UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

BETH ANN MILLER, Personal Representative of the ESTATE OF BETH ANN KELLY,

Plaintiff,

v.

MYLAN INC., MYLAN PHARMACEUTICALS INC., and MYLAN TECHNOLOGIES, INC.,

Defendants.
_____/

Case No. 12-11684

Paul D. Borman
United States District Judge

OPINION AND ORDER GRANTING DEFENDANTS' MOTION TO DISMISS (ECF NO. 5)

This matter is before the Court on Defendants Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan Technologies, Inc.'s ("Mylan" or "Defendants") Motion to Dismiss. (ECF No. 5.) Plaintiff filed a response (ECF No. 9) and Defendants filed a reply (ECF No. 10.) The Court held a hearing on the motion on Wednesday, September 26, 2012. For the reasons that follow, the Court GRANTS Defendants' motion to dismiss.

INTRODUCTION

Plaintiff Beth Ann Miller ("Plaintiff") filed this product liability action against the Mylan Defendants claiming that the Mylan Fentanyl Transdermal System ("MFTS") caused the death of Plaintiff's decedent, Beth Ann Kelly. Mylan argues in its motion to dismiss that all of Plaintiff's claims are barred by Michigan law, Mich. Comp. Laws § 600.2946(5), because her claims relate to the safety and efficacy of a drug (MFTS) that was validly approved by the Federal Drug

Administration ("FDA").[1]

Plaintiff does not disagree that Mich. Comp. Laws § 600.2946(5) provides an absolute defense to such a drug product liability claim, but argues that her product liability claim is not premised on defects of the pharmacologically active ingredient of the MFTS, i.e. fentanyl, but on defects in the delivery system, i.e. the surrounding "film" or "adhesive" layers, that are pharmacologically inactive components of the patch. Plaintiff claims that these "layers" are not a "drug," but are more akin to a medical device, and therefore her claims are not subject to Michigan's drug immunity law. Defendants argue that MFTS, the entire transdermal system that comprises the fentanyl patch, is a "drug" and therefore falls within the immunity afforded by Mich. Comp. Laws § 600.2946(5).

The Court concludes that there is no factual or legal basis to disassociate the pharmacologically active and inactive components of the MFTS, and that MFTS, including all of its system components, is an FDA-approved drug. Therefore, Plaintiff's product liability claims are barred in their entirety by Michigan law.

I. FACTUAL BACKGROUND

This is a products liability action involving claimed defects in Mylan's MFTS, a patch

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[1] Plaintiff does not contest the dismissal of her Michigan Consumer Protection Act ("MCPA") claim (Count VII) based on the Michigan Court of Appeals' ruling in *Duronio v. Merck & Co.*, No. 267003, 2006 WL 1628516, at *6-7 (Mich. Ct. App. June 13, 2006) (holding that a claim cannot proceed against manufacturer of an FDA-approved drug under the MCPA given the comprehensive federal regulatory scheme controlling the manufacturing, marketing and distribution of drugs). Plaintiff also does not contest dismissal of any claim based on a failure to warn in light of the Supreme Court's ruling in *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011) (holding that claims challenging the warning content of an FDA-approved drug are preempted by federal law). (ECF No. 9, Pl.'s Resp. 2.) The sole remaining issue before the Court is whether the MFTS is a "drug" as that term is defined for purposes of the immunity afforded by Mich. Comp. Laws § 600.2946(5).

applied directly to the skin of the user to deliver the controlled substance fentanyl at a regulated rate for the treatment of moderate to severe chronic pain. Plaintiff Beth Ann Miller, as Personal Representative of the Estate of Beth Ann Kelly ("decedent"), filed this wrongful death action in the Circuit Court for the County of Oakland, State of Michigan, on January 25, 2012. The Mylan Defendants timely removed the action to this Court. (ECF No. 1, Notice of Removal.) The Mylan Defendants now move to dismiss Plaintiff's Complaint in its entirety, based principally on Michigan law which bars pharmaceutical product liability claims that challenge the efficacy and safety of validly FDA-approved drugs.

On January 28, 2005, the FDA approved Mylan's Abbreviated New Drug Application ("ANDA") for MFTS, and deemed the drug to be the "bioequivalent," and thus a generic version, of the name-brand product Duragesic®. (ECF No. 5, Ex. A.) As a generic product, the labeling and warnings provided with MFTS were required to be the same as those of Duragesic®, *see PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567, 2574-75 (2011). (ECF No. 5, Exs. B and C.)[2] As both the MFTS and the Duragesic® labeling that was in circulation at the time of Plaintiff's decedent's death indicated,

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[2] On a motion to dismiss, the Court may consider letters from a federal agency, as well as matters of public record whose authenticity cannot be questioned, when such documents are incorporated by reference into or are central to the claims set forth in Plaintiff's Complaint, without converting the motion to one for summary judgment. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 2499, 2509 (2007). *See also Greenberg v. Life Ins. Co. Of Virginia*, 177 F.3d 507, 514 (6th Cir. 1999) (finding that documents attached to a motion to dismiss that are referred to in the complaint and central to the claim are deemed to form a part of the pleadings). In the instant case, Plaintiff's Complaint specifically refers to the warnings and labels that accompanied MFTS and neither party questions the authenticity of these exhibits. *See Salvio v. Amgen, Inc.*, 810 F. Supp. 2d 745, 751 (M.D. Pa. 2011) (considering on a motion to dismiss the actual drug packaging, labeling and warnings that were referred to generally in plaintiff's complaint). Neither party questions the authenticity of Defendants' Exhibits A, B and C, which the Court finds fall into this category of inherently authentic documentation and thus they are considered by the Court in ruling on the instant motion to dismiss.

the "drug" being approved in both cases was a transdermal system. The MFTS "system components" were described, in relevant part, as follows:

> **System Components and Structure**. The amount of fentanyl released from each system per hour is proportional to the surface area (25 mcg/hr per 6.25 cm^2). The composition per unit area of all system sizes is identical.
>
> Fentanyl transdermal system is a translucent rectangular patch with rounded corners comprising a protective liner and two functional layers. Proceeding from the outer surface toward the surface adhering to the skin, these layers are: 1) a backing layer of polyester film; and 2) a fentanyl containing silicone adhesive layer. Before use, a protective liner that is attached to and covering the adhesive layer is removed and discarded.
>
> Fentanyl transdermal systems are packaged with additional pieces of protective film above the system within each pouch. These are also discarded at the time of use.
>
> The active component of the system is fentanyl. The remaining components are pharmacologically inactive.

ECF No. 5-3, Ex. B (Chart and diagrams omitted).[3]

Plaintiff alleges that on June 14, 2009, Beth Ann Kelly, who was wearing a single Mylan

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[3] The Court notes that Defendants' Exhibits B (MFTS Labeling) and C (Duragesic® Labeling) appear to describe a matrix design (Exhibit B) and a reservoir design (Exhibit C). The diagram in Exhibit C clearly labels a "drug reservoir." (ECF No. 5, Ex. C.) Although the Court did not inquire into this distinction at the hearing on this motion, counsel for Mylan explained during the course of his argument that Plaintiff in the instant case was not wearing a patch with a "reservoir" but was wearing a "matrix" patch in which apparently the fentanyl is delivered through molecular diffusion and controlled by the surface area of the patch on the skin. (ECF No. 11, Transcript of September 27, 2012 Hearing, 21.) Adding to the confusion, Plaintiff in her response brief states that it was the patch described in Defendants' Exhibit B (the matrix design) that her decedent was wearing but refers to "the fentanyl reservoir" that allowed for excessive delivery of the drug. (ECF No. 9, Pl.'s Resp. 13-14.) In any event, the Court need not dwell further on this issue. This Court is not concerned with issues relating to the alleged mechanism of failure of the patch or labeling issues. In both Exhibit B and Exhibit C, the system components include both the pharmacologically active and inactive ingredients of MFTS and thus this Court's determination that MFTS is a "drug" as that term is used in the Michigan statute would apply equally to either the matrix or the reservoir patch. Because Plaintiff refers to Defendants' Exhibit B, the Court quotes the relevant language from that Exhibit in this Opinion.

MFTS patch, died from a fatal overdose of fentanyl due to defects in the MFTS "patch," which was prescribed by decedent's physician for the treatment of her chronic pain. Plaintiff alleges that the decedent was last seen alive working in her yard in the early afternoon hours of June 14, 2009, and was found approximately two hours later unresponsive and declared dead shortly thereafter. (ECF No. 1, Ex. F, Complaint ¶¶ 4-18.) An autopsy report indicated that the concentration of fentanyl in Plaintiff's decedent's blood was 39 mg/ml, an amount that Plaintiff claims was a lethal level and caused the death of Beth Ann Kelly. (*Id.* ¶¶ 15, 19, 21.)

II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(b)(6) provides for the dismissal of a case where the complaint fails to state a claim upon which relief can be granted. When reviewing a motion to dismiss under Rule 12(b)(6), a court must "construe the complaint in the light most favorable to the plaintiff, accept its allegations as true, and draw all reasonable inferences in favor of the plaintiff." *DirectTV, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007). But the court "need not accept as true legal conclusions or unwarranted factual inferences." *Id.* (quoting *Gregory v. Shelby County*, 220 F.3d 433, 446 (6th Cir. 2000)). "[L]egal conclusions masquerading as factual allegations will not suffice." *Eidson v. State of Term. Dep't of Children's Servs.*, 510 F.3d 631, 634 (6th Cir. 2007).

In *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), the Supreme Court explained that "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level . . . ." *Id.* at 555 (internal citations omitted). Dismissal is appropriate if the plaintiff has failed to offer sufficient factual allegations that make the asserted claim plausible on its face. *Id.* at 570. The Supreme Court

clarified the concept of "plausibilty" in *Ashcroft v. Iqbal*, 129 S.Ct. 1937 (2009):

> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." [*Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556, 570 (2007)]. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Id.* at 556. The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. *Ibid.* Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Id.*, at 557 (brackets omitted).

Id. at 1948-50. A plaintiff's factual allegations, while "assumed to be true, must do more than create speculation or suspicion of a legally cognizable cause of action; they must show *entitlement* to relief." *LULAC v. Bredesen*, 500 F.3d 523, 527 (6th Cir. 2007) (emphasis in original) (citing *Twombly*, 127 S.Ct. at 1965). Thus, "[t]o state a valid claim, a complaint must contain either direct or inferential allegations respecting all the material elements to sustain recovery under some viable legal theory." *Bredesen*, 500 F.3d at 527 (citing *Twombly*, 127 S.Ct. at 1969).

In ruling on a motion to dismiss, the Court may consider the complaint as well as (1) documents that are referenced in the plaintiff's complaint or that are central to plaintiff's claims (2) matters of which a court may take judicial notice (3) documents that are a matter of public record and (4) letters that constitute decisions of a government agency. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 2499, 2509 (2007). *See also Greenberg v. Life Ins. Co. Of Virginia*, 177 F.3d 507, 514 (6th Cir. 1999) (finding that documents attached to a motion to dismiss that are referred to in the complaint and central to the claim are deemed to form a part of the pleadings). Where the claims rely on the existence of a written agreement, and plaintiff fails to attach the written instrument, "the defendant may introduce the pertinent exhibit," which is then considered part of the

pleadings. *QQC, Inc. v. Hewlett-Packard Co.*, 258 F. Supp. 2d 718, 721 (E.D. Mich. 2003). "Otherwise, a plaintiff with a legally deficient claims could survive a motion to dismiss simply by failing to attach a dispositive document." *Weiner v. Klais & Co., Inc.*, 108 F.3d 86, 89 (6th Cir. 1997).

III. ANALYSIS

Michigan law provides an absolute defense to product liability claims that relate to the safety and efficacy of validly FDA-approved drugs. Mich. Comp. Laws § 600.2946(5) sets forth the bar to such claims:

> (5) 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 with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. 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, chapter 675, 52 Stat. 1040, 21 U.S.C. 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.
> >
> > (b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

Mich. Comp. Laws § 600.2946(5).

The Michigan Supreme Court has determined that Mich. Comp. Laws § 600.2946(5) validly

acts as a complete bar to a product liability claim if the statutory requirements are met. In *Taylor v. Gate Pharmaceuticals*, 468 Mich. 1, 7 (2003), the Michigan Supreme Court concluded that Mich. Comp. Laws § 600.2946(5) was a legitimate exercise of legislative authority that barred product liability claims against the manufacturers of the diet drugs fen-phen and Redux, explaining:

> Pursuant to this statute, unless the fraud exception in subsection a or the bribery exception contained in subsection b applies (plaintiffs make no such claim here), a manufacturer or seller of a drug that has been approved by the FDA has an absolute defense to a products liability claim if the drug and its labeling were in compliance with the FDA's approval at the time the drug left the control of the manufacturer or seller. Thus, the Legislature has determined that a drug manufacturer or seller that has properly obtained FDA approval of a drug product has acted sufficiently prudently so that no tort liability may lie.

468 Mich. at 7. *See also White v. SmithKline Beecham Corp.*, 538 F. Supp. 2d 1023, 1027 (W.D. Mich. 2008) (recognizing that under Mich. Comp. Laws § 600.2946(5), "[a] drug manufacturer enjoys an "absolute defense" from such product liability suits" if neither the fraud nor bribery exceptions apply). Further, there is no dispute that under the law in the Sixth Circuit, the fraud and/or bribery exceptions only apply if the federal agency itself has determined that fraud or bribery infected the approval process. *See Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961, 965-67 (6th Cir. 2004) (holding that manufacturer of FDA approved drug is immune from suit absent evidence that the FDA itself has determined that the manufacturer engaged in fraud or bribery); *In re Aredia and Zometa Pdcts. Liab. Litig.*, 352 F. App'x 994, 995 (6th Cir. 2009) ("In this circuit, the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, preempts [fraud-on-the-FDA exception] claims, unless some federal agency has already found the requisite fraud on the FDA.") (citing *Garcia, supra*).

Plaintiff does not contest the law on this point and concedes that if her claims relate to the

safety and efficacy of an FDA-approved drug, and if there is no evidence that the FDA has determined that Mylan intentionally withheld or misrepresented information to the FDA or bribed a federal official to secure approval of that FDA-approved drug, and the drug remains available for sale on the market, Michigan law absolutely bars her claims. Plaintiff concedes this point in her responsive brief:

> According to Defendant, MCL 600.2946(5) stands as an "absolute defense" to drug product liability claims against drug manufacturers. Plaintiff does not disagree with Defendant on this point.

ECF No. 9, Pl.'s Resp. 8. There is no claim in this action that the FDA did not issue its approval of MFTS. Nor is there any claim that there has been a finding of fraud or bribery with respect to MFTS. Nor is there evidence, or even a claim, that MFTS has been withdrawn from the market. Defendants' counsel confirmed these facts at the hearing on this Motion.

The essence of Plaintiff's claim is that the MFTS "patch," which Plaintiff's decedent applied to her skin, which Plaintiff alleges was "made up of several layers of adhesive and film sandwiched around a reservoir of a "drug," is not a "drug" because the several layers of film and adhesive which surround the reservoir are "not pharmacologically active" and "act[] only to meter the dose of the "drug" over the course of 72 hours." (ECF No. 9, 13.) Plaintiff urges the Court to conclude that the non-pharmacologic components of the MFTS are a "device," separate and apart from the active pharmacologic agent fentanyl which is the "drug," and further to conclude that the failure of this "device" was the cause of Plaintiff's decedent's death and therefore Plaintiff's product liability claims are not subject to the absolute bar against claims regarding the safety and efficacy of FDA-approved drugs set forth in Mich. Comp. Laws § 600.2946(5).

Accordingly, the parties agree that the issue in this case is whether MFTS is an FDA-

approved "drug."[4] Further focusing and simplifying the issue for the Court, the parties agree that the controlling definition of the term "drug" as used in the Michigan statute, is set forth in the federal Food Drug and Cosmetic Act ("FDCA") 21 U.S.C. § 301 *et seq.*, which provides in relevant part as follows:

> 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, prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the 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. 321(g)(1).

The FDCA further defines a "device," in relevant part, as follows:

> The term "device" . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagant, 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, or
> >
> > (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 purpose 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 purpose.

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[4] At the hearing on the instant motion, Plaintiff's counsel remarked: "[D]efense counsel is right. This case is narrowly focused on the definition of drug as it is referenced in the [FDCA] . . . And the issue simply is this, is whether or not the adhesive backing, the padding, the mesh, are, quote, unquote, components of the fentanyl medication." (ECF No. 11, Tr. September 27, 2012 Hr'g 15.)

21 U.S.C. § 321(h).

As an initial matter, the Court notes that it appears beyond dispute that the FDA deemed and approved the MFTS (the system – not some discrete part of the system) as a drug. As noted above, on January 28, 2005, the FDA issued its approval of Mylan's Abbreviated New Drug Application for "Fentanyl Transdermal Systems," concluding that "the drug is safe and effective for use as recommended in the submitted labeling." (ECF No. 5, Defs.' Mot. Ex. 2, Jan. 28, 2005 Letter.) The January 28, 2005 Letter continues, explaining in pertinent part that the "Division of Bioequivalence has determined that your Fentanyl Transdermal Systems . . . are bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Duragesic Transdermal Systems . . . ." *Id.* There is no question that in considering Mylan's ANDA, the FDA deemed the MFTS, the patch, to be a drug; not a device and not something less than its whole.

Notwithstanding that the FDA considered the MFTS a drug, Plaintiff suggests that the Court must make an analytical and legal distinction between what Plaintiff describes as the "film layers" that "surround the reservoir" (the pharmacologically inactive components) from the fentanyl itself (the pharmacologically active component), for purposes of analyzing her product liability claims: "The transdermal patch used by Defendant to deliver fentanyl is no different in concept to a syringe or IV which are also "delivery systems" of drugs, and yet no one would contend that such articles are "drugs." Such implements would be more properly characterized as medical devices, and as such, they are specifically exempted from the immunity protection provided by MCL 600.2946." (ECF No. 9, 10-11.) Plaintiff has failed to bring to the Court's attention, however, any FDA-approved drug which defines as part of its system components the syringe or IV apparatus that will be used to deliver the drug. Moreover, the definition of a "device" dictates that the primary purpose

of the device cannot be achieved through chemical reaction and cannot be dependent upon being metabolized for achieving its primary purpose, which would seem to preclude Plaintiff's characterization of the MFTS as a "device." 21 U.S.C. § 321(h).

The MFTS product information label and warning expressly defines the "film" and "adhesive" layers, which Plaintiff claims were defective, as components of the MFTS system that are pharmacologically inactive:

> **System Components and Structure**. . . . Fentanyl transdermal system is a translucent rectangular patch with rounded corners comprising a protective liner and two functional layers. Proceeding from the outer surface toward the surface adhering to the skin, these layers are: 1) a backing layer of polyester film; and 2) a fentanyl containing silicone adhesive layer. . . . The active component of the system is fentanyl. The remaining components are pharmacologically inactive.

ECF No. 5, Defs.' Mot. Ex. B, p. 1, Labeling for MFTS.[5] According to the unambiguous statutory definition of "drug" in 21 U.S.C. §321(g)(1), "articles intended for use as a component of any article specified in clause (A), (B), or (C)," meet the definition of a "drug." The "system components" of MFTS are not limited in the product labeling to the pharmacologically active ingredients but include the pharmacologically inactive ingredients that also comprise the "drug" MFTS. Thus, it follows that the pharmacologically inactive "film layers" which Plaintiff claims were defective are "intended for use as a component of an[] article specified in clause (A), (B) or (C)." In this case, disassociating the film or adhesive layers of the patch from the fentanyl, as Plaintiff suggests is appropriate here, appears to the Court more analogous to separating the non-pharmacologically active components of a gel cap in a time-release capsule, for example, from the active pharmacologic ingredient it

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[5] The Duragesic® Labeling similarly includes each of the film and adhesive layers as components of the system, and similarly concludes: "The active component of the system is fentanyl. The remaining components are pharmacologically inactive." (ECF No. 5, Ex. C, Duragesic® Labeling, p. 3.)

encapsulates, an obvious absurdity. Plaintiff simply has not provided the Court with any evidence or argument that supports the pharmacologically active/inactive distinction that she urges the Court to adopt.

The Court fails to see the relevance of Plaintiff's reliance on the Sixth Circuit's opinion in *Harris v. Olszewski*, 442 F.3d 456 (6th Cir. 2006), in which the court concluded, in the context of ruling on the legality of Michigan's single-source contract for incontinence products, that the definition of "medical device" encompassed incontinence products, including protective undergarments. *Id.* at 466. Plaintiff states in her brief that: "Incontinence products have padding and a fluid barrier and are considered devices. The "patch" or transdermal delivery system here consists of adhesive and film backing. Within the ordinary meaning of device, or within the FDCA definition, Plaintiff believes the film and backing which form the "patch" Plaintiff alleges was defective, falls within either definition." (ECF No. 9, 15.) Plaintiff's point in relying on *Harris* eludes the Court. Is Plaintiff suggesting that because the Sixth Circuit has observed that an absorbent pad that serves as a barrier to fluid to protect an incontinent individual's clothing constitutes a "medical device" under the FDCA, that the film or adhesive layers of the MFTS serve as a barrier to the skin and therefore are likewise a "medical device?" If this is Plaintiff's suggestion, what is the relevance to this case, where the alleged "barrier" is defined in the drug labeling as a system component of the drug? The Court fails to see the relevance of *Harris* to the facts before the Court.

On the contrary, courts that have specifically considered the novel approach to product-splitting suggested by Plaintiff in the instant case have impliedly or expressly rejected such a notion as applied to a "patch" product. *See Bower v. Johnson & Johnson*, 795 F. Supp. 2d 672, 677 (N.D.

Ohio 2011) (finding that plaintiff's claims of alleged defects in a contraceptive patch, that delivered its pharmacologically active ingredient through "a thin, matrix-type transdermal contraceptive patch consisting of three layers," was precluded as a matter of law by MCL 600.2946(5)). In *Lake-Allen v. Johnson & Johnson, L.P.*, No. 08-cv-930, 2009 WL 2252198 (D. Utah July 27, 2009), the court expressly rejected such a notion relating to MFTS's brand-name equivalent, Duragesic®. Rejecting the "nonsensical" argument that the patch was more like a container than a drug, the court observed:

> Plaintiffs' argument that the patch is more akin to a container is unpersuasive. The Duragesic® patch was approved by the FDA as a drug and to categorize it as a container is akin to categorizing any substance available in a time release capsule as a container. In the case of prescription pharmaceutical patches, it is nonsensical to separate the liability of the overall product and the substance that it releases.

2009 WL 2252198, at *3.

So too here. Plaintiff has offered no basis, legal or otherwise, on which the Court can embrace the suggestion that the "non-pharmacologic" "film" or "adhesive" layers of the patch can be viewed as a separate "medical device," distinct from the pharmacologically active ingredient fentanyl, for purposes of this product liability claim. There is no evidence that the FDA made such a distinction when it referred to MFTS throughout the approval process as a "drug," and ultimately approved the drug with labeling that defines as one of the drug's "system components" the very layers that Plaintiff claims were defective and caused her decedent's death. Given that the applicable statutory definition of "drug" expressly includes such component parts, the Court cannot see how it can adopt Plaintiff's suggested interpretation of the relevant "product" in this case as being some type of "medical device," distinct from the FDA-approved "drug" MFTS, which includes each of its system components, both pharmacologically active and inactive.

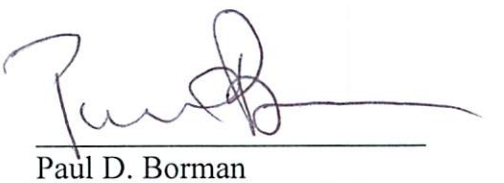
Because the Court concludes that MFTS is a "drug" as that term is used in MCL 600.2946(5),

and because there is no dispute that the FDA approved MFTS nor any suggestion that the FDA or any other federal agency has ever made a finding of fraud or bribery in connection with approval of MFTS, which remains on the market today, the Court GRANTS the Mylan Defendant's motion to dismiss Plaintiff's Complaint in its entirety.

IV. CONCLUSION

For the foregoing reasons, the Court GRANTS Defendants' Motion to Dismiss and DISMISSES Plaintiff's Complaint with prejudice.

IT IS SO ORDERED.



Paul D. Borman
United States District Judge

Dated: 10-25-12