

What Happened to Rule 11?

By Amy K. Fisher

The “sue first and investigate later” mentality abuses the judicial process and drains our clients’ resources.

Baseless Pleadings and Product Identification

The Federal Rules of Civil Procedure require attorneys and their clients to “stop, think, investigate, and research” before filing papers to initiate suits or to conduct litigation. *Gaiardo v. Ethyl Corp.*, 835 F.2d 479, 482 (3d Cir. 1987).

Specifically, FED. R. CIV. P. 11 requires an attorney—or a party, personally, if unrepresented—to sign every pleading to certify that “to the best of the person’s knowledge, information, and belief, formed after an inquiry reasonable under the circumstances: ... the factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery[.]” FED. R. CIV. P. 11(b)(3).

Defense lawyers and our clients generally assume that plaintiffs first obtain the relevant medical records and contact medical providers to identify relevant products *before* filing suit. See *Aaberg v. ACandS Inc.*, 152 F.R.D. 498, 501 (D. Md. 1994) (there is a “reasonable expectation[.]... that a complaint at least identify... the specific products... that, plaintiff claims, caused his injury”). Yet many litigants commence legal actions without conducting research to uncover the necessary information to identify those products. Perhaps counsel signed up a client over the Internet, without screen-

ing the records or speaking with the client. Perhaps he or she was motivated by a rapidly running statute of limitations. Perhaps plaintiff’s counsel only dabbles in pharmaceutical litigation and has no concept of the steps necessary to identify a product. Perhaps a provider’s notes do not definitively identify a product, instead only mentioning a general, or generic, product name. Regardless of the reason, FED. R. CIV. P. 11 requires more effort—either an investigation of a patient’s pharmacy and billing records or a discussion with the health care provider about a product’s identity.

Nonetheless, it is in vogue in the plaintiffs’ bar to file claims against a slew of potential defendants and sort out the right ones during discovery—an approach that completely nullifies FED. R. CIV. P. 11(b), which mandates that before initiating a suit, a plaintiff should engage in an “inquiry reasonable under the circumstances” to find evidentiary support for all factual contentions. FED. R. CIV. P. 11(b)(3). Just this year, a California district court



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expressly held that those tactics ran afoul of Rule 11 when it rejected the plaintiffs' request for leave to conduct further discovery in an attempt to amend their complaint to identify the specific medications at issue and the responsible defendants:

Despite alleging no factual basis for their claims against [defendant] and indeed admitting that they have none, Plaintiffs request discovery in order to identify the anesthetic used, arguing that discovery may reveal which one of the eight anesthetic manufacturer defendants they sued, if any, manufactured the anesthetic [plaintiff] received. However, a plaintiff who fails to meet the pleading requirements of Rule 8 is not entitled to conduct discovery with the hope that it might then permit her to state a claim. Further, allowing plaintiffs to file first and investigate later, as Plaintiffs here would have done, would be contrary to Rule 11(b), which mandates an "inquiry reasonable under the circumstances" into the evidentiary support for all factual contentions prior to filing a pleading.

Timmons v. Linvatec Corp. et al., 263 F.R.D. 582, 585 (C.D. Cal. 2010) (citations omitted).

As mass tort litigation has blossomed over the years, so have the number of cases in which product identification is an issue. Sadly, our pharmaceutical industry clients can spend enormous amounts of time and money defending cases in which the products at issue were not theirs. For our clients it is crucial to quickly and inexpensively dispose of these ostensibly frivolous cases while preventing future filings. The federal rules specifically disallow baseless pleadings and, courtesy of *Twombly* and *Iqbal*, Federal Rules of Civil Procedure 8 and 12 now have some teeth. There are several approaches defense counsel can take in cases such as these. Client goals and case-specific facts dictate which strategy is optimal.

Typically, when product identification is an issue, a complaint's lack of specificity will range from identifying only a class of products to a compound name or various trade names. Multiple manufacturers are often named as defendants, clearly indicating that counsel has not conclusively established product identification and that further investigation or motion practice is warranted. If a complaint names only one

defendant but fails to identify the product by trade name, while one could assume that the product has been identified, the complaint may still fail to meet pleading requirements. In *Haskins v. Zimmer Holdings Inc.*, 2010 WL 342552 (D. Vt. Jan. 29, 2010), the plaintiffs identified the anesthetic at issue by compound name only—bupivacaine. The plaintiffs argued that their complaint sufficiently identified the product and proper defendant because the defendant was the only bupivacaine manufacturer named. The plaintiffs were claiming damage caused by the administration of bupivacaine, and the relevant operative report clearly identified the defendant's product by brand name. *Id.* at *1. The court disagreed:

Plaintiffs' arguments reveal a fundamental misconception of the pleading requirements. A document not attached to the complaint cannot save deficiently pleaded claims. Whether AstraZeneca knows which medication was administered to Plaintiff following her surgery is irrelevant and does not affect whether Plaintiffs adequately pleaded their claims in the complaint. Further, rather than expecting the Court to 'infer that [AstraZeneca] is the proper defendant,' to survive a motion to dismiss Plaintiffs must at least allege in their complaint that an AstraZeneca product was administered to Ms. Haskins via the pain pump following her surgery. This threshold allegation is necessary to show a plausible entitlement to relief.

Id. at *2 (citations omitted). *See also Gilmore v. DJO Inc.*, 663 F. Supp. 2d 856, 862 (D. Ariz. 2009) (court disregarding extrinsic evidence on motion to dismiss "because even if the [defendant] knew which medication has been used that would not mean that plaintiffs' claims were adequately pleaded.")

Educating Plaintiffs' Counsel

While the naming convention for drugs is elementary for defense lawyers in this practice area, many plaintiffs' counsel experimenting with pharmaceutical litigation may lack even a basic understanding of how drugs are named or identified. A client may resist doing an opposing counsel's work for him or her, but it may be necessary to either personally conduct product identification research or educate a plaintiff's

counsel on how products receive names and how to identify them.

An initial pre- or postservice letter to opposing counsel, enclosing a company's product guide and relevant portions of some or all of the items discussed below, such as a copy of an entry from the Physician's Desk Reference, or the National Drug Code number, threatening motion prac-

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tice based on a complaint's failure to allege a causal relationship between a product and your client, will occasionally result in a quick and clean voluntary dismissal. At a minimum, an initial meet-and-confer letter is often required by local practice prior to filing a motion to dismiss.

Primer for Rookie Opposing Counsel on Drug Identification

Drugs often have several names, and any combination may be found in medical records. A drug has a chemical or compound name, which describes the atomic or molecular structure of the drug. When a drug is approved by the Food and Drug Administration (FDA), it receives a generic name and a trade name, also referred to as the proprietary or brand name. The generic name is typically a shorthand version of the drug's chemical name. The trade name is provided by the company requesting approval for the product and identifies the product as the exclusive property of that company. While a drug is under patent protection, the company that holds the patent markets the drug under its trade name. After a patent has expired, other companies may produce and sell a generic version of the drug with FDA approval. A generic drug maker can sell the generic version



under its “official” generic name, which it received when the FDA first approved it, or a company manufacturing a generic version can create its own trade name, referred to as a branded generic, but it cannot use the trade name developed by the original patent holder. Once a drug patent expires, the original innovator may market the company’s original product under either

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the generic name or the trade name. As a result, the same generic drug may be sold under either the official generic name or one of many trade names.

Occasionally, you can simply tell an opponent that your client never sold the type of product at issue or, at least, did not sell it during the relevant time frame. Most companies publish a product guide, which lists all of the products sold and distributed by a particular company and their National Drug Code numbers. Much of this information is also available in the Physicians’ Desk Reference (PDR), a widely available, annually updated, commercially published compilation of manufacturers’ prescribing information on prescription medications.

The Orange Book

A lesser known source of product identification information than the PDR is the *Approved Drug Products with Therapeutic Equivalence Evaluations*—commonly known as the “Orange Book.” Under federal law, no one may market or distribute a drug that it is not authorized to market or distribute. 21 U.S.C. §355(a). The companies authorized to market and distribute particular drugs are listed in the Orange Book, which federal law requires the FDA to publish and update every 30 days. 21 U.S.C. §355(j)(7)(A)(ii); *Eisai Co., Ltd. v. Mut. Pharm. Co. Inc.*, 2007 WL 4556958, at *1 (D.N.J. Dec.

20, 2007) (explaining that all drug manufacturers must submit a new drug application to the FDA for approval and that once approved, the FDA lists the drug information in the “Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the ‘Orange Book’”); *In re K-Dur Antitrust Litig.*, 2009 WL 508869, at *2 (D.N.J. Feb. 6, 2009). The information maintained in the Orange Book is based on the FDA’s own records and research. 21 U.S.C. §355(j)(7)(A); 45 Fed. Reg. 72582 (“[a]ll drug products on the List have been fully reviewed and approved for safety and effectiveness by the FDA”); see also *Merck & Co. Inc. v. Hi-Tech Pharmacal Co., Inc.*, 482 F.3d 1317, 1318 (Fed. Cir. 2007) (recognizing that the Orange Book is a register published by the FDA that provides notice of patents covering name brand drugs).

The Orange Book can be very helpful in demonstrating to opposing counsel, or a court, that your client did not market, sell or distribute either the compound at issue or a particular trade name product in the relevant time frame, but rather, the relevant product was sold in the United States exclusively by others. The Orange Book primarily lists all prescription drugs by chemical name. Under each chemical name category the book lists the various trade names and formulations and the distributors of each. It also includes an appendix sorting product names by applicant, listing all of the products that a particular manufacturer is authorized to distribute.

The Electronic Orange Book (EOB) is updated daily and is searchable by active ingredient, proprietary name, patent, applicant holder, and application Number. U.S. Food and Drug Admin., *Electronic Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>. The most recent *Annual Edition* and the *Current Cumulative Supplement* are also available in PDF on the FDA website. U.S. Food and Drug Admin., Orange Book Publications, <http://www.accessdata.fda.gov/scripts/cder/ob/eclink.cfm>. Prior to 2005, which is when the *Annual Edition* and *Current Cumulative Supplement* were made available exclusively electronically, libraries designated as federal repositories received a copy of the Orange Book on microfiche. Subsequently, many of these libraries con-

tinued to print and maintain copies from the Internet. Interested parties can obtain copies of the relevant years’ Orange Books directly from those libraries for copying costs or through the Freedom of Information Act (FOIA), although these requests often take several months to process. Federal Depository Library Directory, <http://catalog.gpo.gov/fdlpdir/FDLPdir.jsp>.

Courts may take judicial notice of the Orange Book because it is “not subject to reasonable dispute in that it is... capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.” FED. R. EVID. 201(b); see also *Timmons*, 263 F.R.D. at 585 (taking judicial notice of the Orange Book and holding that “judicially-noticeable facts demonstrate that AstraZeneca did not manufacture or sell Marcaine in the United States during the relevant time period”); *Horne v. Novartis Pharm. Corp.*, 541 F. Supp. 2d 768, 777 (W.D.N.C. 2008) (stating that a court “may take judicial notice of and consider the public records of the FDA... without transforming this motion into a motion for summary judgment”).

National Drug Code System

Another useful tool in identifying a specific product and seller of a product at issue in a suit is the National Drug Code (NDC) number. The Drug Listing Act of 1972 requires registered drug establishments to provide the FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. 21 U.S.C. §360. Drug products are identified and reported using a unique, three-segment number, the NDC number, which is a universal product identifier for human drugs. 21 C.F.R. §§207.25, 207.35.

A drug’s NDC number identifies the labeler, product, and trade package size. The first segment, the labeler code, is assigned by the FDA. 21 C.F.R. §207.35(b)(2)(i). A labeler is any entity that manufactures, including a repacker or relabeler, or distributes, under its own name, a drug. The second segment, the product code, identifies a specific strength, dosage form, and formulation for a particular firm. The third segment, the package code, identifies package sizes and types. The product and package codes are assigned by the entity. 21 C.F.R. §207.35(b)(2)(ii). Information about

NDC numbers and the *National Drug Code Directory*, which the FDA updates regularly, is located on the FDA's website. U.S. Food and Drug Admin., National Drug Code Directory, <http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm>. The fully searchable *National Drug Code Directory* is available online at <http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm>.

Determining Product Identity

Even if your opposing counsel understands drug identification, you or a plaintiff's counsel must still take steps to determine if the plaintiff's medical provider can supply evidence identifying the product at issue. Although you should obtain medical records, as discussed below, those records may not conclusively identify a product, requiring you to search other types of records.

Basic Medical Records

Obviously, the first step is to review the relevant medical records. It is necessary to review the physician's progress notes and the records of the pharmacy where a prescription was filled. If a plaintiff's use of a product stemmed from a hospital setting, relevant records would include (1) the physician progress notes, (2) nursing notes, (3) the intra-operative report, (4) patient-specific billing records, and (5) patient-specific pharmacy records. Often a plaintiff's insurance records will include a drug NDC number along with a product's generic or trade name.

A patient is typically entitled to obtain these records without a subpoena, and defense counsel should immediately demand, either informally or formally, such records. Occasionally, this is all that is necessary because a provider's records may reveal the product's trade name or NDC number. In those situations, FED. R. CIV. P. 11 is clearly implicated because your opposing counsel clearly has failed to take even this most basic step before filing suit. If a plaintiff's medical records reveal that the product at issue is not your client's, and your opposing counsel refuses to voluntarily dismiss the suit, both a motion to dismiss for failure to state a claim and a sanctions motion may be warranted. Even with a voluntary dismissal, requesting costs may be appropriate depending on the law of the venue.

Other Records

If basic medical records offer inconclusive evidence that a provider used the drug or device at issue, you can request other records, such as hospital or pharmacy inventory or national wholesale distributor shipping records. This strategy, however, has downsides. First, such records are never plaintiff-specific and can help you only if one single company supplied the relevant product or formulation to the provider during the relevant timeframe. Second, if you engage in such discovery, it is difficult to contemporaneously argue in a motion to dismiss that a court should dismiss the complaint without leave to conduct further discovery or amend the complaint. However, depending on the controlling jurisdiction's law, occasionally the most cost-effective route to dismissal is conducting limited, product identification-only discovery and, ultimately, filing a motion for summary judgment.

Motion Practice Under Federal Rules 8 and 12

There is a developing body of case law that supports a swift motion to dismiss under Federal Rules of Civil Procedure 8 and 12. Rule 8 requires that a complaint set forth "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). To survive a motion to dismiss, "[f]actual allegations must be enough to raise a right to relief above the speculative level" and must state "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007). A complaint need not contain detailed factual allegations, but must provide more than "a formulaic recitation of the elements of a cause of action." *Id.* at 555. And, as noted in *Ashcroft v. Iqbal*, "[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference *the defendant* is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (emphasis added).

In filing a Rule 12 motion to dismiss in this context, a defendant can argue that (1) the plaintiff has not demonstrated a causal connection between the defendant's product and the alleged injury because the plaintiff failed to identify the specific medication that the plaintiff received or

the specific manufacturer; (2) the pleadings are formulaic, vague, and conclusory; (3) the allegations are not factually specific enough to state a plausible claim under FED. R. CIV. P. 8; and (4) the plaintiff has failed to plead individualized allegations against multiple defendants. *See Atuahene v. City of Hartford*, 10 Fed. Appx. 33, 34 (2d Cir. 2001) (affirming dismissal because

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complaint "lump[ed] all the defendants together in each claim and provid[ed] no factual basis to distinguish their conduct"). Another argument that you can offer is that the plaintiff failed to plead facts sufficient to establish standing. *See Daugherty v. I-Flow, Inc.*, 2010 WL 2034835, at *3 (N.D. Tex. April 29, 2010) (dismissing the plaintiff's complaint for lack of product identification against named defendants, holding that plaintiff "has not pled facts sufficient to establish that he has Article III standing to pursue a direct claim against any of the defendants for his own personal injury."). Also, if a plaintiff does not adequately identify the product at issue, fraud claims (which may lack the requisite particularity regardless of failure to plead product identification) are subject to dismissal under FED. R. CIV. P. 9(b). *See Gilmore*, 663 F. Supp. 2d at 860 (dismissing fraud claims for failure to comply with Rule 9(b)).

A defendant can argue that a plaintiff has either sued a host of defendants without alleging specific use of any particular defendant's product, or simply that the plaintiff has failed to plead in the complaint that one particular defendant manufactured the product. In most cases, a plaintiff's complaint will fall short of the requirements of Federal Rules of Civil Procedure 8 and 11, even failing to plead a claim "upon information and belief." Regardless,



courts have held that determining compliance with Federal Rules of Civil Procedure 11(b) and 8 require separate inquiries; merely alleging compliance with Rule 11 does not release a party from the obligation to advance sufficient factual allegations to satisfy Rule 8. *Elan Microelectronics Corp. v. Apple, Inc.*, 2009 WL 2972374, at *4 (N.D. Cal. Sept. 14, 2009). The pain pump litiga-

A plaintiff cannot establish the essential element of causation if discovery has yielded no evidence that a defendant's product was used by the plaintiff.

tion, as well as other helpful cases, have yielded numerous recent district court opinions (regarding pharmaceuticals and devices) dismissing cases at the initial stages due to failure to plead product identification. *Wolicki-Gables v. Arrow International, Inc.*, 2008 WL 2773721 (M.D. Fla. June 17, 2008); *Sherman v. Stryker Corp.*, 2009 WL 2241664 (C.D. Cal. Mar. 30, 2009); *Dittman v. DJO, LLC*, 2009 WL 3246128 (D. Colo. Oct. 5, 2009); *Gilmore*, 663 F. Supp. 2d 856; *Combs v. Stryker Corp.*, 2009 WL 4929110 (E.D. Cal. Dec. 14, 2009); *Gomez v. Pfizer, Inc.*, 675 F. Supp. 2d 1159 (S.D. Fla. 2009); *Timmons*, 263 F.R.D. 582; *Haskins*, 2010 WL 342552; *Washington v. Wyeth, Inc.*, 2010 WL 450351 (W.D. La. Feb. 8, 2010); *Adams v. I-Flow Corp.*, 2010 WL 1339948 (C.D. Cal. Mar. 30, 2010); *In re: Fosamax Products Liability Litigation*, 2010 WL 1654156 (S.D.N.Y. Apr. 9, 2010); *Peterson v. Breg, Inc.*, 2010 WL 2044248 (D. Ariz. Apr. 29, 2010); *Daughtery*, 2010 WL 2034835; *Kester v. Zimmer Holdings Inc.*, 2010 WL 2696467 (W.D. Pa. June 16, 2010). *But see Jozwiak v. Stryker Corp.*, 2010 WL 743834, at *5 (M.D. Fla. Feb. 26, 2010) (plaintiffs plausibly established each defendants' relationship to the product at issue by alleging that each manufactured and sold the product at issue; court rejected

as premature and assuming of facts not in evidence the defendants' argument that both could not have manufactured specific product); *Koch v. I-Flow Corp.*, ___ F. Supp. 2d ___, 2010 WL 2265670 (D.R.I. June 7, 2010).

A defendant should further argue that a court should not allow a plaintiff additional discovery. That "shoot first, aim later" approach would violate Federal Rule 8 and be antithetical to Federal Rule 11(b). As the advisory committee comment to Rule 11 explained, "[t]olerance of factual contentions in initial pleadings by plaintiffs or defendants when specifically identified as made on information and belief *does not relieve litigants from the obligation to conduct an appropriate investigation into the facts that is reasonable under the circumstances; it is not a license to join parties, make claims, or present defenses without any factual basis or justification.*" FED. R. Civ. P. 11 advisory committee's note, 1993 Amendments §§(b) and (c), ¶3 (West 2009) (emphasis added). The Supreme Court has made it clear that if a plaintiff fails to meet the pleadings requirements of FED. R. Civ. P. 8(a)(2) at the outset, a court should not allow that plaintiff to proceed to the discovery phase of the case in the hope that discovery might provide the evidence needed to support a claim against the defendant. *See Twombly*, 550 U.S. at 559 ("[i]t is no answer to say that a claim just shy of a plausible entitlement to relief can, if groundless, be weeded out early in the discovery process through 'careful case management'..."); *Iqbal*, 129 S. Ct. at 1954-55 ("[b]ecause [plaintiff's] complaint is deficient under Rule 8, he is not entitled to discovery, cabined or otherwise"). Granting a plaintiff's request for discovery "would allow plaintiffs to name anyone as a defendant in a lawsuit without making the allegations necessary to state a claim upon which relief might be granted and then to seek to discover in hope of finding a basis for a claim." *In re Rezulin Prods. Liab. Litig.*, 168 F. Supp. 2d 136, 141 (S.D.N.Y. 2001).

It is widely held that although a district court has discretion to allow leave to amend a complaint under FED. R. Civ. P. 15(a), if amendment is futile, dismissal without leave to amend is appropriate. *See, e.g., U.S. ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 822 (8th Cir. 2009)

("[f]utility is a valid basis for denying leave to amend"). Drug and medical device cases are no different:

Plaintiffs' Complaint does not allege that their injuries were caused by [the defendant]. They admit in their Opposition that they do not know which entity manufactured the anesthetic administered to [the plaintiff]. Thus, Plaintiffs admit that they do not have the requisite evidentiary support to permit them in good faith to amend their Complaint to state a claim against [the defendant]. Consequently, leave to amend would be futile. *Timmons*, 263 F.R.D. at 585-86. *See also Combs*, 2009 WL 4929110, at *2-3; *Sherman*, 2009 WL 2241664, at *5; *Dittman*, 2009 WL 3246128, at *3 (all granting motions to dismiss with prejudice and without leave to conduct discovery or amend complaint).

Many states have adopted what several commentators call the "Twiqbal" interpretation of Rule 8. *See Iannacchino v. Ford Motor Company*, 888 N.E.2d 879, 890 (Mass. 2008) ("retiring" previous standard for evaluating adequacy of complaint articulated by *Conley v. Gibson* and formally adopting *Twombly* standard). Many others have equally valuable pre-"Twiqbal" decisions. *See Bockrath v. Aldrich Chem. Co.*, 21 Cal.4th 71, 80 (Cal. 1999) (holding that California law requires plaintiffs to plead the identity of the specific, alleged injury-causing product, as well as the specific defendant who manufactured and distributed the product). Consequently, defense lawyers have forceful tools for motion practice in both federal and state courts.

Summary Judgment Motions

Unfortunately, not all jurisdictions require a plaintiff to identify a product at the initial pleadings stage. *See Koch*, 2010 WL 2265670, at *4 ("Defendants' assertion that Rhode Island products liability law requires product identification is mistimed. Yes, the product must be identified, but failure to do so is not fatal at the initial pleading stage.") In those cases, consider filing for summary judgment after obtaining all of the records.

It is well established that to survive summary judgment a plaintiff asserting product liability claims against a manufacturer must establish that the injury-causing product was manufactured, designed,

or distributed by the defendant whom he or she has sued. *See, e.g., Garcia v. Pfizer, Inc.*, 268 Fed. Appx. 270 (5th Cir. 2008) (holding it insufficient for plaintiff to demonstrate that Wyeth distributed a substantial number of doses of relevant vaccine to the state during relevant time period; rather plaintiff must produce evidence Wyeth actually supplied the vaccine she ingested and which allegedly caused her injury); *White v. Celotex Corp.*, 907 F.2d 104, 105–06 (9th Cir. 1990) (affirming summary judgment where plaintiffs “were unable to identify any of the Defendants as having manufactured, sold or distributed any particular... product with which [the decedent] came in contact”). A plaintiff must demonstrate that there is at least a genuine issue of material fact about whether his or her injuries were caused by a named defendant’s product. As a matter of law, a plaintiff cannot establish the essential element of causation if discovery has yielded no evidence that a defendant’s product was used by the plaintiff. If awarded summary judgment, the moving party can often submit a bill of costs under local rule to recover certain costs.

Costs and Sanctions Motions

In addition to dispositive motion practice, a motion for costs or sanctions may be warranted. A court can award attorneys’ fees and sanctions for a violation of Fed. R. Civ. P. 11(c), which may be justified if the plaintiff and his or her counsel have failed to comply with “Rule 11’s obligation to conduct a reasonable inquiry into the law and facts before signing papers filed with the court...” *Rentz v. Dynasty Apparel Industries, Inc.*, 556 F.3d 389, 401 (6th Cir. 2009). Defendants must be sure to comply with Fed. R. Civ. P. 11’s “safe harbor” provision requiring that a party seeking sanctions first serve the motion to the opposing party and then wait at least 21 days, or another period designated by the court, before filing the motion. Fed. R. Civ. P. 11(c)(2). Moreover, a Fed. R. Civ. P. 11 motion for sanctions must be made separately from any other motion.

Courts strongly disfavor Rule 11 motions, especially when used as a “bargaining chip... in hopes of securing a strategic advantage.” *Bartronics, Inc. v. Power-One, Inc.*, 245 F.R.D. 532, 538 (S.D.

Ala. 2007). Defense counsel should employ Rule 11 motions sparingly and consider other options, such as seeking attorneys’ fees or costs under local rules or statutes within the body of substantive motions.

Potential Pitfalls

Watch out for several pitfalls when plaintiffs have inadequately identified specific products in their complaints. To avoid dismissal, they may try to (1) argue that they couldn’t investigate adequately because they didn’t have subpoena power, (2) sue brand name manufacturers along with generic manufacturers even though plaintiffs only took generic drugs, (3) impose market-share liability or burden shifting, or (4) argue that pleading in the alternative allows them to file suit without identifying the product at issue and responsible defendant. Also, your co-defendants can create obstacles to disposing of cases quickly.

No Subpoena Power

Counsel may claim that their ability to investigate presuit was curtailed because they did not have subpoena power. Nevertheless, most often the information necessary to determine a product’s identity is in a plaintiff’s records, and a patient can usually obtain those without subpoena.

Brand vs. Generic

A plaintiff suing the sellers of both the brand name and generic versions of a medication may argue that the name brand manufacturer should be held liable to an individual who took only the generic version for alleged defects in the generic’s labeling. *See Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008). This argument offends traditional principles of causation, and the majority of courts addressing the issue since *Conte* have rejected outright the argument and *Conte*’s holding. *See Finnicum v. Wyeth, Inc.*, ___ F. Supp. 2d ___, 2010 WL 1718204 (E.D. Tex. Apr. 28, 2010); *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009); *Meade v. Parsley*, 2009 WL 3806716 (S.D. W. Va. Nov. 13, 2009); *Moretti v. Wyeth*, 2009 WL 749532 (D. Nev. Mar. 20, 2009). With generic manufacturers’ ability to make a preemption argument curtailed by *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), a justification no longer exists for expanding liability to a

brand name manufacturer when a plaintiff did not use the brand name product and instead ingested the generic version. Consequently, the threshold causation burden of product identification should hold equally true in cases in which a plaintiff purchases and ingests the generic version of a drug that is manufactured by a company separate from the name brand innovator of the drug.

Market-Share Liability and Burden-Shifting

Market-share liability was first imposed in pharmaceutical litigation in DES cases. While many states have subsequently declined to adopt market-share liability, plaintiffs continue to raise this tired theory when they are unable or unwilling to identify the product at issue. Additionally, plaintiffs may argue that burden-shifting is appropriate under an application of *Summers v. Tice*, 199 P.2d 1 (Cal. 1948) and the Restatement (Second) of Torts, §433B(3). Under the rule articulated by both, if two defendants acted negligently toward a plaintiff, the burden shifts to each to prove that it did not cause the plaintiff’s injury. You can rebut market-share liability or burden-shifting arguments can by differentiating the facts in your case from DES or other cases applying either theory, such as: the product *is* identifiable; it is made by a fewer number of manufacturers; the product exposure is more recent; and the product was properly labeled. Touting public policy is another effective argument: the defendants are not in any better position to identify the product or manufacturer at issue; and the plaintiff is not left without a remedy, if there is a medical malpractice or negligent record keeping claim. Or, you can also clarify the law: this jurisdiction has rejected market-share liability, or burden-shifting, applications in this context. *See, e.g., Cloud v. Pfizer, Inc.*, 198 F. Supp. 2d 1118, 1138–39 (D. Ariz. 2001) (noting that burden-shifting only occurs after the plaintiff has shown general and specific causation); *Lee v. Baxter Health Care Corp.*, 898 F.2d 146, 1990 WL 27325, at *4 (4th Cir. 1990) (refusing to impose market-share liability because Maryland requires product identification); *Matter of New York State Silicone Breast Implant Litig.*, 631 N.Y.S.2d 491, 494 (N.Y. Sup. Ct. 1995) (not-



ing that market-share liability should not be applied to breast implants where the products are not fungible, designs differ, warnings vary, and the majority of women involved in the litigation were able to identify the manufacturer).

Pleading in the Alternative

A plaintiff may contend that the complaint is sufficient because FED. R. CIV. P. 8(d) allows a plaintiff to plead in the alternative and assert inconsistent theories—in this context, that two or more defendants sold the product at issue. Even though FED. R. CIV. P. 8(d) allows pleading of alternative and inconsistent theories, this does not relieve a plaintiff of his or her burden to meet the requisites of Rule 8 for each theory, as set forth in *Twombly*. To the contrary, each of a plaintiff's theories must satisfy FED. R. CIV. P. 8 and state a viable claim, regardless of the number of theories presented. See *Kester*, 2010 WL 2696467, at *7 (rejecting the plaintiff's argument that Rule 8(d) permits pleading in the alter-

native if a plaintiff is unable to determine which of multiple defendants manufactured the product); *Baisden v. I'm Ready Prods., Inc.*, 2008 WL 2118170, at *9–11 (S.D. Tex. 2008); *Orange County Choppers, Inc. v. Olaes Enters.*, 497 F. Supp. 2d 541, 557 (S.D.N.Y. 2007); *Song v. PIL, L.L.C.*, 640 F. Supp. 2d 1011, 1016 (N.D. Ill. 2009). *But see Koch*, 2010 WL 2265670, at *4 (at the initial stage of litigation the plaintiff's alternative pleading against multiple defendants without product identification was facially plausible).

Co-Defendants

Perhaps surprisingly, a final hurdle can often come from our colleagues. Too often, our co-defendants will refuse to stipulate to a dismissal for fear that later discovery will implicate our client's product and the co-defendant's right to file a crossclaim against us or assert a nonparty defense will be lost. The rebuttals to this position are usually fact- and jurisdiction-specific. Often, the time for filing crossclaims has

already expired, or under the law of the jurisdiction agreeing to stipulate to a dismissal does not waive a nonparty defense. If your client has filed neither answer nor summary judgment, remind the plaintiff's counsel of the availability of voluntary dismissal under FED. R. CIV. P. 41(a)(1)(A)(i), in which the stipulation of the other appearing parties is unnecessary nor could be held against them.

Conclusion

The "sue first and investigate later" mentality abuses the judicial process and drains our client's resources. As compliance with FED. R. CIV. P. 11 erodes, perhaps the strategies identified above will assist you to achieve dismissal, or even sanctions, opinions that will deter plaintiffs from filing suits absent good-faith bases. At the very least, these tools should ensure that only those claims proceed against our clients in which products have been definitively identified. 