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While federal statutes and agencies such as the Food and Drug Administration ("FDA") regulate the safety of pharmaceutical products, civil litigation may remain a consumer's final means of recovery from dangerous pharmaceutical products.¹ If a pharmaceutical products liability action alleging wrongful death is brought in Michigan, where there is a statute granting immunity to manufacturers of drugs, courts must interpret statutory language and FDA's regulations to determine whether a pharmaceutical product fits the definition of "drug."² In *Miller v. Mylan Inc. (In re Estate of*...
of Kelly). The United States Court of Appeals for the Sixth Circuit questioned whether the Fentanyl pain relieving patch, manufactured by the defendants, qualified as a “drug” under a Michigan statute, which grants immunity to drug manufacturers. The Sixth Circuit agreed with the plaintiffs that a factual issue remained as to whether the Fentanyl patch qualified as a drug, a medical device, or a combination product, and remanded the case for the lower court to resolve this issue in light of the immunity statute.

On June 14, 2009, the decedent, Beth Ann Kelly ("Kelly"), died shortly after she was found alone and unresponsive in her backyard. The autopsy report revealed Kelly's blood contained a thirty-nine milligram per milliliter concentration of Fentanyl.

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3 See id. at 625. See also Mich. Comp. Laws § 600.2946(5) (2013). A manufacturer of a product that is a drug is not liable if FDA approved the drug for “safety and efficacy” and the drug's labeling complies with FDA's official approval. Id. Michigan uses the same definition of “drug” as the Federal Food, Drug, and Cosmetic Act (hereinafter "FD&C Act") does, but expressly excludes “medical appliance[s] or device[s].” Mich. Comp. Laws § 600.2945(b); 21 U.S.C.S. § 321 (2009) (defining definitions used in FD&C Act).

4 Totten, supra note 4.

5 See Miller v. Mylan Inc., 2012 U.S. Dist. LEXIS 153621, at *7 (E.D. Mich. 2012). The Plaintiff's alleged that Kelly was last seen working alone in her backyard two hours prior to the discovery of her body. Id. at *8. She was unresponsive and was later pronounced dead. Id.

6 Id. at 6-8 (quoting A Poison Legal Pill, Michigan Must Repeal Law that Leaves Victims of Vioxx and Other Bad Drugs Shut Out of Court, DETROIT FREE PRESS, Nov. 18, 2007 at Ed. pg. 1). Although considered “weak,” the sole justification for the drug immunity law was to encourage manufacturers to stay in Michigan. Id. at 8.

The exact measurement for a lethal dose of Fentanyl remains unknown, but it is estimated to be two milligrams. Kelly used Mylan Fentanyl transdermal system ("Fentanyl patch"), a Fentanyl distribution patch, which was prescribed by her physician for severe chronic pain. Beth Ann Miller ("Miller"), the plaintiff and personal representative for the Kelly estate, brought suit against the defendants, Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan Technologies, Inc. (collectively "Mylan"), alleging that the Fentanyl patch caused Kelly’s death.

Miller filed suit in Michigan state court, but Mylan removed the case to federal court. Mylan then filed a motion for dismissal for failure to state a claim based upon a


Fentanyl, EUROPEAN MONITORING CENTRE FOR DRUGS AND DRUG ADDICTION, http://www.emcdda.europa.eu/publications/drug-profiles/fentanyl. (last visited Oct. 12, 2014). “The estimated lethal dose of fentanyl in humans is 2 mg,” which must be injected fully for fatal effects. Id. Fentanyl overdoses can result in sudden death by cardiac arrest or a critical anaphylactic reaction. Id. Regarding recommended use of Fentanyl:

The recommended serum concentration for analgesia is 1–2 ng/ml and for anaesthesia it is 10–20 ng/ml. Blood concentrations of approximately 7 ng/ml or greater have been associated with fatalities where poly-substance use was involved. While fatalities have been reported after therapeutic use, many deaths have occurred as a result of the misuse of pharmaceutical products. Id. See also Ingo Voigt, Fatal Overdose due to Confusion of an Transdermal Fentanyl Delivery System (2013), Case Reports in Critical Care vol. 2013, available at http://www.hindawi.com/journals/crcc/2013/154143/ (discussing misuse and fatal outcomes of various fentanyl patches).

Miller, 2012 U.S. Dist. LEXIS 153621 at 8.


Michigan statute protecting manufacturers of "drugs" from products liability lawsuits.12 Because FDA approved the Fentanyl patch as a "drug" and referred to it as such during the approval process, the District Court agreed with Mylan and dismissed the case.13 The Sixth Circuit granted Miller's appeal solely on the issue of whether or not the Fentanyl patch was a "drug" for the purposes of the Michigan statute.14 On appeal, Miller asserted that her original claim rested on the safety of the adhesive patch, not on the pharmacologically active Fentanyl itself, and therefore her suit did not focus on a "drug" and the court should not afford Mylan the protection of the Michigan immunity statute. 15 Concluding that a factual issue remained as to whether the Fentanyl patch constituted a "drug," "medical device" or "combination product," the Sixth Circuit the case nor its prior history indicates Mylan's reason for removing to federal court. See Miller, 741 F.3d at 675-76; Miller, 2012 U.S. Dist. LEXIS at 4.

12 Id. See MICH. COMP. LAWS § 600.2946(5) (2013); infra note 25 (quoting pertinent text of Michigan statute). FED. R. CIV. P. 12(b)(6) (governing motions to dismiss for failure to state a claim). Parties may move to dismiss a claim on the grounds that it fails to state an actionable claim on which relief may be granted. Id. See e.g. Nowak v. Ironworkers Local 6 Pension Fund, 81 F.3d 1182, 1187-88 (1996) (stating practical difference is negligible between dismissals under either Rules 12(b)(1) and 12(b)(6)); Goldman v. Belden, 754 F.2d 1059, 1066-67 (1985) (stating court's standard under Rule 12(b)(6) is "whether the complaint itself is legally sufficient"). See DirecTV, Inc. v. Treesh, 487 F.3d 471, 476 (6th Cir. 2007). In deciding how to rule on a motion to dismiss under 12(b)(6), courts are to view the complaint in the light most favorable to the plaintiff. Id. "[A] Rule 12(b)(6) motion should not be granted unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Id. (citing Ricco v. Potter, 377 F.3d 599, 602 (6th Cir. 2004) (quotations omitted)).

13 Miller, 2012 U.S. App. LEXIS at 25. The Court found that the Miller provided so evidence of a distinction that the adhesive film layer and the pharmacologically active Fentanyl "drug" portion. Id. The Court then interpreted the relevant statutory definition of "drug" to include the component parts. Id.; Miller, 741 F.3d at 675-76. The District Court determined the Fentanyl patch fit within the definition of "drug" under federal law, and therefore Mylan, as the Fentanyl patch manufacturer, was protected from products liability suits. Miller, 741 F.3d at 676. See 21 U.S.C.S. § 321 (2014) (FD&C Act). A "drug" is an article intended for treatment or mitigation of a disease. Id. See also MICH. COMP. LAWS § 600.2946(5) (2013). The Michigan immunity statute uses the Food, Drug, and Cosmetic Act definition of "drug," with the added requirement that the manufacturer must obtain FDA approval and label the product in compliance with the official approval of the "drug." Id.

14 Miller, 741 F.3d at 675-76.

15 Id. The plaintiff claims because the adhesive film is pharmacologically inactive, it is actually a medical device, and thus not subject to the Michigan drug manufacturer immunity statute. Miller, 2012 U.S. Dist. LEXIS 153621, at *3. The plaintiff does not disagree with the defendant's argument supporting their motion for dismissal. Id. On appeal, Mylan argued that immunity applied regardless of the Fentanyl patch's label because FDA approved it as a drug. Miller, 741 F.3d at 677. The court of appeals did not consider Miller's other claims heard before district court; Miller consented to dismissal of the claims she made under the Michigan Consumer Protection Act and the "products-liability claim insofar as it was premised on a failure to warn." Id. at 676 n.1. On appeal, Mylan argued the definition of device is nearly identical as that of drug, except a device may not achieve its primary purpose through a chemical effect. See 21 U.S.C.S. § 321(g)(1) (2014) (defining "device" for purposes of FD&C Act).
reversed the judgment of the district court and remanded the case for further proceedings.16

Prior to 1990, FDA categorized medical and pharmaceutical products as either "drugs" or "medical devices" under the Food, Drug, and Cosmetic Act ("FD&C Act").17 A 1984 amendment allowed for generic versions of branded drugs and for the

16 Miller, 741 F.3d at 675, 677. Judge Gibbons concurred, basing his reasoning for remand on the broader issue of the district court's review, where, according to Gibbons, the district court's reasoning was based on the documents submitted by the defendant and on Michigan law, but completely ignored assertions made in the plaintiff's complaint. Id. at 678-80. Gibbons asserted that "[t]he district court did not focus on the complaint as pled, however, but instead focused on documents submitted by Mylan in support of its motion to dismiss." Id. at 678. Although Gibbons agreed with the majority's reasoning and with the decision to remand the case, Gibbons felt the majority lacked care for "[m]aintaining the integrity of the procedures contemplated by the Federal Rules of Civil Procedure." Id. at 679. Judge McKeague dissented, concluding no issue of fact exists because the Fentanyl patch is indeed a "drug" for purposes of the immunity statute. Id. at 680-85. McKeague disagreed that the Michigan, federal, and FDA definitions of "drug" created ambiguity. Id. at 681. McKeague compared the definitions of "drug" and "device" with the official labeling of the Fentanyl patch, and "conclud[ed] that the patch does not include a 'device.'" Miller, 741 F.3d at 681. He rationalized that the "primary purpose" of the patch could only be achieved through Fentanyl's "metabolization." Id. at 682. He further concluded that the "FDA's statutory scheme and limited case law did not support inclusion" of the Fentanyl patch within the "combination product" definition. Id. He noted that although Mylan never filed a "request for designation" and FDA returned a "letter of designation" pursuant to 21 C.F.R. § 3.2 (2014), FDA Office of Generic Drugs, Center for Drug Evaluation and Research submitted the "Approval Letter" to Mylan. Miller, 741 F.3d at 683. See 21 C.F.R. § 3.2(c) (2014) (explaining letter of designation that specifies the agency responsible for combination products). McKeague noted that the FDA Office of Combination Products is now responsible for combination products, not the Office of Generic Drugs. Miller, 741 F.3d at 683 n.7. Summarily, McKeagues remarked that "the only evidence in the record shows that FDA designated the fentanyl patch as a 'drug.' In my view, the inquiry stops there." Id. at 684. McKeague preferred to dismiss the appeal and affirm the district court's holding. Id. at 485. Mylan petitioned for a rehearing en banc to reconsider the remand, the proceedings for which occur in a different case. Id. at 678. See Miller v. Mylan Inc., No. 12-2502, 2014 U.S. App. LEXIS 4884, at *5 (6th Cir. Mar. 13, 2014). The Court denied Mylan's motion for a rehearing because the issues raised in the petition were fully considered in the case. Id.


The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the
generics' ability to remain on the market after a branded drug was recalled. In 1983, the court held in United States v. Generix Drug Corp., that the term "drug" applied to both active and inactive ingredients in a product, and thus products with both drug and structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

21 U.S.C.S. § 321(g)(1) (emphases added). The FD&C Act defines medical "devices" as:

- "The term 'device' . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.


FDA enacted the FD&C Act on June 25, 1938 in response to the condition of the drug market in the 1930s, when trends in advertising promised numerous false claims resulting in deaths of consumers. Id. The turning point in drug public policy directly followed the 1937 Elixir Sulfanilamide incident, where a Tennessee drug company marketed a sulfa product, which was never tested and was a highly toxic analogue of antifreeze, to pediatric patients, resulting in the death of over one hundred children. Id. See also Federal Food and Drugs Act (Wiley Act) of 1906, Pub. L. No. 59-384, (34 Stat.) 786, invalidated by 21 U.S.C.S. § 321, available at http://www.fda.gov/regulatoryinformation/legislation/ucm148690.htm (describing Wiley Act).

The FD&C Act replaced the previous statute, the Wiley Act of 1906, under which the strictest provision merely required drug labels to list any ten ingredients deemed "dangerous." Id. See 21 U.S.C.S. § 355(j)(7) (LexisNexis 2014). The FD&C Act also includes the 1984 amendment allowing for market approval of generic drugs. Bill Summary and Status 98th Congress (1983-1984), S.1538 CRS Summary, THE LIBRARY OF CONGRESS (THOMAS), http://thomas.loc.gov/cgi-bin/Zbdquery/z?d098:SN01538:@@D&summ2=m&jTOM:bss/d098query.html (last visited Oct. 12, 2014). The 1984 Amendment "[d]eclare[d] that it is not a patent infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulated the manufacture, use, or sale of drugs." Id. This 1984 amendment allowed for market approval of generic drugs, and for approved generic drugs to remain on the market after withdrawal of the brand-name version. Id. See 21 U.S.C. § 271. Thus, if FDA recalled a brand-name drug for health reasons, the generic version of the hazardous drug may remain on the market. Food and Drug Admin., Recalls and Field Corrections – Drugs Class II, FDA ENFORCEMENT REPORT, April 2, 2008. In February 2008, FDA recalled the Activis Fentanyl Transdermal System, a generic variation, like Fentanyl patch, of the Duragesic fentanyl patch, in dosages including 25 mcg/hr. Id.

18 460 U.S. 453 (1983) (holding that "drug" refers to a whole product and includes pharmacologically active ingredients and excipients).
device components qualified as "drugs."  

After 1990, amendments to the FD&C Act added regulation of a new third category called the Combination Product, defined as a "combination of a drug, device, or biological product." In determining what category a pharmaceutical or medical product is defined by under the FD&C Act, courts rely upon statutory interpretations by FDA. Courts consider FDA interpretations through FDA authored warning letters and guidance documents when determining whether to grant a motion to dismiss. In  

20 Id. at 454. The court held that "inactive ingredients" included drug application materials, "such as coatings, bindings, and capsules." Id. The court recognized that the active ingredients may make up less than ten percent of the whole product and "drug" is still the proper term. Id.  
21 21 U.S.C.S. § 353(g) (LexisNexis 2014). The term Combination Product includes three complex definitions, the simplest being a "product comprised of two or more regulated components" including drugs, medical devices, and biological products "that are physically, chemically, or otherwise combined or mixed and produced as a single entity." Guidance for Industry: Classification of Products as Drugs and Devices and Additional Product Classification Issues, FDA OFFICE OF COMBINATION PRODUCTS, http://www.fda.gov/RegulatoryInformation/Guidances/ucm258946.htm (last visited Oct. 13, 2014). Other products classified as combination products may be two or more regulated components packaged together and intended for use in connection with each other, or a product packaged independently but intended for use in conjunction with another. Id. Preference in categories is generally given to the term "device" when issues in definition arise. Id. "[I]f a product is shown to meet both the drug and device definitions, the Agency generally intends to classify the product as a device," but if "there is uncertainty regarding whether it also meets the device definition, the Agency generally intends to classify the product as a drug." Id. Regulation of combination products falls within the jurisdiction of the FDA Office of Combination Products. 21 C.F.R. § 3.6. An agent of the Office of Combination Products submits the "letter of designation" to the applicant seeking approval of a combination product. 21 C.F.R. § 3.8.  
22 See K Mart Corp. v. Cartier, Inc., 486 U.S. 281, 291 (1988) (discussing how courts ought to interpret statutory language). If a statute is "silent" on how to interpret language or an issue, the court may look to interpretive regulations by the agency, and if there is no conflict between the agency interpretation and the plain language, "a reviewing court must give deference to the agency's interpretation of the statute." Id. at 291-92. FDA is "primarily responsible for categorizing 'combination products.'" 21 U.S.C.S. 353(g); Air Brake Sys., Inc. v. Mineta, 357 F.3d 632 (6th Cir. 2004) (holding weight of authority in statutory interpretation is given to regulating agency). Federal courts give authority to agency interpretations due to their "power to persuade," unless they are inconsistent on their face with the statute. Id. at 643 (quoting Skidmore v. Swift & Co., 323 U.S. 134, 137 (1944)). See also Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 627 (1973) (holding FDA has authority over product identification as "new drug," subject to court review). See e.g., Nationwide Mut. Ins. Co. v. Cisneros, 52 F.3d 1351, 1357 (6th Cir. 1995) (discussing plain language interpretation of 42 U.S.C.S. § 3604 (2014)). In interpreting plain language, inclusion of one definition may infer exclusion of another. Id.  
23 See Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322-24 (2007) (discussing process to determine if valid claim exists). The Tellabs court authorized consideration of "letters from a federal agency and matters of public records whose authenticity cannot be questioned, when those documents are incorporated by reference into or are central to the claims set forth in plaintiff's complaint." Miller v. Mylan Inc., 741 F.3d at 678. See also Greenberg v. Life Insurance
2009, a Utah district court held a fentanyl transdermal patch with the brand name Duragesic, constituted a “drug” under FDA’s definitional interpretation.\textsuperscript{24}

In an effort to encourage drug manufacturers to continue to do business within the state, in 1996 Michigan amended its regulation of products liability actions to provide immunity to manufacturers of prescription drugs against products liability claims.\textsuperscript{25} Many Michigan policymakers advocated that the nature of M.C.L.S. section Co. of Virginia, 177 F.3d 507, 514 (6th Cir. 1999) (deeming documents attached or referred to in complaint are part of pleadings). See Guidance for Industry: How to Write a Request for Designation (RFD), FDA, (April 2011), http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM251544.pdf (explaining FDA requirements for requesting letter of designation). FDA guidance makes no mention on procedure in a civil suit, much less how to prepare a claim in response to a motion to dismiss. \textit{Id. But see} Pension Benefit Guar. Corp. v. White Consol. Indus., 998 F.2d 1192, 1197 (3d Cir. 1993) (holding requested correspondence under Freedom of Information Act not public records for motions to dismiss purposes). See generally Barney v. Holzer Clinic, 110 F.3d 1207, 1213 (6th Cir. 1997) (holding courts must “conform to the arguments that the parties have made in this court”). This case also held courts should generally avoid discussing issues not directly raised by parties. \textit{Id. (citing} Hines v. United States, 971 F.2d 506 (10th Cir. 1992)). Although the \textit{Barney} Court discussed their belief that the lower court erred by failing to “modify the scope of the class when it became clear that the named plaintiffs were not appropriate representatives of such a broad class,” which “neither party has raised the issue on appeal,” the \textit{Barney} Court decided to amend sua sponte the class certification solely to “conform to the arguments that the parties have made in this court.” \textit{Id. See} Hines v. United States, 971 F.2d 506, 508 (10th Cir. 1992) (holding general rule against sua sponte review of unraised issues has two exceptions). Although courts generally cannot sua sponte review issues not raised by parties, there are two exceptions when a court can, such as “if that defense implicates the court’s subject matter jurisdiction” and if “a defense substantially implicates important nonjurisdictional concerns that transcend the interests of the parties to an action . . . .” \textit{Id.}

\textsuperscript{24} Lake-Allen v. Johnson & Johnson, No. 08-cv-930, 2009 U.S. Dist. LEXIS 64860, at 26-27 (D. Utah Jul. 27, 2009) (addressing fentanyl patch categorization specifically). A products liability case, \textit{Lake-Allen} involved a plaintiff who claimed the Duragesic fentanyl transdermal patch caused the death of Allen, the victim, by transmitting a terminal dose of fentanyl “via the reservoir system” of the patch. \textit{Id. at 3}. To avoid Utah’s strict liability jurisprudence for design defects, the plaintiff argued the Duragesic patch compared more to a “drug container” than a drug itself. \textit{Id. at 7}. The court held the Duragesic patch constituted a “drug” because FDA approved it as a “drug”, and, moreover, the court compared the patch to an ingestible pill, a type of product that it refused to consider a “drug container.” \textit{Id. at 7}. See Bower v. Johnson & Johnson, 795 F. Supp. 2d 672, 677-78 (N.D. Ohio 2011) (holding Michigan statute precluded products liability claim regarding birth control patch).

\textsuperscript{25} MICH. COMP. LAWS § 600.2946(5) (2014) (protecting drug manufacturers from product liability actions for products approved by FDA). The Michigan statute defines the drug manufacturer immunity as:

\begin{quote}
In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance
\end{quote}
600.2946(5) was unethical because injured plaintiffs can only argue that either the allegedly injurious product is not a "drug," or that M.C.L.S. section 600.2946(5) is inapplicable to their case. However, this statute, which allows drug manufacturer


This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following: (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act... and the drug would have not been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted. Id. at 6-7. See White v. SmithKline Beecham Corp., 538 F. Supp. 2d 1023, 1027 (W.D. Mich. 2008) (holding "drug manufacturer[s] enjoys 'an absolute defense' from... product liability suits") (quoting Taylor, 658 N.W.2d at 131). In the amendment to add drug manufacturer immunity, Michigan legislatures intended to persuade drug manufacturers to remain in Michigan. Melpolder, supra note 4. See also KRISTEN R. LAUR, MICHIGAN'S DRUG IMMUNITY: NOT A MODEL TO FOLLOW, in NEAL FORTIN, ED., FOOD & DRUG REGULATION: A WEB BOOK OF STUDENT PAPERS (Fall 2006) (on file with the Institute for Food Laws and Regulations at Michigan State University) (discussing history of MICH. COMP. LAWS § 600.2946(5) and outlining its unethical nature). Prior to enactment of the MICH. COMP. LAWS § 600.2946(5) amendment, Michigan state law recognized two forms of products liability: negligence and breach of implied warranty. Id. at 5. See Dana Cilla, Michigan Tort Reform: A Constitutional Haven for Pharmaceutical Companies and a Tough Pill to Swallow for Consumers, 19 T.M. COOLEY L. REV. 331, 334 (2002). The previous statute merely allowed a drug manufacturer to enter into evidence any compliance with federal laws, rules or regulations. See Abel v. Eli Lilly & Co., 94 Mich. App. 59, 70 (Mich. App. 1980) (holding negligence and breach of implied warranty as products liability claim causes of action); Smith v. E.R. Squibb & Sons, 69 Mich. App. 375, 380-81 (Mich. App. 1976).

immunity, is ambiguous as to whether combination products manufacturers are protected from products liability.  

business ahead of the safety and health of Michigan residents,' said State Rep. Lisa Brown.”

Id. Democratic Michigan State Representative Ellen Cogen Lipton argues that the drug manufacturer immunity law prohibits Michigan from recovering millions of dollars annually. See Carol Lundberg, Less Information is a Good Thing? THE MICHIGAN LAWYER (Aug. 29, 2014 1:03 PM), http://michiganlawyerblog.wordpress.com/category/drug-immunity-law/. The advocacy ignited after the Michigan Supreme Court refused to entertain a drug immunity suit by the Michigan Attorney General, who sought recovery of twenty million dollars paid by the state for Vioxx prescriptions for Medicaid patients. See AG v. Merck Sharp & Dohme Corp., 490 Mich. 878 (2011) (affirming lower court holding). Judge Marilyn Kelly dissented that the appeals court confused the issue and treated the plaintiff’s claim as seeking redress for property damage instead of seeking “return of payments procured through fraudulent conduct.” Id. at 879. She asserts the “defendant duped the state” into paying Medicaid funds for faulty and dangerous drugs. Id. See also AG v. Merck Sharp & Dohme Corp., 292 Mich. App. 1, 5 (2011) (holding that when FDA approves a drug, actions alleging fraud are barred). Vioxx, a pain treatment drug, failed to treat pain, increased the likelihood of heart attacks, and sometimes caused fatal strokes. Merck Sharp & Dohme Corp., 292 Mich. App. 1 at 5, 16. After the district court denied the Vioxx manufacturer’s motion for summary judgment, the appeals court granted summary judgment in favor against the State, concluding that Vioxx clearly fit the “drug” definition and thus MICH. COMP. LAWS § 600.2946(5) protected the Vioxx manufacturer from products liability. Id. at 15.

The Michigan Attorney General asserted the case was not a products liability action, but actions alleging fraud are barred). Vioxx, a pain treatment drug, failed to treat pain, increased the likelihood of heart attacks, and sometimes caused fatal strokes. Merck Sharp & Dohme Corp., 292 Mich. App. 1 at 5, 16. After the district court denied the Vioxx manufacturer’s motion for summary judgment, the appeals court granted summary judgment in favor against the State, concluding that Vioxx clearly fit the “drug” definition and thus MICH. COMP. LAWS § 600.2946(5) protected the Vioxx manufacturer from products liability. Id. at 15. The Michigan Supreme Court denied the state’s appeal, simply because they “not persuaded that the question presented should be reviewed by this Court.” Merck Sharp & Dohme Corp., 490 Mich. at 878. The Michigan legislature enacted MICH. COMP. LAWS § 600.2946(5) under the justification that FDA is uniquely capable to protect consumers. Ed Wesoloski, Drug Immunity Law: Politicos Jockey for Position, MICHIGAN LAWYERS WEEKLY (Aug. 29, 2014 1:26 PM), http://michiganlawyerblog.blogspot.com/2008/01/drug-immunity-law-politicos-jockey-for.html#links. MICH. COMP. LAWS § 600.2946(5) is not entirely without support in the legal and political realm because immunity statutes are “one step closer to the high-regulation, low-litigation model of product liability.” See e.g. Steven Boranian, A Drug is a Drug… Except in Michigan?, ASSOCIATION OF CORPORATE COUNSEL (Aug. 29, 2014 1:29 PM), http://www.lexology.com/library/detail.aspx?g=7b3cb587-2fd1-4221-b481-22c451d54cfd. 

27 MICH. COMP. LAWS § 600.2946(5) (2014). The statute provides immunity for the manufacturers or sellers of “a product that is a drug,” and makes no manufacturers or sellers of products that are either combination products or medical devices. Id. See supra note 12 (discussing Mylan’s motion for dismissal for failure to state a claim). Under the Michigan statutory scheme, “[d]rug” means that term as defined in section 201 of the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 321. “However, drug does not include a medical appliance or device.” M.C.I.S. § 600.2945(b) (emphasis added). The Michigan statutory scheme does not define “device” pertaining to medical products, and entirely omits mention of “combination products.” Id. The section of the FD&C Act defining “drug,” from which the
In *Miller v. Mylan, Inc.*, the Sixth Circuit Court of Appeals ("Miller court") disagreed with the district court that the FD&C Act definition of "drug" applied to the Fentanyl patch, although the definition applies to "coatings, bindings, and capsules." \(^{28}\) Secondly, the *Miller* court deemed the district court failed to consider that the Fentanyl patch could constitute a "combination product," when the district court categorized the Fentanyl patch as a "drug" and outright dismissed Miller's complaint. \(^{29}\) Refusing to subject a potential "combination product" to "drug" regulation, the *Miller* court applied no immunity coverage to combination products under the drug manufacturer immunity provision. \(^{30}\)


\(^{28}\) See 21 U.S.C.S. § 321(g)(1)(D); *supra* note 17 (providing full text of "drug" definition under FD&C Act). *See also Miller, 741 F.3d* at 676-77. The district court held the patch portion of the Fentanyl patch was "akin to a time-release capsule in a pill and that it qualified as an 'article intended for use as a component of any article specified in clause (A), (B), or (C)" of 21 U.S.C.S. § 321(g)(1), but the *Miller* court remained unconvinced that the clause "most naturally understood" applied to the Fentanyl patch. *Id.* Although the clause applied to "coatings, bindings, and capsules," which have a chemical effect according to *Generix Drug Corp.* *Id.* The *Miller* court argued an item such as a patch had a "mechanical (rather than chemical) effect on the human body." *Id.* at 677. *See United States v. Generix Drug Corp.*, 460 U.S. 453, 454 (1983) (considering "coatings, bindings, and capsules" in FDA drug definition under 21 U.S.C.S. § 321(g)(1)(D)). Although the defendants argued that the Fentanyl patch component ought to be considered a drug because FDA regulated as a drug, the *Miller Court* viewed this argument as inconsistent with the statutory language of both the FD&C Act and M.C.L.S. § 600.2946(5). *Id.* at 676-77.

\(^{29}\) *Miller, 741 F.3d* at 676-77. The *Miller* court viewed the district court's holding as "fail[ing] to take full account of the statutory scheme governing federal drug regulation." *Id.* In seeking to define the Fentanyl patch as either a "drug" or a "device," the district court "assumed a binary scheme," according to the *Miller court*. *Id.* A binary scheme "is how things used to work, but no longer," stated the *Miller court* majority while indicating that the amending of the FD&C Act that added "combination products" as a third category. *Id.* Acknowledging the 1990 amendment to the FD&C Act, which included the designation "combination product" the *Miller court* noted that Congress's deletion of language regarding "components, parts, or accessories" reflected a "tripartite scheme" replacing the binary scheme. *Id.* The lower court did not look to the plain statutory language of the FD&C Act. *Id.* at 676-77. *See K Mart Corp. v. Cartier*, 486 U.S. 281, 291 (1988) (discussing court interpretation of statutory language). "In ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole." *Id.*

\(^{30}\) *Miller, 741 F.3d* at 678. After finding fault with the district court's analysis and conclusion, the *Miller court* arrived at "[t]he remaining question [of] whether the fentanyl patch is indeed a 'combination product' rather than a 'drug...' Whether the fentanyl patch meets this definition is a question of fact that we are unprepared to answer in the first instance." *Id.* The *Miller* court would not apply the Michigan drug immunity statute because of the uncertainty of the Fentanyl
The issue of proper categorization of Fentanyl patches remained unanswered, as the Miller Court determined a factual issue remained concerning whether Fentanyl patches constitute a “drug” or a “combination product.” Judge Gibbons offered a concurring opinion, adding that the lower court focused too heavily on documents provided by Mylan to support its motion, instead of focusing on the complaint as pled. In his dissenting opinion, Judge McKeague viewed both the patch component and the whole product as undoubtedly fitting within the definition of “drug” under the FD&C Act because the Fentanyl patch achieved its “primary purpose” through chemical action, and therefore immunized Mylan from products liability action. The reversal of the patch’s status as a “drug” or “combination product,” and “[a]t best, Michigan law is ambiguous as to whether the manufacturer of a combination product should be immune from suit.” Id. at 677 (emphasis added). The Miller Court blamed Michigan legislation for failing to clearly include combination products in manufacturer immunity. Id. The Court also noted that when statutory language remained ambiguous, “accepted canons of statutory construction require this ambiguity to work against immunity for manufacturers of combination products.” Id. See ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 318 (2012) (discussing standards of statutory interpretation). “[S]tatutes will not be interpreted as changing the common law unless they effect the change with clarity.” Id. The Miller Court noted that common law currently does not provide immunity for combination products. Miller, 741 F.3d at 678.

31 Miller, 741 F.3d at 678. The Court reversed the grant of the defendants’ motion to dismiss and remanded the case for further proceedings on the issue of fact. Id.

32 Id. Judge Gibbons disagreed with the lower court’s determination that Mylan’s documents “were referenced in the complaint and central to the claim” and “because neither party questioned their authenticity.” Id. at 679. Although Judge Gibbons acknowledged these documents, as well as reference to statutes, are important for this litigation, he argued these should not be considered part of the complaint for purposes of deciding a motion to dismiss for failure to state a claim. Id. at 679-80.

33 Id. at 680-82. Judge McKeague noted the FD&C Act definition of device precludes components that achieve their primary purpose via chemical action or metabolism. Id at 682. See 21 U.S.C.S. 321(h)(3) (2014) (setting forth definition of “device.”) Referring to the official labeling of the Fentanyl patch, Judge McKeague notes the product achieves its primary purpose of relieving pain outside the “device” definition because Fentanyl must be metabolized to take effect. Miller, 741 F.3d at 681-82. Judge McKeague also observed the labeling did not refer to the Fentanyl patch as a device or combination product. Id. at 682. Judge McKeague argued Fentanyl patches fit the FD&C Act definition of drug as well, where it is an “articles intended for use as a component of any article,” it is “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man,” or it is an article “intended to affect the structure or any function of the body of man.” Id at 682 (quoting 21 U.S.C.S. § 321 (2014)). Judge McKeague also cites the final step for designation of “combination product,” which requires the manufacturer to file a “request for designation” and then receive a responding “letter of designation” from FDA, which transfers agency jurisdiction of the product to FDA’s department of Office of Combination Products. Id. at 682-84. Mylan’s letter of designation from FDA, which Mylan provided to support its motion, also only referred to the Fentanyl patch as “drug.” Id. at 683-84. Judge McKeague disapproved of the majority’s apparent lack of deference to FDA designation of Fentanyl patches, which Judge McKeague argued Mylan
district court’s holding limited the statutory analysis, and they declined to categorize the fentanyl patch and remanded the case to the district court for proceedings consistent with the majority’s rational.34

In reviewing Miller’s appeal of the district court’s decision to grant to plaintiff’s motion to dismiss, the Miller court properly focused on whether the plaintiff’s claim stated a redressable cause of action, and not whether her claim succeeded on the merits.35 The lynchpin to the district court’s holding was its finding that the Fentanyl

validated with their submitted documents. Miller, 741 F.3d at 683-84. The district court relied on documents Mylan submitted in support of their motion to dismiss, as opposed to simply relying on the plaintiff’s complaint as pled. Id. at 678-79. These documents included a letter from FDA, and, although not the formal “letter of designation” pursuant to FDA regulations, the FDA letter only used the term “drug” in referring to its approval of Fentanyl patches. Id. at 683. See 21 C.F.R. § 3.9 (governing “letters of designation,” which constitute a formal “agency determination”). Judge McKeague argued, moreover, that the Office of Generic Drugs submitted the approval letter, and thus, FDA clearly intended for it to regulate Fentanyl patches as “drugs.” Miller, 741 F.3d at 683. Only the Product Jurisdiction Officer may change which FDA division regulates a product. Id. Although not a “formal” designation, the submitted letter served to indicate Fentanyl patches qualified for “drug” regulation, and Judge McKeague would prefer the analysis go no further. Id. at 684 (citing Air Brake Sys., Inc., 357 F.3d at 643 (discussing where agency interpretation of language is given deference). Finally, Judge McKeague cited previous case law where the brand-named fentanyl transdermal patch, Duragesic, was designated as a “drug” both because of deference given to FDA interpretation and because the court in that case refused to consider a delivery system, analogous into a container, as a medical device. Id. at 684-85 (citing Lake-Allen, No. 2:08CV00930DAK, 2009 U.S. Dist. LEXIS 64860 at *3).

34 Miller, 741 F.3d at 678. The Miller court determined “that a remand is appropriate” because they were unprepared to answer the factual question of whether Fentanyl patches should be treated as “drugs” or “combination products.” Id. As a result, the district court will need to “determine whether the fentanyl patch should be designated as only a ‘drug’ for purposes of the Michigan statute” “[i]n light of the now tripartite division of products into drugs, devices, and combination products.” Id. (emphasis added). The Miller court’s prominent disagreement with the district court centered on the district court’s reliance on a historic “binary” division of products as “drugs” and “devices.” Id. at 677.

35 Miller, 741 F.3d at 676. The court properly determined the sole issue they must consider on appeal was whether the district court properly granted the defendants’ motion to dismiss for failure to state a claim, and, in order to do so, the Court needed to determine whether the Miller claim stated a redressable cause of action. Miller, 741 F.3d 674. See Fed. R. Civ. P. (12)(b)(6) (allowing dismissal of complaints for failure to state a legally actionable claim); A determination of the facts at hand is not appropriate for determining, on appeal, if a 12(b)(6) motion was proper, but the determination must focus on whether a legally actionable claim was made by the plaintiff. Fed. R. Civ. P. (12)(b)(6). The district court dismissed Miller’s claim under R. 12(b)(6) based on their agreement with the defendants that Miller failed to raise a redressable claim because the Fentanyl patch is a “drug” and thus Mylan was immune from liability under M.C.L.S. § 600.2946(5). Miller, 741 F.3d at 676; supra notes 11, 12 and accompanying text (discussing drug immunity statute, and relevant text of M.C.L.S. § 600.2946(5)). Thus, on appeal, the Miller court needed to determine whether the district court properly categorized the Fentanyl patch as a
patch fit the “drug” definition pursuant to Mich. Comp. Law 600.2946(5). The Miller court found they need not determine if the Fentanyl patch definitely qualified as a “drug,” but whether or not the district court properly categorized the Fentanyl patch as a “drug” for purposes of product regulation.

“drug.” Miller, 741 F.3d at 676. See M.C.L.S. § 600.2946(5) (protecting drug manufacturers from products liabilities for “drugs” as defined by FDA).

See Miller, 741 F.3d at 676. See also Miller v. Mylan Inc., No. 12-11684, 2012 U.S. Dist. LEXIS 153621, at *25-26 (E.D. Mich. 2012) (district court granting defendant’s motion to dismiss). The district court focused entirely on whether the Fentanyl patch constituted a drug for purposes of the products liability protection statute. Id. If the Fentanyl patch did not equate to a “drug,” then Mylan would enjoy no products liability immunity, and Miller’s claim would be determined by the facts presented at trial. See id. at 3. See also White v. SmithKline Beecham Corp., 538 F. Supp. 2d 1023, 1027 (W.D. Mich. 2008) (holding a product constituted a “drug” because it was approved by FDA as such); supra note 25 (providing relevant text of M.C.L.S. § 600.2946(5) (protecting drug manufacturers from product liability actions). Before the district court, Miller focused her complaint on the patch portion of the Fentanyl patch and not the Fentanyl drug itself, and thus her claim involved a “device” and not a “drug.” Miller, 2012 U.S. Dist LEXIS 153621, at *3. After analyzing the definitions of both “drug” and “device” pursuant to the FD&C Act, the district court determined the patch portion of the Fentanyl patch still qualifies as a “drug” pursuant to the legislative definition of “drug.” Id. at *25-26. See supra note 17 (providing full text of FD&C Act definitions for “drug” and “device,” and accompanying discussion).

Miller, 2012 U.S. Dist. LEXIS 153621, at *25-26. The question before the Miller court was whether the district court applied the proper analysis in determining whether the fentanyl patch was a “drug” and subsequently granting the defendant’s 12(b)(6) motion to dismiss for failure to state a claim. Id. The court did not need to determine how to best define the Fentanyl patch, because this case was an appeal on the decision to grant a motion to dismiss for failure to state a claim. Id. See Miller, 741 F.3d at 675-76. The ultimate determination of whether the fentanyl patch qualifies as a “drug” is a question of fact to be determined on remand by the district court. Id. at 678. See also Fed. R. Civ. P. 12(b)(6); Nowak v. Ironworkers Local 6 Pension Fund, 81 F.3d 1182, 1187-88 (2d Cir. 1996) (discussing standard of claim dismissal under a 12(b)(6) motion). A dismissal under a 12(b)(6) motion is justified on the merits of the claim, or if a plaintiff fails to factually allege a legal cause of action. Id. at 1187. See Goldman v. Belden, 754 F.2d 1059, 1066 (2d Cir. 1985) (reversing dismissal of complaint where district court improperly considered extraneous documents); supra note 35 and accompanying text (discussing standard of review for appeal of granting 12(b)(6) motion to dismiss). Courts should not dismiss a claim under a 12(b)(6) motion without a showing “beyond doubt” that the plaintiff cannot show factual support for entitlement to relief. Goldman, 754 F.2d at 1065-66 (citing Conley v. Gibson, 355 U.S. 41, 45-46 (1957)). The district court’s holding did not convince the Miller Court that no question of fact remained. Miller, 741 F.3d at 678. See also DirecTV, Inc. v. Treesh, 487 F.3d 471, 476 (6th Cir. 2007) (holding courts must construe complaint in “light most favorable to the plaintiff”). Although the majority never decided if the Fentanyl patch accurately qualified as a “drug,” they determined the district court’s categorization analysis was improper because the district court neglected to consider the possibility that the Fentanyl patch was a “combination product.” Miller, 741 F.3d at 677. See supra note 34 (discussing justification for and appropriateness of a remand to district court). Alternatively, the Miller court majority could have agreed entirely that the Fentanyl patch fit the “drug” definition regardless of the addition of FDA regulations for “combination products,” and thus deemed irrelevant the district court neglect of “combination products.” Miller, 741 F.3d at 678. In this alternative, the district court's
A plain language reading of Mich. Comp. Law 600.2945(b) and Mich. Comp. Law 600.2946(5) indicates ambiguity as to the definition of "drug."38 Additionally, Miller rested her complaint neither on the whole Fentanyl patch nor the pharmacologically active fentanyl portion, but on the adhesive film portion of the Fentanyl patch.39 Although regulated as a drug by FDA, the Fentanyl patch may equally fit the "drug" or "combination product" definitions provided by the FD&C Act and FDA regulations.40 Moreover, the adhesive film portion alone may fairly constitute a determination that Miller failed to raise a redressable claim would be affirmed by the Miller majority, and there would have been no remand. Id.

38 See supra note 27 (articulating text of Michigan statutory "drug" definition). The Michigan immunity statute applies to makers of a product that is a "drug" as defined by the Michigan statutory scheme, which has received FDA approval. Id. The statute incorporates the FD&C Act definition of "drug", as well as the requirement that "the drug was approved for safety and efficacy by the United States Food and Drug Administration." Supra note 12 (stating full text of relevant Michigan statute). The FD&C Act defines "drug" generally as "articles intended for use in the ... treatment ... of disease ... affect[ing] the structure or any function of the body...." Supra note 17 (stating full text of relevant FD&C Act language). The Michigan statutory scheme does not define medical "devices", and fails to mention "combination products." MICH. COMP. LAWS § 600.2946(5).

39 Miller, 2012 U.S. Dist. LEXIS 153621, at *3. The Fentanyl patch has two parts: fentanyl, the active chemical ingredient, and the "transdermal system," the patch that adheres to the user's skin and delivers regulated doses of fentanyl. Id. at *3-5. See Miller, 741 F.3d at 675. See also Transdermal Technology, MYLAN , http://www.mylan.com/products/packaging-and-delivery-systems/transdermal-technology (last visited Oct. 11, 2014). According to its website, Mylan Inc. employs a Matrix Transdermal Delivery System as the transdermal system in their fentanyl patches. Id. The Matrix System "typically comprise[s] three main components." Id. (emphasis added). These components are a backing film, the "adhesive layer that incorporates the main ingredient," and a release liner, which is a removable coated film. Id. "While many options and additives exist for today's skin contact medical devices, the core elements are backing films and pressure-sensitive adhesives." Id. (emphasis added). While FDA regulates the Fentanyl patch as a "drug," Mylan's own website both states the product is made of several components and labels the skin-adhering component as a "device." Id. See also supra note 7 (providing further discussion on fentanyl).

40 See supra note 17 (providing full text of relevant FD&C Act language). A "drug" is an article intended for treatment or mitigation of a disease. Id. Kelly suffered chronic pain, an ailment which the Fentanyl patch mitigated or treated. See Miller, 741 F.3d at 675. Any article intended for "use as a component" of any other article defined as "drug" is also incorporated into the definition of "drug." Supra note 17. Thus, the patch portion may be considered a component of the whole Fentanyl patch product, and may therefore fall under the "drug" definition. Id. See supra note 21 (listing text of relevant FD&C Act language regulating combination products). FDA defines "combination products" in a recently finalized rule, and separates them into four categories: "single entity" combination products, co-packaged combination products, and two types of "cross-labeled combination products," which are combination products sold in separate packages. Food and Drug Administration, 21 C.F.R. § 3.2(e) (2014). A "single entity combination product" is defined as "[a] product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are
"device" under these regulations.  

The *Miller* court aptly recognized the questionable categorization of the Fentanyl patch, and properly applied the "canons of statutory construction," which require courts to use such ambiguity against a manufacturer.  

As Judge Gibbons amply noted in his concurrence, the district court should have relied solely on the complaint as pled, and not have given deference to the documents Mylan submitted in support of their motion to dismiss.  

physically, chemically, or otherwise combined or mixed and produced as a single entity."  

See 21 U.S.C.S. § 321(h) (2009) (defining "device" under the FD&C Act). The FD&C Act defines "device" generally as an article "intended for the use in the diagnosis of disease or... treatment... of a disease, in man... which does not achieve its primary intended purposes through chemical action within or on the body..."  

See supra note 14 (providing full text of relevant statute). Thus, the Fentanyl patch may also be a "device" under the FD&C Act because it is either an "instrument, apparatus" or "other similar... article" used for the "mitigation [or] treatment" of a "disease" and does not achieve its "primary intended purposes through chemical action" and is "metabolized" to achieve this purpose.  

Id. See [Badaracco v. Comm'r, 464 U.S. 386, 403 (1984) (Stevens, J., dissenting) (holding statutes impeding common law must be narrowly construed), cited in Miller, 741 F.3d at 678. Common law allows redressability to injured parties by those liable in a tortious action, and in products liability, the manufacturer of the product is liable.  

See Davis v. C.R. Bard, Inc., No. 11-12556, 2012 U.S. Dist. LEXIS 172925, at *7 (E.D. Mich. Dec. 6, 2012) (holding plaintiff must show the product to be defective). Manufacturers are typically responsible for defective or dangerous products, and the Miller Court refused to impede common law by construing M.C.L. § 600.2946(5) broadly to grant immunity to manufacturers in products liability claims for "combination products."  

Miller, 741 F.3d at 678. The Miller Court refused to impede common law in this case because of the significant ambiguity in both the Michigan statutes and the proper definition of the Fentanyl patch.  

Id. See SCALIA & GARNER, supra note 30. "[S]tatutes will not be interpreted as changing the common law unless they effect the change with clarity."  

Id., cited in Miller, 741 F.3d at 678.  

Judge Gibbons criticized the district court for relying too heavily on the documents that Mylan submitted to support their motion to dismiss for failure to state a claim.  

Id. at 679. See Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007) (discussing process to determine if valid claim exists); Greenberg v. Life Ins. Co. of Va., 177 F.3d
majority considered that the complaint as pled potentially indicates Miller’s claim arose from a “device,” then the district court, on remand, would need to determine whether to analyze the claim as a “device” as well as a “drug” or “combination product.”44 One might theorize the Miller majority ignored the possibility of the device to focus on combination products, leading to precedent precluding more products from statutory immunity for their manufactures and sellers.45 In his dissent, Judge McKeague correctly noted that Fentanyl patches may fit the statutory definition of “drug,” but he failed to realize both that Fentanyl patches also fairly fit the statutory definition of “combination product” and that the complaint referred strictly to the adhesive film component, which may constitute either a “drug” or “device.”46 The Miller decision breaks ground in the interpretation of the unpopular Mich. Comp. Law 600.2946(5) and paves a path to find industry liability for “combination products” in Michigan, since every previous drug product liability cases in Michigan centered on products clearly within the “drug” definition.47

507, 514 (6th Cir. 1999) (deeming documents attached or referred to in complaint are part of pleadings). “[T]his document is in no way referenced in the complaint, and it is not central to plaintiff’s claim.” Miller, 741 F.3d at 679. Courts may only consider agency letters when they “...are incorporated by reference into or are central to the claims set forth in plaintiff’s complaint.” Miller, 741 F.3d at 678 (Gibbons, J., concurring) (vellabe, Inc., 551 U.S. at 322). The district court thus should have relied solely on the complaint as pled. See Miller, 741 F.3d at 679. 44 See Miller v. Mylan Inc., No. 12-11684, 2012 U.S. Dist. LEXIS 153621, at *12; supra note 32 (discussing Judge Gibbons reasoning for disagreeing with the district court’s analysis). The Miller majority only criticized the use of a “binary” categorization scheme instead of a “tripartite” scheme, and not how the district court used the “binary” scheme improperly. See supra note 29 (discussing Miller majority finding error with district court for neglecting “tripartite” scheme). In its use of a “binary” scheme, the district court did not consider that the claim potentially arose from a “device” and not a “drug” because they did not take the complaint as pled. See supra note 41 and accompanying text (determining claim may arise from a “device” because complaint emphasizes patch portion). The remaining question, to be answered on remand by the district court consistent with the Miller majority’s proceedings, would then include “device” as a possible definition, and not just “drugs” or “combination product.” See supra note 34 (discussing district court’s responsibility on remand); supra note 30 (discussing remaining question according to majority).

45 See supra note 26 (discussing public criticism of drug manufacturer’s statutory immunity from products liability). The majority’s decision may result from significant public and political opposition to the immunity Michigan provides to drug manufacturers and vendors from products liability actions. Id. Miller, 741. F.3d at 677 (discussing majority combination products regulatory scheme). The majority discusses how the Michigan statutory scheme regarding medical and pharmaceutical products liability does not include combination products as a possibility for product categorization. Id.

46 See supra note 36 and accompanying text (discussing the lower court defining Fentanyl patch as drug); supra notes 6-8 and accompanying text (discussing events leading to Kelly’s death and Miller’s claim against Mylan).

47 Supra note 26 and accompanying text (discussing public and political criticism of M.C.L.S. § 600.2946(5)). Currently, M.C.L.S. § 600.2946(5) causes much controversy among Michigan
In *Miller v. Mylan, Inc.*, the court addressed whether the district court properly granted Mylan’s motion for dismissal for failure to state a claim. The *Miller* court reversed the motion and remanded the case, finding a question of fact remained as to whether the Fentanyl patch constituted a “drug” for the purposes of the Michigan immunity statute for drug manufacturers. The *Miller* decision properly recognized the ambiguity in the definitions of “drug” and “combination product” provided by the FD&C Act and FDA.

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*Supra* notes 6-16 and accompanying text (summarizing facts of the *Miller* case). *Supra* notes 26-32 and accompanying text (discussing history of Michigan’s immunity for drug manufacturers against products liability actions).

*Miller*, 741 F.3d at 678 (holding uncertainty remained whether Fentanyl patch fit ambiguous statutory definition of “drug”); *supra* notes 28-32 and accompanying text (discussing majority’s interpretation Michigan’s immunity statute).

*Supra* notes 38-42 and accompanying text (analyzing *Miller* court’s reasoning).