human misery caused by the abuse of prescription drugs, particularly including OxyContin. Lives wasted, families disrupted, communities devastated, because of misuse of these drugs. Did Purdue over-sell OxyContin, for its own profit? Does the relief afforded by high-dosage opioids to those with severe, life-altering pain outweigh the risks of harm from addiction? These cases do not answer those questions. I simply hold that because of the particular circumstances of these three plaintiffs, the evidence does not support a finding that OxyContin, or Purdue, caused them injury. Purdue's motions for summary judgment will thus be granted and final judgments entered.

DATED: August 18, 2004

/s/ JAMES P. JONES
Chief United States District Judge