IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT ILLINOIS
EASTERN DIVISION

MICHAEL HOUSTON,	)	
	)	
Plaintiff,	)	**No. 14 C 1042**
	)	
v.	)	**Judge Jorge L. Alonso**
	)	
UNITED STATES OF AMERICA and QUALITEST PHARMACEUTICAL, INC.,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

In 2011, plaintiff took Allopurinol, a generic drug manufactured by Qualitest, for treatment of gout. (Compl. ¶¶ 6, 40-41.) After taking the medication as prescribed, plaintiff developed Stevens-Johnson Syndrome ("SJS"), a serious disorder that produces severe skin rashes and can cause blindness. (*Id.* ¶¶ 7-10, 13.) Plaintiff brings state-law claims alleging that Qualitest defectively designed Allopurinol (Count VI (First), Count VII, Count XI, and Count XII), failed to warn that the drug was dangerous (Counts VI (Second) and VIII), and failed to ensure that the drug performed as described and was fit for its intended purpose (Counts IX and X). Qualitest asks the Court to dismiss these claims as preempted by the federal Food, Cosmetic and Drug Act.

Under the Supremacy Clause of the Constitution, federal law is "the supreme Law of the Land" notwithstanding any state laws to the contrary. U.S. Const. art. IV, cl. 2. "Accordingly, it has long been settled that state laws that conflict with federal law are without effect." *Mutual Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013) (quotation omitted). Thus, if "it is impossible for a private party to comply with both state and federal [law]," the state law is preempted. *Id.* (quotation omitted).

Qualitest contends that the Federal Food, Drug, and Cosmetic Act preempts plaintiff's claims against it. That statute and the regulations promulgated under it require a generic drug to be bioequivalent to the brand-name drug, to have the same active ingredients, route of administration, dosage form, and strength of the brand-name drug, and to have the same labeling as the brand-name drug. 21 U.S.C. § 355(j)(2)(A)(ii)-(v). Moreover, once a generic drug is approved by the FDA, the manufacturer is prohibited from changing the drug's formulation or labeling. *Bartlett*, 133 S. Ct. at 2471.

This so-called "duty of sameness," *PLIVA v. Mensing*, 131 S. Ct. 2567, 2575 (2011),[1] that federal law imposes on Qualitest directly conflicts with its duties under state law, which as relevant here, are: (1) to design [a] reasonably safe product[]," *Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 264 (Ill. 2007) (Counts VI (First), VII, XI, and XII); (2) "to warn of a product's dangerous propensities," *Kirk v. Michael Reese Hospital & Medical Center*, 513 N.E.2d 387, 391 (Ill. 1987); *Connick v. Suzuki Motor Co.*, 675 N.E.2d 584, 593 (Ill. 1996) (Counts VI (Second) and VIII); and (3) to ensure that goods perform as described and are fit for the purpose for which they are sold, 810 Ill. Comp. Stat. §§ 5/2-313, 315; *Berry v. G.D. Searle & Co.*, 309 N.E.2d 550, 554-55 (Ill. 1974) (holding that prescription of drugs is a sale subject to the UCC) (Counts IX and X). Qualitest can only abide by these state-law duties if it changes the design or labeling of Allopurinol, steps that federal law prohibits it from taking. Because it is impossible for Qualitest to comply with both federal and state law, plaintiff's state-law claims are preempted. *See Bartlett*, 133 S. Ct. at 2470 (holding that "state-law design-defect claims that turn on the adequacy of a drug's warnings are pre-empted" (quotation

[1]Unlike the claims in *Mensing*, plaintiff's claims arose after the enactment of the Food and Drug Administration Amendments Act of 2007 ("FDAAA"). That statute did not, however, alter or eliminate the duty of sameness. *See* FDAAA, Pub. L. No. 110-85, 121 Stat. 823 (2007).

omitted); *Mensing*, 131 S. Ct. 2567, 2577 (2011) (holding that federal law preempted state failure-to-warn claims against generic drug manufacturers because "[i]t was not lawful under federal law for the Manufacturers to do what state law required of them," *i.e.*, "to use a different, stronger label" than the one approved by the FDA). Therefore, the Court grants Qualitest's motion to dismiss [13] and dismisses with prejudice the claims plaintiff asserts against it.

SO ORDERED. **ENTERED: April 20, 2015**

HON. JORGE L. ALONSO
United States District Judge