No. 17–230

IN THE

Supreme Court of the United States

ALICE IVERS

Petitioner,

v.

WESTERLY PHARMACEUTICAL, INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Twelfth Circuit

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BRIEF FOR RESPONDENT

Date: September 21, 2017

Team # 2610

Counsel for Respondent

Oral Argument Requested

QUESTIONS PRESENTED

1. *PLIVA v. Mensing* and *Mutual Pharmaceutical Co. v. Bartlett* hold the FDA's drug laws preempt claims against generic drug manufacturers for defectively designing and failing to update warnings labels. Petitioner alleges that Respondent violated Illinoza law in defectively designing and failing to update the label on its generic drug. Are Petitioner's claims against Respondent preempted when this Court has held the FDA's laws preempt similar claims?

2. Rule 41(d) provides courts discretion to award "costs" against a party when it voluntarily dismisses a suit and files a second suit involving the same claim. The rule does not define costs, but it is designed to prevent forum shopping and vexatious litigation. Petitioner nonsuited her case and subsequently filed a second suit involving the same claim. Was it proper for the lower court to award the Respondent attorney's fees under Rule 41(d)?

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OPINIONS BELOW

The United States District Court for the District of Illinoza granted Westerly's motion for judgment on the pleadings. R. at 8. The court found that Ivers alleged that Westerly failed to warn of the spending and gambling side effect that caused her injury. R. at 5. However, her claim was no different than the plaintiffs' claims *in PLIVA v. Mensing* and *Mutual Pharmaceutical Company v. Bartlett*. *Id.* Therefore, the court held that Ivers's claims were preempted. *Id*.

The district court also granted Westerly's motion for an award of costs in part and denied it in part. R. at 8. The court held that Federal Rule of Civil Procedure 41(d) only permits Westerly to recover litigation costs from Ivers other than attorney's fees. R. at 7.

The United States Court of Appeals for the Twelfth Circuit affirmed the district court's order dismissing the complaint. R. at 18. The court agreed with the district court that the federal law preempts Ivers's state-law claims under the Illinoza Products Liability Act, based on either form of conflict preemption. R. at 16. The court also affirmed the district court's Order awarding Westerly costs, and reversed the portion of the order denying Westerly's attorney's fees. R. at 18. The court held that Rule 41(d)'s award for costs includes attorney's fees. *Id.*

CONSTITUIONAL AND STATUTORY PROVISIONS

U.S. Const. art. III

U.S. Const. art. VI, cl. 2

21 U.S.C. § 301 (2017).

21 U.S.C. § 355 (2017).

28 U.S.C. § 1920 (2008).

28 U.S.C. § 2072 (1988).

28 U.S.C. § 2074 (1988).

STATEMENT OF THE CASE

Lawsuits inherently involve risk. Like a game of Texas Hold 'Em, each party has a starting hand. The pleadings and discovery responses represent the shared cards, which each player uses to make the best possible hand. In the middle of the game, a turn card is revealed that often makes or breaks an opponent's hand. There are only two real ways to end the game: (1) the players reveal their hands in a showdown; or (2) someone bets enough that it convinces the other party to fold.

Alice Ivers ("Ivers") decided to try her hand when she filed a products-liability claim against Westerly Pharmaceutical, Inc. ("Westerly") on January 15, 2013, in the Western District of East Texas state court. R. at 5. One month later, the turn card was revealed by the Fifth Circuit's opinion in *Morris v. PLIVA, Inc.*, illustrating to Ivers that her claim was likely preempted. *Id.* At that point, Ivers decided to fold. She filed a notice of voluntary dismissal on February 25, 2013. *Id.*

Unsatisfied with her attempt at the game, Ivers decided to try her luck again. She knew she faced a dominated hand and that the stakes were higher than before, but that did not stop her. Ivers filed a second complaint against Westerly on September 15, 2015, in the state court of Illinoza. R. at 1. She laid out the shared cards, alleging that Westerly's ropidope medication caused her to develop compulsive spending and gambling behaviors. R. at 3. Westerly properly removed the action to the Illinoza District Court on October 14, 2015. *Id.* Westerly sought an end to the game by moving for judgment on the pleadings and an award of costs on November 2, 2015. *Id.*

The district judge saw that Westerly's hand was stronger, so it granted the motion for judgment on the pleadings and partially granted an award of costs excluding attorney's fees. R. at 7. The court reasoned that attorney's fees are not recoverable under Federal Rule of Civil Procedure 41(d). R. at 5, 7. Ivers, refusing to walk away from the table, appealed to the United States Court of Appeals for the Twelfth Circuit on January 14, 2016. R. at 9, 11.

The Twelfth Circuit affirmed the district court's dismissal of the complaint and award of costs to Westerly. R. at 18. Additionally, the court reversed the district court's decision to deny attorney's fees under Rule 41(d) and remanded the case for proceedings consistent with its opinion. *Id.* Ivers petitioned this Court for certiorari.

This exhausted game of Hold 'Em should have ended long ago, but some people just refuse to walk away with a loss. This case provides this Court the opportunity to resolve the following two issues in the law: (1) state law tort claims against generic drug manufacturers for design defects and inadequate labeling are wholly preempted; and (2) federal courts are authorized to award attorney's fees under Rule 41(d).

SUMMARY OF THE ARGUMENT

The lower courts in this case did exactly what Article Three of the United States Constitution requires: they followed Supreme Court precedent as inferior courts of law and held that state law tort claims against generic drug manufacturers are preempted. With guidance from a majority of its sister circuits, the Twelfth Circuit also interpreted an ambiguous rule by adhering to the canons of

construction, logic, and reason. The Respondent is before the Supreme Court today to request that it affirm those well-reasoned decisions.

Petitioner's claims under Illinoza's Products Liability Act are clearly preempted by the Federal Food, Drug & Cosmetic Act ("FDCA"), therefore rendering any tort action asserted by Ivers regarding defective design or inadequate labeling ineffective. Congress passed the FDCA to enable the Food and Drug Administration ("FDA") to ensure that Americans only consume safe products. Quality control can be expensive, and the cost of healthcare has continued to increase annually. Prescription pharmaceuticals account for a significant portion of healthcare costs.

In order to lower the costs of prescription drugs and increase their availability to Americans, Congress amended the FDCA with the Hatch-Waxman Act. The Act enables generic drug manufacturers to submit abbreviated applications to the FDA to demonstrate that a generic version is bioequivalent to a name-brand drug that has lost its patent protection. The Act does not permit generic manufacturers to unilaterally change warning labels; rather, the manufacturer must wait until the brand-name manufacturer changes its label. After the brand-name label is approved, the generic drug's label must be updated to match the brand-name label.

Individual consumers have attempted to bring state law tort claims against generic manufacturers rooted in products liability in the past, but this Court's decisions in *PLIVA v. Mensing* and *Mutual Pharmaceutical Company v. Bartlett*, preempt Petitioner's claims in this case. In both of those cases, this Court reasoned

that the FDA's specific requirements for generic drug manufacturers are supreme federal law. State laws that place additional burdens on a generic manufacturer to unilaterally update a label create a conflict of law, thereby hindering Congress's objectives and making it impossible for the generic manufacturer to comply with both laws. Illinoza's Products Liability Act is no different.

Congress does not evince any intent to hold generic manufacturers liable for the contents of a label. In amending the FDCA, Congress could have placed a duty on generic manufacturers to unilaterally update labels if the company discovered any additional side effects. The lack of such an amendment demonstrates that Congress intends this burden to remain on the brand-name manufacturer. While it is unfortunate that an individual harmed by a generic drug is without recourse, it is not this Court's role to decide a change in statutory law.

Petitioner anticipated that her claims were preempted, which is why she voluntarily nonsuited her first state law claim in Texas. This anticipation created the second issue in this case because Petitioner does not want to pay for the burdens and inconveniences she has caused Respondent. Courts may award attorney's fees under Federal Rule of Civil Procedure 41(d) because the rule itself implies it, the term "costs" has a broad meaning, and Rules 54 and 68 have separate interpretations. Rule 41 does not expressly mention attorney's fees, but when read in its entirety, Rule 41 implicitly authorizes attorney's fees.

A majority of courts that have considered this issue hold that Rule 41(d) can permit an awarding of attorney's fees. Rule 41(d)'s purpose of deterring forum

shopping and vexatious litigation is best met by awarding attorney's fees under the broad definition of "costs," which includes services. With the underlying purpose of Rule 41(d) in mind, it is apparent that it was appropriate for the Twelfth Circuit to award Westerly costs including attorney's fees. For these reasons, the opinions of the courts below should be affirmed so that Petitioner's game will finally end and Respondent may be fairly compensated.

ARGUMENT

When a court evaluates a dismissal on the pleadings, it applies a de novo standard of review. *Minch Family LLLP v. Buffalo–Red River Watershed Dist.,* 628 F.3d 960, 965 (8th Cir. 2010). Furthermore, courts review an award of attorney's fees under Rule 41(d) for abuse of discretion. *Evans v. Safeway Stores, Inc.*, 623 F.2d 121, 122 (8th Cir. 1980). Here, Ivers raises the legal question of whether the Illinoza state law claims against Westerly are preempted, and the question of whether Rule 41(d) permits courts to award costs including attorney's fees. Because both issues center on the lower court's dismissal on the pleadings and award of attorney's fees, this Court should apply a de novo standard of review to the dismissal and an abuse of discretion standard of review to the Twelfth Circuit's order.

I. Ivers's claims under Illinoza's Products Liability Act 1998-4(1) are clearly preempted by the Federal Food, Drug & Cosmetic Act, therefore rendering any state tort action asserted by Ivers regarding defective design or inadequate labeling of a generic drug under Illinoza law ineffective.

Last year, the United States spent over $3 trillion on healthcare. *See* David Lind & Yogesh Shah, M.D., *Time to Move Upstream and 'Invest' in our Health*,

HEARTLAND HEALTH & RESEARCH INST., (July 18, 2017), https://hhri.net/tag/institute-of-medicine. The Institute of Medicine recently reported that over $750 billion of healthcare spending is on unnecessary and overpriced goods and services. *Id.* At just over $9,000 per capita, the United States citizen spends more on healthcare than citizens in any other developed country. *Id.* If one-third of costs are wasted, then each citizen spends $3,000 per year on unnecessary healthcare expenses.

Pharmaceutical spending amounts to $300 billion of overall healthcare spending. *Id.* The FDA has been working to decrease this amount since 1848, when it first began as a function of the Department of Agriculture. *See* U.S. Food & Drug Admin., *History*, FDA www.fda.gov/aboutfda. (last visited Sept. 20, 2017). As the "oldest comprehensive consumer protection agency in the U.S. federal government," the FDA is designed to ensure that businesses only produce safe, quality products for U.S. consumers. *Id.* In 1938, Congress passed the Federal Food Drug & Cosmetic Act ("FDCA"), which authorizes the FDA to regulate the safety of food, drugs, and cosmetics. 21 U.S.C. § 301 *et seq.* (2017) (current through P.L. 115-52).

In an attempt to decrease the costs of pharmaceuticals, the FDA's Office of Generic Drugs and Center for Drug Evaluation and Research approve generic versions of brand name drugs, "which in turn creates more affordable treatment options for patients." *Id.* at www.fda.gov/officeofgenericdrugs, (last visited Sept. 20, 2017). The FDA's efforts have not been in vain. Drug spending is growing at "less than half the rate" that it used to. QuintilesIMS, *U.S. Drug Spending Growth of 4.8*

Percent in 2016 1 (May 5, 2016). This reduction is, in large part, due to the availability of generic prescriptions. *See id.* at 2-4.

In 1984, Congress amended the FDCA by passing the Drug Price Competition Act and Patent Term Restoration Act, informally known as the Hatch-Waxman Act. 21 U.S.C. § 355 (2012). When a branded product loses its patent, the Act permits a generic drug company to file an Abbreviated New Drug Application (ANDA), which is a shorter version of the drug application than a brand-name drug manufacturer files. U.S. Food & Drug Admin, *Office of Generic Drugs,* www.fda.gov/officeofgenericdrugs, (last visited Sept. 20, 2017). The generic drug must be pharmaceutically and biologically equivalent to the name brand-drug, and the warning labels must match. *See* 21 U.S.C. § 355(j)(2)(A)(iii)-(iv). The availability of generic drugs "helps to create competition in the marketplace, which helps to make treatment more affordable and increases access to healthcare for more patients. U.S. Food & Drug Admin., *Generic Drug Facts,* FDA, www.fda.gov/drugs. (last visited Sept. 20, 2017).

While the FDA strives to ensure that citizens only consume safe drugs, the pharmaceuticals are manmade and thus, are not perfect. Additionally, all human beings are different, and each person may react to a medication in a different way. The FDA requires that the labels accompanying all drugs contain sufficient warnings for the consumer; however, the federal law places the burden of the contents of those labels on the brand-name manufacturer and not the generic manufacturer.

This brief details the federal law of preemption and how it applies in the pharmaceutical context. The Supreme Court authority on this issue holds that it is improper for consumers to hold generic manufacturers liable based on the contents of a drug's label. The case law from this Court explicitly preempts state law tort claims against generic drug manufacturers for defective design and inadequate labeling. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011); *see also Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013). Additionally, Congress has amended the FDCA several times, with amendments as recent as August 18, 2017. *See* The FDA Reauthorization Act of 2017, P.L. No. 115-52, H. Rep. No. 2430 (2017). While Congress has had the opportunity to do so, it has never amended the law to place a duty on generic manufacturers to independently update warning labels. This Court should affirm the district court and Twelfth Circuit decisions holding that the federal law preempts state law tort claims against generic manufacturers based on design defects and inadequate labeling.

A. This Court's decisions in *PLIVA v. Mensing* and *Mutual Pharmaceutical Co. Inc. v. Bartlett* preempt Petitioner's claims in this case.

The Constitution enables states to pass laws to protect citizens, so long as they are not preempted. *See* U.S. Const. art. VI, cl. 2. Many consumer protections are included in state tort law, especially in the pharmaceutical industry. State tort laws regarding pharmaceuticals are designed to incentivize drug manufacturers to discover and disclose the risks associate with their products. *See Wyeth v. Levine*, 555 U.S. 555, 579 (2009). The state laws also seek to compensate individuals who

have been harmed by a drug; however, if federal laws are already in place, a state law may be preempted. *Id.* at 577–580.

The Supremacy Clause of the United States Constitution provides the basis for preemption:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.
>
> U.S. CONST. art. VI, cl. 2.

There are three categories of preemption recognized by the courts: (1) express preemption; (2) field preemption; and (3) conflict preemption. *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 152 (1963). Express preemption occurs when a federal law specifies that state legislation is preempted. *See generally Chamber of Commerce of the U.S. v. Whiting*, 563 U.S. 582, 592 (2011) (holding federal law expressly preempted sanctioning employers of illegal aliens). Field preemption occurs when Congress controls an area of law. *See generally Arizona v. United States*, 567 U.S. 387, 401-02 (2012) (holding the Federal Government occupies the field of immigration law).

This brief concerns the third category, conflict preemption, which occurs when a party cannot comply with both the federal and state law. *E.g.*, *Fla. Lime & Avocado Growers,* 373 U.S. at 152 (holding the state law was not preempted because farmers could comply with both laws). The third category is divided into "impossibility" preemption and "obstacle" preemption. *Id.* For impossibility preemption, the movant has the burden of proving it is impossible to comply with

both laws. *See id.* To prove obstacle preemption, the movant must show the state law creates an "obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). When courts evaluate a preemption decision based on Congress's delegation of authority to a federal agency, it gives deference to the federal agency's views. *Geier v. Am. Honda Motor Co.,* 120 S.Ct. 1913, 1926 (2000).

In *Wyeth v. Levine*, this Court held that brand-name drug companies could be liable for inadequate drug labeling. *Wyeth,* 555 U.S. at 575–77. Two years later, in *PLIVA, Inc. v. Mensing*, this Court held that generic drug companies could not be sued for the inadequacy of drug labels. *PLIVA, Inc.,* 564 U.S. 604, 616-18.

In *PLIVA*, two consolidated suits involved claims against the manufacturer of metoclopramide, a generic version of the brand-name equivalent drug Reglan. *Id.* at 608–09. The drug was prescribed to the plaintiffs to treat complications with their digestive tracts. *Id.* The plaintiffs took metoclopramide and subsequently developed tardive dyskinesia—a condition affecting the nervous system. *Id.* The plaintiffs alleged that the manufacturer of metoclopramide was liable to them for failing to adequately warn them, via the label, that consuming the drug could cause one to develop tardive dyskinesia *Id.* at 610. The manufacturer argued that the FDA's regulations and statutes regarding generic labeling preempted state law tort claims, and this Court agreed. *Id.* at 618.

In the majority opinion, Justice Thomas pointed out that a primary reason that the Court departed from its opinion in *Wyeth* is that generic drug

manufacturers do not have the ability to unilaterally change drug labels. *Id.* at 620–21. In *Wyeth*, the Court explained that a name-brand manufacturer is able to comply with both state and federal laws that require it to unilaterally update a label. *Wyeth*, 555 U.S. at 580–81. However, the FDA's "duty of sameness" requirement forces generic drug manufacturers to have the same label as the name-brand equivalent. *PLIVA*, 564 U.S. at 616. This requirement prevented the manufacturers of metoclopramide from changing the safety label until the name-brand drug's label had been changed. *Id.* at 617. In this way, it was impossible for the generic manufacturer to comply with both the federal law's duty of sameness and the state law's duty on all drug manufacturers to update the labels. *Id.* at 624.

The FDA provides three methods for drug manufacturers to update warning labels. *Id.* at 614. One method is the "Changes Being Effected" ("CBE") process. *Id.* This permits a manufacturer to add to and strengthen labels without waiting for the FDA to approve. *Id.* Subsequently, the manufacturer sends the FDA the updated information, which it reviews and decides if it should be approved. *See id.* The second method is commonly referred to as the "Dear Doctor" letter, which allows a manufacturer to mail updated information to physicians regarding recently discovered side effects of the drug. *Id.* at 615. A generic manufacturer can neither initiate the CBE method nor the Dear Doctor method. *See id.*

The last method allows any drug manufacturer, generic or brand name, to request the FDA to strengthen the drug's warning label. *Id.* at 616. The manufacturer sends the new information to the FDA, which reviews it and decides

whether or not to require an update. *Id.* Proponents of generic drug manufacturer liability, including Justice Sotomayor in her dissent, argue that the third method of label updating imposes a *duty* of drug manufacturers rather than a *means* of notifying the FDA of side effects. *Id.* at 626-27 (Sotomayor, J., dissenting) (emphasis added). Justice Sotomayor argued that the generic manufacturer should not be able to prevail on a preemption defense "if they have not even attempted to employ that mechanism." *Id.* at 627. The majority, however, considered this argument and still held the claims were preempted *Id.* at. 618.

The FDA clearly distinguishes between generic and brand name drug manufacturers. *See id.* at 613. Brand name manufacturers must prove the accuracy and adequacy of a label, while a generic manufacturer is only "responsible for ensuring that its warnings label is the same as the brand name's." *Id.* (citing 21 U.S.C. §§ 355(b)(1), (d), (j)(2)(A)(v), (j)(4)(G), 21 C.F.R. §§ 314.94(a)(8), 127(a)(7) and *Wyeth v. Levine*, 555 U.S. 555, 570-71 (2009)). Regardless of the FDA's logic behind such a distinction, this Court adhered to the federal law in *PLIVA* and held that state law tort claims against generic drug companies for inadequate labeling are preempted. *Id.* at 625-26.

Like the defendant in *PLIVA*, Westerly manufactures generic pharmaceuticals. R. at 2. In January 2011, the name brand manufacturer, GlaxoCline, requested a change to its Equip® label that was approved by the FDA in June 2011. *Id.* Westerly submitted a CBE in January 2012, which the FDA approved a month later. *Id.* Under the Supremacy Clause of the Unites States

Constitution, federal law preempts a state law that mandates Westerly to unilaterally change its label. *See* U.S. Const. art. VI, cl. 2. The Twelfth Circuit looked to this Court's precedent, as it is required to do under Article III of the Constitution, and properly concluded that it was impossible for Westerly to comply with Illinoza state law without violating federal law. *See* U.S. CONST. art. III, § 1; *see also* R. at 13. Therefore, Petitioner's claim under the Illinoza Products Liability Act cannot survive.

In 2013, this Court granted certiorari in *Mutual Pharmaceutical Co. v. Bartlett*, and solidified that design defect claims based on a generic manufacturer's failure to strengthen warning labels are preempted. *See Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013). In *Bartlett*, the plaintiff developed a rare disease called Toxic Epidermal Necrolysis ("TEN"). *Id.* at 2471. She alleged that she developed the disease as a result of taking a generic drug for shoulder pain, clinoril. *Id.* The plaintiff sued the manufacturer in state court, and the manufacturer removed to federal court. *Id.* The jury found the manufacturer liable and the court of appeals affirmed. *Id.* This Court reversed, holding that the design defect claims based on a failure to strengthen the label are preempted due to the impossibility for the manufacturer to comply with both the federal and state law. *Id.* at 2477.

Ivers claims that she developed her compulsive spending and gambling habits in July 2011. R. at 3. Westerly was not permitted to file the CBE for ropidope until GlaxoCline's Equip® label change had been approved. After GlaxoCline changed its label, Westerly filed its CBE in a reasonable amount of time. *See id.*

Westerly complied with the federal duty of "sameness" as required by *PLIVA* and matched the labeling of the brand name drug. *Id.* While Ivers alleged that Westerly unreasonably failed to update its label to include warnings of the gambling side effect, such a claim is preempted.

Ivers continually used ropidope for three years after the label was changed to match the Equip® label. R. at 1, 3. This Court has already disposed of a party's ability to recover from generic manufacturers via design defect and failure to update claims. *Bartlett*, 133 S. Ct. at 2477. Westerly ensured that its warning label was the same as the brand-name drug, thereby complying with federal law. 21 U.S.C. §§ 355(b)(1), (d), (j)(2)(A)(v), (j)(4)(G), 21 C.F.R. §§ 314.94(a)(8), 127(a)(7); *Wyeth v. Levine*, 555 U.S. 555, 570-71 (2009). Based on it's reasoning in *PLIVA* and *Bartlett*, this Court should affirm that the claims against Westerly are preempted under federal law.

B. Congress did not intend to hold generic manufacturers liable and it is not this Court's role to decide a change in law.

Congress passed the Hatch-Waxman Act to improve the affordability of pharmaceutical drugs for consumers. Specifically, the Hatch-Waxman Act was created by Congress to ensure that certain beneficial prescription drugs were freely available to both patients and their physicians. *See Bartlett*, 133 S. Ct. at 2480. The Act is designed to lower the cost of healthcare for all by promoting the availability of low-cost generic drugs for Americans. *See* Julia Rosenthal, *Hatch-Waxman Use or Abuse? Collusive Settlements Between Brand-Name and Generic Drug Manufacturers*, 17 BERKELEY TECH. L.J. 317, 319–20 (2002). Since its enactment in

1984, consumers have saved billions of dollars by purchasing generic equivalents of brand name drugs. *Id.*

"The purpose of Congress's enactment of a particular act is the 'ultimate touchstone' in every case." *See Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485–86 (1996) (citing *Cipollone v. Liggett Group, Inc.,* 505 U.S. 504, 516 (1992)). To understand the scope of the Hatch-Waxman Act, this Court should have "a fair understanding of congressional purpose." *Cipollone*, 505 U.S. at 530, n. 27. This Court may best understand congressional intent from the language of the statute and the framework that surrounds it. *See Gade v. Nat'l Solid Wastes Mgmt. Ass'n,* 505 U.S. 88, 111 (1992). "This goes beyond the text and into the courts reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Medtronic,* 518 U.S. at 485–86.

Congress has amended the Hatch-Waxman Act several times. The most recent amendment, the FDA Reauthorization Act of 2017, was passed last month on August 18, 2017. P.L. No. 115-52, 2017, H. Rep. No. 2430. Despite the opportunity to do so, Congress has never placed a duty on generic manufacturers to update warning labels with the discovery of new side effects. The failure to implement such a duty on generic manufacturers suggests that Congress intends that this burden remain with the brand name manufacturers in order to streamline drug approvals and reduce overall healthcare expenses. In fact, the FDA Reauthorization Act of 2017 requires a speed-up approval process for several types of generic drugs,

because Congress determined that several brand-name drugs were only available at "egregious prices." 21 U.S.C. § 355(j)(5), (11)-(12); *see also* Food Drug Cosm. L. Rep. P 200218 (C.C.H.), 2017 WL 4018457 (2017).

Congress could have created an express preemption provision in the FDCA for generic pharmaceuticals. *See Bartlett*, 133 S. Ct. at 2480. Because it has not done so, this Court is "left to divine Congress'[s] will from the duties the statute imposes." *Id.* The Act and its amendments demonstrate a continuing desire by Congress to make generic drugs more accessible to consumers by expediting, rather than hindering, the approval process. It is clear from the text of the Hatch-Waxman Act, the purpose behind amendments, and the reasoned understanding of Congress's intent, that there has never been a duty on generic drug manufacturers to update their warning labels after the discovery of new side effects and before the brand name manufacturer updates its label.

Although Congress has not placed the duty or liability on the generic manufacturer, generic drugs are not just placed on the shelves of pharmacies without passing guidelines. *Bartlett*, 133 S.Ct. at 2470-71. The FDA must first review the ANDA and determine that it is the same as the brand name equivalent based on clinical and nonclinical studies. *See* 21 U.S.C. § 355(a). The FDA must also determine that the drug is safe, meaning that the drug's benefits exceed its risks. *Bartlett*, 133 S.Ct. at 2470-71; 60 Fed. Reg. 39180; 71 Fed. Reg. 3934.

If consumers purchase the more expensive brand-name drug, they are afforded the legal protection that comes with paying the higher retail price, i.e. the

ability to sue the manufacturer. As the First Circuit pointed out in *Bartlett*, the decision to take the generic drug is made by the consumer's doctor, the distributing pharmacy, or the individual consumer. *See Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 34 (1st Cir. 2012), *rev'd*, 133 S. Ct. 2466 (2013). The generic manufacturer has no say in whether the consumer ultimately purchases and consumes its product; therefore, in addition to federal preemption, it is illogical that Congress intended the generic manufacturer to be the responsible party.

Consumers pay less for generic prescriptions than brand-name drugs. "Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public." *PLIVA*, 564 U.S. at 626. If Congress intended generic manufactures of to undergo the same process of relabeling as brand name manufacturers do, it would defeat the Congressional objective of lowering prescription costs for the American people. If such a requirement existed, generic manufactures would have to spend the same amount of time and money as brand name manufactures, thereby requiring them to charge more for the product.

A study of 5.6 million prescriptions revealed that generic drugs have lowered the overall healthcare costs in terms of public insurance, private insurance, and consumer costs. *See* William H. Shrank et. al., *The Consequences of Requesting "Dispense as Written,"* 124 AM. J. MED. 309 (2011). The study also revealed that consumers are more likely to ignore a doctor's recommendation when a generic drug cannot be substituted for the brand name version. *Id.* at 311. Without generic

substitutes, patients are less likely to initially purchase a prescription or refill one. *Id.* at 313. If only brand-name drugs were available, most consumers would suffer due to the inability to pay for treatment. *See id.*

One month before Petitioner alleged she developed her "compulsive spending and gambling behaviors," the FDA approved GlaxoCline's label change. R. at 2. Six months later, Westerly notified the FDA of its label change to match the new GlaxoCline label, which became effective on February 1, 2012. R. at 3. It was not until the end of 2012, when petitioner depleted her entire savings and her husband divorced her, that she filed suit against Westerly. *Id.*

Within this time period, it is highly unlikely that Ivers did not receive a refill of the generic prescription with the new label. For Westerly to be liable to Petitioner, the Court would have to assume that Petitioner received a bottle of ropidope with the new label, but was already so addicted to gambling from using the drug that it caused her to deplete her savings. If Petitioner had been given a one-year supply of ropidope from her pharmacy, which prevented her from seeing the new label, or she read the new label, but chose to ignore it, it is still inconceivable that Westerly could be liable under basic tort law principles. Westerly is only required to update its label once GlaxoCline's was updated, which it did within less than one year of the Equip® label change. R. at 3.

Congress could one day amend the Hatch-Waxman Act to hold generic manufacturers liable for drug labels. But it is for the legislature, not the Court, to decide what information must be disclosed to consumers and what entity should be

liable when information is not disclosed or properly updated. *PLIVA*, 564 U.S. at 625 (citing *Cuomo v. Clearing House Assn., LLC,* 557 U.S. 519 (2009) (Thomas, J., concurring in part and dissenting in part)). This Court should affirm the lower courts' decisions and hold that such state law tort claims, as brought by the Petitioner, are preempted.

II. Courts may award attorney's fees under Federal Rule of Civil Procedure 41(d) because the rule itself implies it, the term "costs" has a broad meaning, and Rules 54 and 68 have separate interpretations.

In 1934, Congress passed the Rules Enabling Act to empower the Supreme Court to create procedural rules that govern over district and appellate courts. Act of June 19, 1934, Pub. L. No. 73-415, 48 Stat. 1064. In 1988, this power was reiterated in the Judicial Improvements and Access to Justice Act created to update the federal court rulemaking process. *See* 28 U.S.C. § 2072(a) (1988). The fact that Congress delegated rulemaking power to this Court implies that it has more power to interpret the Federal Rules of Civil Procedure than it does a statute like the Hatch-Waxman Act. *See* Karen Nelson Moore, *The Supreme Court's Role in Interpreting the Federal Rules of Civil Procedure*, 44 HASTINGS L.J. 1039, 1093 (1993). "Given substantial, although largely unexercised, powers of the Court in the promulgation process, a more activist role in the interpretative stage, one that considers purpose and policy, is appropriate." *Id.*

The power of rule interpretation is not unlimited. Congress specified that "[s]uch rules shall not abridge, enlarge or modify any substantive right." 28 U.S.C. § 2072(b) (1988). Additionally, Congress may reject any rule it disapproves of. *Id.* at. §

2074(a). In the past, Congress has also delayed the implementation of certain rules and enacted its own amendment to rules without involving the judiciary in the process. *See* Moore, at 1056-57. The cooperation between Congress and the judiciary with regard to rulemaking is essential to maintain a separation of powers; however, this Court is often best equipped to interpret the rules because of its expertise in procedural matters. *Id.* at 1060; *See* Jack B. Weinstein, *Reform of Court Rule-Making Procedures*, 76 COLUM. L. REV. 905, 929 (1976). This expertise is particularly relevant in interpreting Rule 41 to assess what costs should be awarded to certain parties in litigation.

The issue of whether Rule 41(d) permits the recovery of attorney's fees has divided federal practitioners and circuit courts alike. The Eighth and Tenth Circuits have upheld an award of attorney's fees under Rule 41(d). *See Evans v. Safeway Stores, Inc.*, 623 F.2d 121, 122 (8th Cir. 1980); *see also Meredith v. Stovall*, 216 F.3d 1087 (10th Cir. 2000). The Sixth Circuit holds that attorney's fees are not included as part of "costs" because the plain language of Rule 41(d) does not expressly include the phrase "attorney's fees." *Rogers v. Wal-Mart Stores, Inc.*, 230 F.3d 868 (6th Cir. 2000).

The Fourth and Seventh Circuits take a middle-ground position and hold that attorney's fees are not generally awardable under Rule 41(d) "unless the substantive statute that formed the basis of the original suit allows for the recovery as costs." *Andrews v. Am.'s Living Ctrs., LLC*, 827 F.3d 306, 311 (4th Cir. 2016); *Esposito v. Patrowski*, 223 F.3d 497, 501 (7th Cir. 2000).

This argument will address and deconstruct the language and purpose behind Rule 41, and illustrate that it authorizes courts to award attorney's fees to a defendant that is financially burdened by a plaintiff's voluntary dismissal and re-filing of a lawsuit. The second part will explain why the definition of "costs" should be construed broadly. The third part will distinguish Rule 41(d) from other rules that courts have used as a basis to hold that attorney's fees are not permitted under Rule 41(d). Additionally, this brief will acknowledge interpretations of the rule that do not permit an awarding of attorney's fees, and explain how they ultimately fail to align with the purpose of Rule 41. This Court should resolve this circuit split in favor of the majority and affirm the Twelfth Circuit's decision that costs under Rule 41(d) may include attorney's fees.

A. Read in its entirety, Rule 41 implicitly authorizes attorney's fees.

When interpreting federal rules, this Court begins its analysis with the plain language of a rule. *See Pavelic & LeFlore v. Marvel Entertainment Group*, 493 U.S. 120 (1989). This is the most logical starting point, because if the language is unambiguous there is no need for further inquiry. *See id.* at 124. In *Pavelic*, this Court sought to interpret who was included in the term "person" under Rule 11. *Id.* The disagreement between the majority and the dissent in *Pavelic* demonstrate how even simple terms such as "person" may have various interpretations. *See id.* at 128-29 (Marshall, J., dissenting). Therefore, it is necessary to consider the underlying policies behind a rule in addition to the rule's language.

It is easy to misconstrue the intent of a rule by interpreting a subsection out of context. Therefore, it is important for this Court to consider all of Rule 41—including its language, purpose, and effect. Rule 41(a) permits a plaintiff to voluntarily dismiss a case by (1) filing a notice of dismissal before the defendant answers or moves for summary judgment, or (2) filing a stipulation signed by the parties who appeared. FED. R. CIV. P. 41(a)(1)(A). The dismissal is without prejudice unless the "notice or stipulation states otherwise." *Id.* at 41(a)(1)(B). The plaintiff may also move the court to dismiss the case without prejudice if Rule 41(a)(1)(A) is not followed. *Id.* at 41(a)(2).

Rule 41 also provides a method of dismissal for the defendant to dismiss the case. The defendant may motion to dismiss the action due to the plaintiff's failure to prosecute the claim or comply with the federal rules. *Id.* at 41(b). A dismissal under Rule 41(b) acts as an adjudication on the merits. *Id.*

Rule 41's purpose is to deter plaintiffs from vexatious conduct by requiring them to compensate defendants for harm or prejudice caused by such conduct. *See* FED. R. CIV. P. 41; *see also Esposito*, 223 F.3d at 501 (citing *Esquivel v. Arau*, 913 F. Supp. 1382, 1391 (C.D. Cal. 1996). Rule 41(d) accomplishes this purpose by requiring the plaintiff to repay the defendant for the requisite expenses of defending the action that the plaintiff dismissed and subsequently re-filed. The specific language of Rule 41(d) provides:

> If a plaintiff who previously dismissed an action in any court files an action based on or including the same claim against the same defendant, the court: (1) may order the plaintiff to pay all or part of the

> costs of that previous action; and (2) may stay the proceedings until the plaintiff has complied. FED. R. CIV. P. 41(d).

There is a general consensus in the United States that each party in litigation pays their own attorney's fees; this consensus is commonly referred to as "the American Rule." *Alyeska Pipeline Servs. Co. v. Wilderness Soc'y*, 421 U.S. 240, 259-60 (1975). Under the American Rule, there are two circumstances that warrant the opposing party to pay attorney's fees: (1) when a statute or rule that forms the basis for the original lawsuit allows attorney's fees, or (2) when a court exercises its inherent equitable powers and orders them against an opposing party due to vexatious or bad-faith conduct. *Marek v. Chesny*, 473 U.S. 1, 36–37 (1985). In addition to the statutory and bad-faith exceptions, this Court has held that attorney's fees may be awarded if a rule "otherwise evinces an intent to provide for such fees." *Key Tronic Corp. v. United States*, 511 U.S. 809, 815 (1994).

Rule 41(d) gives courts broad discretion to award costs. *Esposito*, 223 F.3d at 501. The fact that Rule 41(d) does not expressly reference attorneys' fees does not mean they are not recoverable. Rule 41 as a whole "evinces an intent to provide for such fees." *Key Tronic Corp.,* 511 U.S. at 815. Additionally, Rule 41(d) is merely an extension of the American Rule's bad-faith exception. *Behrle v. Olshansky*, 139 F.R.D. 370, 374 (W.D. Ark. 1991).

Federal courts have the power to issue orders against the plaintiff for the payment of defendant's costs, but this power should not be abused. Plaintiffs are entitled to sue a proper defendant for compensation when they have been injured, and in the same way, the rules permit plaintiffs to voluntarily nonsuit. However,

the situation repeatedly arises where plaintiffs re-file the same suit after a court has granted the voluntary dismissal. This situation was specifically considered by the drafters of the rules and is the very reason that Rule 41(d) was created.

The Federal Rules of Civil Procedure grant courts the power to award attorney's fees in multiple provisions. While Rule 41(d) does not expressly state that attorney's fees are awardable, it provides courts with the discretion to issue any order against the plaintiff for the payment of "costs" for the action that it dismissed. FED. R. CIV. P. 41(d). A majority of courts that have considered this issue hold that Rule 41(d) can permit an awarding of attorney's fees. *Evans*, 623 F.2d at 121-22; *Stovall*, 216 F.3d at 1087; *Esposito*, 223 F.3d at 500-01 (taking the hybrid approach that attorney's fees may be awarded if the statute forming the basis of the cause of action allows for it); *Andrews*, 827 F.3d at 311 (adopting the Seventh Circuit's hybrid approach).

In contrast, the Sixth Circuit holds that the rule does not provide for attorney's fees. *See Rogers,* 230 F.3d at 874; *Duffy v. Ford Motor Co.*, 218 F.3d 623, 632-33 (6th Cir. 2000). The court's primary reason for prohibiting an award of attorney's fees under Rule 41(d) is that the rule does not expressly provide for it. *Rogers*, 230 F.3d at 874.

The Sixth Circuit has ignored the ultimate intent of the drafters who created 41(d). The purpose of Rule 41(d) is "to serve as a deterrent to forum shopping and vexatious litigation." *Simeone v. First Bank Nat'l Ass'n*, 971 F.2d 103, 108 (8th Cir. 1992). Allowing plaintiffs to voluntarily dismiss a case and subsequently re-file it

puts an expensive burden on defendants. Vexatious litigation delays the judicial process by placing a frivolous case on the court's docket. *See* Thomas Southard, *Increasing the Costs of Nonsuit: A Proposed Clarifying Amendment to Federal Rule of Civil Procedure 41(d)*, 32 SETON HALL L. REV. 367, 398 (2002).

With the underlying purpose of Rule 41(d) in mind, it is apparent that it was appropriate for the Twelfth Circuit to award Westerly costs including attorney's fees. Ivers initially filed suit against Westerly in the Western District of East Texas. R. at 17. After she filed, the Fifth Circuit held that state law claims against a generic manufacturer for failure to warn and breach of express warranty were preempted. *See Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013). Eleven days later, Ivers filed her Notice of Voluntary Dismissal under Rule 41(a). R. at 5. Ivers filed a subsequent lawsuit "plainly seek[ing] to trade disadvantageous law in one forum for advantageous law in another." R. at 17-18. Rule 41(d) is designed to allow parties like Westerly to recover the costs of having to defend a subsequent suit for the same cause of action. If courts are not permitted to award attorney's fees to deter this type of behavior, Rule 41(d) would serve no purpose. Congress did not intend for Rule 41(d) to be futile.

B. Rule 41(d)'s purpose of deterring forum shopping and vexatious litigation is best met by awarding attorney's fees under the broad definition of "costs."

Since attorney's fees are not expressly provided for in Rule 41(d), it is necessary to determine what the drafters' meant by "costs." Under the plain meaning construction, words in a statute that are not defined should be interpreted

as taking their ordinary and common meaning. *Williams v. Taylor*, 529 U.S. 420, 448 (2000). In the past, this Court has looked to dictionary definitions to interpret words that are not defined by statute or through case law. *Schreiber v. Burlington N., Inc.*, 472 U.S. 1, 7 (1985) (turning to the dictionary to establish the meaning of "manipulative").

Black's Law Dictionary defines costs as "the amount paid or charged for something; price or expenditure." BLACK'S LAW DICTIONARY 397 (9th ed. 2009). The definition also directs the reader to see the definition of expenses, which is defines as "an expenditure of money, time, labor, or resources to accomplish a result." *Id.* at 658. Admittedly, the term "attorney's fee" is separately defined as "[t]he charge to a client for services performed for the client, such as an hourly fee, a flat fee, or a contingent fee." *Id.* at 148. However, that does not mean that "costs" cannot include the portion of litigation expenses referred to as attorney's fees. Rule 41(d) grants courts "significant discretionary authority to impose any type of monetary sanction." *Southard*, at 378.

Attorney's fees are a significant part of litigation costs for defendants, especially when considering that most defense attorneys charge by the hour. *See* Thomas R. Malia, *Attorneys' Fees in Products Liability Suits*, 53 A.L.R. 4th 414 (1987). Some courts that allow attorney's fees under Rule 41 have held that they are not appropriate when the plaintiff only voluntary dismisses some of the claims—since the attorney's work was not in vain because he has to defend the remaining claims. *See Belkow v. Celotex Corp.*, 772 F. Supp. 1547 (N.D. Ill. 1989).

This limitation on awarding attorney's fees is logical; however, it is inapplicable to this case. Ivers voluntarily nonsuited her entire case. R. at 5. When she filed again in a separate state, Westerly incurred several costs. Westerly had to pay filing fees to remove the case, file an answer, and file its Motion for Judgment on the Pleadings and a Motion for an Award of Costs. *See* R. at 3. Westerly also had to pay its attorney to defend the subsequent suit, which includes paying counsel for all of the time spent drafting and filing said motions. The Twelfth Circuit correctly awarded Westerly its attorney's fees. Rule 41 is distinct from other rules, and its terms should be construed within the context of its purpose.

C. Rules 54 and 68 are distinguishable from Rule 41

The term "costs" is also used in other federal rules. Rule 54 requires courts to award costs "other than attorneys' fees" to the winning party unless it specifies otherwise. FED. R. CIV. P. 54. Courts have held that these Rule 54 "costs" are set out in 28 U.S.C. § 1920 and do not include attorney's fees. *See In re Paoli R.R. Yard PCP Litig.*, 221 F.3d 449, 457 (3d Cir. 2000). Rule 54 partially repays the successful party for specific expenses it incurred. *See id.* This rule is insignificant, especially when compared to Rule 41(d), because the drafters did not articulate a specific purpose for Rule 54, and courts largely ignore it in adhering to the American Rule. *See* John M. Blumers, *A Practice in Search of a Policy: Considerations of Relative Financial Standings in Cost Awards Under Federal Rule of Civil Procedure 54(d)(1),* 75 B.U. L. REV. 1541, 1563 (1995) (asserting there is no underlying policy to support awarding costs under Rule 54).

Unlike Rule 54(d), Rule 41(d) does not restrict courts to a specified list of costs in a statute. *See Behrle v. Olshansky*, 139 F.R.D. 370 (W.D. Ark. 1991). In *Behrle*, the court compared these two rules and concluded that courts have broader discretion under Rule 41(d) to award costs it deems appropriate. *Id.* at 374. Therefore, the term "costs" encompasses a broader scope of expenses under Rule 41(d) than those identified in respect to Rule 54(d). This distinction suggests that this word is not restricted to a single definition throughout the Federal Rules of Civil Procedure.

Rule 68 is another rule that some courts have relied on when holding that Rule 41(d) does not permit attorneys' fees in certain situations. *See Esposito*, 223 F.3d at 501. Rule 68 allows a defendant to make an offer to the plaintiff for a judgment against the defendant for a specific amount. *See* FED. R. CIV. P. 68. If the plaintiff refuses the offer, and the ultimate judgment is less than the offer, the plaintiff must absorb their own costs and pay the defendant's costs. *See id.*

This Court has held that Rule 68 only provides for attorneys' fees if the underlying statute provides for them. *Marek v. Chesny*, 473 U.S. 1 (1985). The Respondent does not challenge this contention, but unlike Rule 41(d), Rule 68 does not afford courts any discretion to allow the plaintiff to avoid paying costs. *Delta Air Lines, Inc. v. August*, 450 U.S. 346, 355 (1981). Instead, Rule 68 is restricted to the costs under Rule 54(d) and United States statutes. *Id.* Although its holding comes closer to the purpose of Rule 41 than the Sixth Circuit's decision in *Rogers* does, it was improper for the Seventh Circuit to rely on the language, purpose, and effect of

other rules like Rules 54 and 68 to determine what costs may be awarded to defendants under Rule 41(d).

"Vexatious litigation practices result in extensive and unwarranted use of judicial resources, and cannot be remedied without district courts having authority to formulate an appropriate monetary penalty to fit the particular conduct being sanctioned." *Southard*, at 398. This Court should put an end to the confusion surrounding Rule 41(d). By providing a uniform interpretation of Rule 41, this Court will adhere to the most important purpose of the Federal Rules as a whole—"just, speedy and inexpensive determination of every action." FED. R. CIV. P. 1. The Respondent respectfully asks this Court to affirm the judgment of the United States Court of Appeals for the Twelfth Circuit.

CONCLUSION

For the foregoing reasons, Westerly Pharmaceutical, Inc. respectfully requests this Court affirm the judgment of the Court of Appeals for the Twelfth Circuit.

Respectfully Submitted,

Team 2610

Team 2610
Counsel For Respondent
Date: September 21, 2017

APPENDIX A

21 U.S.C. § 355(a)

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

APPENDIX B

21 U.S.C. § 355(b)(1)

(b) Filing application; contents

(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application

(A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use;

(B) a full list of the articles used as components of such drug;

(C) a full statement of the composition of such drug;

(D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

(E) such samples of such drug and of the articles used as components thereof as the Secretary may require;

(F) specimens of the labeling proposed to be used for such drug, and

(G) any assessments required under section 355c of this title.

The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).

APPENDIX C

21 U.S.C. § 355(d)

(d) Grounds for refusing application; approval of application; "substantial evidence" defined

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that

(1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof;

(2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions;

(3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity;

(4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or

(5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or

(6) the application failed to contain the patent information prescribed by subsection (b) of this section; or

(7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application.

APPENDIX D

21 U.S.C. § 355(j)(2)(A)(iii)-(v)

Abbreviated new drug applications

(2)(A) An abbreviated application for a new drug shall contain--

> **(iii)** information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;
>
> **(iv)** information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);
>
> **(v)** information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

APPENDIX E

21 U.S.C. § 355(j)(4)(G)

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds

> **(G)** information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers.

APPENDIX F

FDA Reauthorization Act of 2017

TITLE VIII—IMPROVING GENERIC DRUG ACCESS

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended by adding at the end the following:

(11)(A) Subject to subparagraph (B), the Secretary shall prioritize the review of, and act within 8 months of the date of the submission of, an original abbreviated new drug application submitted for review under this subsection that is for a drug—

(i) for which there are not more than 3 approved drug products listed under paragraph (7) and for which there are no blocking patents and exclusivities; or

(ii) that has been included on the list under section 506E.

(B) To qualify for priority review under this paragraph, not later than 60 days prior to the submission of an application described in subparagraph (A) or that the Secretary may prioritize pursuant to subparagraph (D), the applicant shall provide complete, accurate information regarding facilities involved in manufacturing processes and testing of the drug that is the subject of the application, including facilities in corresponding Type II active pharmaceutical ingredients drug master files referenced in an application and sites or organizations involved in bioequivalence and clinical studies used to support the application, to enable the Secretary to make a determination regarding whether an inspection of a facility is necessary. Such information shall include the relevant (as determined by the Secretary) sections of such application, which shall be unchanged relative to the date of the submission of such application, except to the extent that a change is made to such information to exclude a facility that was not used to generate data to meet any application requirements for such submission and that is not the only facility intended to conduct one or more unit operations in commercial production. Information provided by an applicant under this subparagraph shall not be considered the submission of an application under this subsection.

(C) The Secretary may expedite an inspection or reinspection under section 704 of an establishment that proposes to manufacture a drug described in subparagraph (A).

(D) Nothing in this paragraph shall prevent the Secretary from prioritizing the review of other applications as the Secretary determines appropriate.

APPENDIX G

FDA Reauthorization Act of 2017

§ 808. INCENTIVIZING COMPETITIVE GENERIC DRUG DEVELOPMENT.

Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (**21 U.S.C. 355(j)(5))** is amended—

(1) in subparagraph (B), by adding at the end the following:

(v) 180-day exclusivity period for competitive generic therapies.—

(I) Effectiveness of application. Subject to subparagraph (D)(iv), if the application is for a drug that is the same as a competitive generic therapy for which any first approved applicant has commenced commercial marketing, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the competitive generic therapy (including the commercial marketing of the listed drug) by any first approved applicant.

(II) Limitation. The exclusivity period under sub-clause (I) shall not apply with respect to a competitive generic therapy that has previously received an exclusivity period under subclause (I).

(III) Definitions. In this clause and subparagraph (D)(iv):

(aa) The term 'competitive generic therapy' means a drug—

(AA) that is designated as a competitive generic therapy under section 506H; and

(BB) for which there are no unexpired patents or exclusivities on the list of products described in section 505(j)(7)(A) at the time of submission.

(bb) The term 'first approved applicant' means any applicant that has submitted an application that—

(AA) is for a competitive generic therapy that is approved on the first day on which any application for such competitive generic therapy is approved;

(BB) is not eligible for a 180-day exclusivity period under clause (iv) for the drug that is the subject of the application for the competitive generic therapy; and

(CC) is not for a drug for which all drug versions have forfeited eligibility for a 180-day exclusivity period under clause (iv) pursuant to subparagraph (D); and

(2) in subparagraph (D), by adding at the end the following:

(iv) Special forfeiture rule for competitive generic therapy. The 180-day exclusivity period described in subparagraph (B)(v) shall be forfeited by a first approved applicant if the applicant fails to market the competitive generic therapy within 75 days after the date on which the approval of the first approved applicant's application for the competitive generic therapy is made effective.

APPENDIX H

Illinoza Products Liability Act. 1998-4(1).

Relief is provided "upon showing that a manufacturer's product was unreasonably dangerous due to (a) manufacturing defect, (b) defective design, (c) inadequate instructions or warnings, or (d) failure to conform to an express warranty."