IN THE

SUPREME COURT OF THE STATE OF ARIZONA

RAYMOND R. CONKLIN, II, ET AL.,
Plaintiffs/Appellants,

v.

MEDTRONIC, INC., ET AL.,
Defendants/Appellees.

No. CV-17-0322-PR
Filed December 18, 2018

Appeal from the Superior Court in Maricopa County
The Honorable Lori Horn Bustamante, Judge
No. CV2015-002965
AFFIRMED

Opinion of the Court of Appeals, Division One
244 Ariz. 139 (App. 2017)
VACATED IN PART

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JUSTICE PELANDER authored the opinion of the Court, in which CHIEF JUSTICE BALES, VICE CHIEF JUSTICE BRUTINEL, and JUSTICES TIMMER, BOLICK, GOULD, and LOPEZ joined.

JUSTICE PELANDER, opinion of the Court:

¶1 The issue here is whether federal law preempts an Arizona common law failure-to-warn claim based on a medical device manufacturer's failure to submit adverse event reports to the United States Food and Drug Administration ("FDA"). We hold that the claim is impliedly preempted.

I.

¶2 After injuring his hip years ago, Raymond R. Conklin, II experienced chronic pain. In 2008, a physician surgically implanted a Medtronic SynchroMed II 40 ml infusion pump and catheter ("Pain Pump") into Conklin to manage pain. Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. (collectively, "Medtronic") designed, manufactured, marketed, and sold the Pain Pump.

¶3 Conklin underwent hip surgery in 2013 and in the aftermath suffered permanent injury allegedly caused by drug over-infusion from his continued use of the Pain Pump. Conklin and his wife sued Medtronic alleging several common law tort claims, including both strict liability and negligence claims for failure to provide adequate and timely warnings. In those claims Conklin alleged that before his 2013 injury, the FDA sent warning letters to Medtronic, advising it that the Pain Pump was adulterated and misbranded and stating that Medtronic had failed to report adverse events to the FDA after the FDA approved the Pain Pump in its pre-market approval ("PMA") process. Conklin also alleged that before his 2013 injury, the FDA issued two recalls of the Pain Pump regarding the unintentional injection or cessation of drugs, and that after his injury the FDA issued another recall relating to the Pain Pump's unintended delivery of drugs that could result in a drug overdose. Conklin further alleged that Medtronic's failure to report post-PMA adverse events to the FDA in violation of federal law gives rise to liability under Arizona common law.

¶4 Medtronic moved to dismiss the claims under Arizona Rule of Civil Procedure 12(b)(6), arguing that all Conklin's claims are expressly and impliedly preempted under federal law. The superior court agreed and dismissed the action

against Medtronic with prejudice.

¶5 The court of appeals affirmed in part, upholding on preemption grounds the dismissal of Conklin's product liability and negligence claims based on alleged design and manufacturing defects, as well as the claim for breach of express warranty. *Conklin v. Medtronic, Inc.*, 244 Ariz. 139, 142 ¶ 3, 147 ¶ 33 (App. 2017). The court determined that those claims were expressly preempted. *Id.* at 144–45 ¶¶ 14–17, 146–47 ¶ 26. But the court of appeals vacated the superior court's dismissal of Conklin's failure-to-warn claim, finding it neither expressly nor impliedly preempted. *Id.* at 145 ¶ 18, 147–48 ¶ 33. In so ruling, the court of appeals followed *Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013), in which the Ninth Circuit found no federal preemption of an Arizona failure-to-warn claim like Conklin's. *See Conklin*, 244 Ariz. at 145–46 ¶¶ 18–25.

¶6 The issue Medtronic presents for our review is whether federal law preempts a failure-to-warn claim predicated on a medical device manufacturer's failure to submit adverse event reports to the FDA. We granted review because this legal issue is of statewide importance and likely to recur. Our jurisdiction is based on article 6, section 5(3) of the Arizona Constitution and A.R.S. § 12-120.24.

II.

¶7 We review a trial court's dismissal of a complaint under Rule 12(b)(6) de novo. *Coleman v. City of Mesa*, 230 Ariz. 352, 355 ¶ 7 (2012). Dismissal under that rule is appropriate "only if as a matter of law plaintiffs would not be entitled to relief under any interpretation of the facts susceptible of proof." *Id.* at 356 ¶ 8 (internal quotation marks and alteration omitted) (quoting *Fid. Sec. Life Ins. Co. v. Ariz. Dep't of Ins.*, 191 Ariz. 222, 224 ¶ 4 (1998)). We also review de novo issues of law relating to alleged federal preemption of state law claims. *Hutto v. Francisco*, 210 Ariz. 88, 90 ¶ 7 (App. 2005).

¶8 As the court of appeals correctly observed, Medtronic has the burden of establishing preemption. *Conklin*, 244 Ariz. at 143 ¶ 8. In addition, although "federal laws are presumed not to preempt state laws, courts do not invoke that presumption when the federal statute contains an express preemption clause." *Id.*; *see also Puerto Rico v. Franklin Cal. Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016); *cf. Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315–30 (2008) (analyzing federal statute's express preemption provision without invoking a presumption against preemption); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347–48 (2001) (finding "no presumption against pre-emption" when device manufacturer's "dealings with the FDA were prompted" and governed by applicable federal law). Medtronic argues that Conklin's failure-to-warn claim is both expressly and impliedly preempted by federal law. Before addressing those assertions, we briefly summarize the legal backdrop of Conklin's claim and Medtronic's argument.

III.

¶9 The Federal Food, Drug, and Cosmetic Act ("FDCA"), Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301–399i), was enacted in 1938 to govern and require FDA approval for introduction of new drugs into the market. *Riegel*, 552 U.S. at 315. Thereafter, states generally were left to supervise the introduction of new medical devices. *Id.* That changed in 1976 when Congress enacted the Medical Device Amendments ("MDA"), Pub. L. No. 94-295, 90 Stat. 539, which "swept back some state obligations and imposed a regime of detailed federal oversight" for medical devices. *Riegel*, 552 U.S. at 316.

¶10 The MDA's most rigorous level of oversight, which includes an extensive PMA process and review of proposed product labeling, applies to medical devices categorized as Class III devices. *Id.* at 317–19; *see also* 21 U.S.C. §§ 360c, 360e; *Buckman*, 531 U.S. at 348 (noting that PMA review "involves a time-consuming inquiry into the risks and efficacy of each device"); 21 C.F.R. § 814.44(a). Medtronic's Pain Pump is a Class III device. The FDA granted PMA for the Pain Pump before the device was surgically implanted into Conklin's body in 2008.

¶11 "Once a device has received [PMA], the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319; *see also* 21 U.S.C. § 360e(d)(5)(A)(i). "If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental [PMA], to be evaluated under largely the same criteria as an initial application." *Riegel*, 552 U.S. at 319; *see also* 21 U.S.C. § 360e(d)(5); 21 C.F.R. § 814.39(c).

¶12 Even after the FDA grants PMA for a device, the device is "subject to reporting requirements." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360i). Those requirements include "the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of," *id.* (citing 21 C.F.R. § 814.84(b)(2)), "and to report incidents in which the device may have caused or contributed to death or serious injury[] or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred," *id.* (citing 21 C.F.R. § 803.50(a)). The documents to which this latter requirement refers are called "adverse event reports." Conklin's failure-to-warn claim is based solely on Medtronic's failure to submit reports in compliance with that requirement.

¶13 The FDA "has at its disposal a variety of enforcement options that allow it to make a measured response" to any product defect or wrongdoing, including "seeking injunctive relief, 21 U.S.C. § 332, and civil penalties, [*id.*] § 333(f)(1)(A); seizing the device, [*id.*] § 334(a)(2)(D); and pursuing criminal prosecutions, [*id.*] § 333(a)." *See Buckman*, 531 U.S. at 349. In addition, "[t]he FDA has the power to withdraw [PMA] based on newly

reported data or existing information and must withdraw [PMA] if it determines that a device is unsafe or ineffective under the conditions in its labeling." *Riegel*, 552 U.S. at 31920 (citing 21 U.S.C. § 360e(e)(1)). The Medtronic Pain Pump was subject to a recall in 2011 and 2012, but the FDA has never rescinded the PMA and the device continues to be sold.

IV.

¶14 The MDA contains an express preemption provision. As relevant here, that provision states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a); *see also* 21 C.F.R. § 808.1(d) (FDA's implementing regulation for the MDA's express preemption provision).

¶15 The United States Supreme Court has interpreted that provision as setting forth the following two-part test for determining whether the MDA expressly preempts a claim: (1) Has "the Federal Government . . . established requirements applicable to [the medical device]"? (2) If so, are the common law claims based on state law requirements "with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness"? *Riegel*, 552 U.S. at 321–22 (quoting 21 U.S.C. § 360k(a)(1)). The first prong is indisputably met here. The PMA process "imposes 'requirements' under the MDA" because that process "is specific to individual devices." *Id.* at 322–23. Therefore, Congress has established requirements applicable to the Medtronic Pain Pump.

¶16 As for the second prong, if the state law requirements "are 'different from, or in addition to' the requirements imposed by federal law," then the state law claims are expressly preempted. *Id.* at 330 (quoting 21 U.S.C. § 360k(a)(1)). If not, however, the claims are not expressly preempted because § 360k(a) "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)).

¶17 The MDA also impliedly preempts certain state law claims. Specifically,

the MDA provides that "all . . . proceedings for the enforcement . . . of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court has interpreted this provision to mean that "it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman*, 531 U.S. at 349 n.4. Thus, state law claims based not on "traditional state tort law which . . . predated the federal enactments in question[]," *id.* at 353, but rather solely on noncompliance with the MDA are impliedly preempted because "Congress intended that the MDA be enforced exclusively by the Federal Government," *id.* at 352.

¶18 Read together, "[t]hese two types of preemption, operating in tandem, have created . . . a 'narrow gap' for pleadings." *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017) (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)). "To make it through, a plaintiff has to sue for conduct that *violates* a federal requirement (avoiding express preemption), but cannot sue *only because* the conduct violate[s] that federal requirement (avoiding implied preemption)." *Id.* (emphasis added).

¶19 Here, the question is whether Conklin's failure-to-warn claim fits within the "narrow gap" so as to avoid express or implied preemption. Medtronic argues that it does not and that the claim is both expressly and impliedly preempted. Relying primarily on *Stengel* and the court of appeals' opinion here, Conklin counters that his failure-to-warn claim is not expressly or impliedly preempted because Medtronic's conduct violated Arizona's "pre-existing state common law of negligence." According to Conklin, that claim is not preempted because a manufacturer is required under federal *and* Arizona law to submit adverse event reports to the FDA.

¶20 As noted above, *supra* ¶ 12, Conklin's failure-to-warn claim is based solely on Medtronic's alleged failure to submit to the FDA post-PMA adverse event reports regarding the Pain Pump. The court of appeals correctly stated that to the extent Conklin "allege[s] a violation of any state-law duty to directly warn [him] or his physicians, . . . such claims are expressly preempted because those duties would be in addition to requirements imposed by federal law." *Conklin*, 244 Ariz. at 146 ¶ 24 (citing *Stengel*, 704 F.3d at 1234 (Watford, J., concurring)). Conklin concedes that point and thus does not base his failure-to-warn claim on any failure by Medtronic to directly warn him or his health care providers about the Pain Pump. And to the extent Conklin argues that the FDA either has or assumed a duty to convey information from adverse event reports to treating physicians, patients, or more broadly public consumers (thereby implicating Medtronic for its failure to submit such reports), Conklin's claim is expressly preempted because it likewise would impose under state law a requirement that is "different from, or in addition to," any applicable federal requirement. 21 U.S.C. § 360k(a)(1); *see Riegel*, 552 U.S. at 321–30.

¶21 For the reasons stated below, we conclude that, as framed, Conklin's failure-to-warn claim is impliedly preempted under federal law, and therefore we do not address whether it is also expressly preempted. *See Buckman*, 531 U.S. at 348 & n.2 (holding that "plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law," and thus "express[ing] no view on whether these claims are subject to express pre-emption under 21 U.S.C. § 360k"); *cf. In re Medtronic, Inc.*, 623 F.3d at 1204 (noting that "[t]he contours of the parallel claim exception [to the MDA's express preemption provision] were not addressed in *Riegel* and are as-yet ill-defined").

V.

¶22 In our view, the dispositive issue is whether Conklin would have a claim under "traditional state tort law" based on Medtronic's failure to submit adverse event reports to the FDA. *Buckman*, 531 U.S. at 352. If not—and the claim instead is one only for violation of FDA reporting requirements—then it is impliedly preempted because only the federal government can seek redress for a violation. *Id.* at 352–53.

¶23 For purposes of our analysis, we assume without deciding that adverse event reports may constitute relevant "warnings" under Arizona law, as Conklin contends and the court of appeals implicitly ruled. *But cf. McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005) (noting that adverse event reports may "reflect complaints called in by product consumers without any medical controls or scientific assessment" and describing such "anecdotal information" as "one of the least reliable sources" of information); 21 C.F.R. § 803.16; *Manufacturer and User Facility Device Experience Database - (MAUDE)*, FDA, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm [https://perma.cc/E6U4-FMKU] (last updated Sept. 11, 2018) (including on FDA's website a disclaimer that an adverse event report "does not necessarily reflect a conclusion by the party submitting the report or by [the] FDA that the report or information constitutes an admission that the device, or the reporting entity or its employees, caused or contributed to the reportable event"); *Medical Device Reporting (MDR)*, FDA, https://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm [https://perma.cc/98V2-9D38] (last updated Sept. 25, 2018) (stating that although the FDA considers reports "a valuable source of information," it cautions that some reports may be based upon "incomplete, inaccurate, . . . unverified, or biased data").

¶24 In Arizona, "[m]anufacturers generally have a duty to warn consumers of foreseeable risks of harm from using their products." *Watts v. Medicis Pharm. Corp.*, 239 Ariz. 19, 24 ¶ 13 (2016); *see also* Restatement (Third) of Torts: Prods. Liab. § 2 (Am. Law Inst. 1998). This is so whether, as in *Watts*, the failure-to-warn claim is couched as one of strict liability in tort based on an alleged informational defect, *see Watts*, 239 Ariz. at 23

¶ 10, or instead as a negligence claim, *see* 2 Dan B. Dobbs, Paul T. Hayden & Ellen M. Bublick, *The Law of Torts* § 464, at 950–51 (2d ed. 2011) (stating "[i]n effect, warning claims are negligence claims, as a number of courts recognize" and citing cases in support, including *Powers v. Taser Int'l, Inc.*, 217 Ariz. 398 (App. 2007) (footnote omitted)).

¶25 In *Watts*, this Court applied the learned intermediary doctrine ("LID"), which recognizes that "a manufacturer satisfies its duty to warn end users by giving appropriate warnings to the specialized class of persons who may prescribe or administer the product." 239 Ariz. at 22 ¶ 1. Under those circumstances, the intermediary (often a treating physician) "assumes the duty to pass the necessary warnings on to the end users." *Id.* at 23 ¶ 10 (quoting *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 154 (Tex. 2012)). *Watts* adopted the Restatement (Third) of Torts provision that sets forth the LID for prescription drug and medical device manufacturers. *Id.* at 24 ¶ 14; *see* Restatement (Third) of Torts: Prods. Liab. § 6(d).

¶26 Under Arizona law, therefore, a manufacturer may satisfy its "duty to warn consumers of foreseeable risks of harm from using their products," *Watts*, 239 Ariz. at 24 ¶ 13, by warning a third party, but the LID does not permit (or require) a manufacturer to warn any and all third parties. Rather, the Restatement (Third) of Torts only extends the LID, as applied to prescription drug and medical device manufacturers, to "prescribing and other health-care providers." Restatement (Third) of Torts: Prods. Liab. § 6(d)(1). The FDA is not a health care provider and does not prescribe anything for patients. (Conklin cites no authority for his assertion at oral argument that the FDA should nonetheless be deemed a learned intermediary in this context.)

¶27 Accordingly, even if we assume that adverse event reports may constitute relevant warnings, Arizona law does not permit a manufacturer to satisfy its duty to warn end-user consumers by submitting adverse event reports to the FDA. And conversely, a manufacturer does not breach its duty to warn end users under Arizona law by failing to submit adverse event reports to the FDA. Conklin cites no authority, and we are aware of none, for the proposition that Arizona law requires a manufacturer to warn a federal agency. *Cf. Norabuena v. Medtronic, Inc.*, 86 N.E.3d 1198, 1207 (Ill. App. Ct. 2017) ("Although Illinois recognizes that a manufacturer may satisfy its duty to warn by conveying information to third-party learned intermediaries, this is not synonymous with an affirmative duty to warn a federal regulatory body." (citation omitted)).

¶28 By adopting the LID as articulated in the Restatement (Third) of Torts, *Watts* implicitly displaced further reliance on a parallel provision in the Restatement (Second) of Torts § 388 (Am. Law Inst. 1965), which the court of appeals has previously applied. *See, e.g.*, *Dole Food Co. v. N.C. Foam Indus., Inc.*, 188 Ariz. 298, 301–05 (App. 1996); *Shell Oil Co. v. Gutierrez*, 119 Ariz. 426, 432–34 (App. 1978). But even if § 388 applied, it would not change the result. First, that section has not been extended to require a manufacturer to submit warnings to a governmental regulatory body. Second, a manufacturer like

Medtronic cannot have a "reasonable assurance" that the information in adverse event reports will reach end users (or end users' health care providers), *see Dole Food*, 188 Ariz. at 302–03 (quoting Restatement (Second) of Torts § 388 cmt. n), because the FDA is not required to publicly release such reports, *see* 21 C.F.R. § 803.9(a) (stating that the FDA "*may* disclose to the public any [adverse event] report" (emphasis added)). Third, and relatedly, when the FDA exercises its discretion to release adverse event reports publicly, it does so only passively by uploading the reports to a database. *See MAUDE - Manufacturer and User Facility Device Experience*, FDA, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM [https://perma.cc/NRJ2-USCC] (last updated Nov. 30, 2018). An end user (or an end user's health care provider) must then affirmatively access the database and search for adverse event reports. *See id.*

¶29 Because only federal law, not state law, imposes a duty on Medtronic to submit adverse event reports to the FDA, Conklin's failure-to-warn claim is impliedly preempted under 21 U.S.C. § 337(a). *See Buckman*, 531 U.S. at 352, 353 (stating that because "Congress intended that the MDA be enforced exclusively by the Federal Government," a state law claim that exists "solely from the violation of [federal] requirements" is impliedly preempted). Absent an independent state law duty to submit adverse event reports to the FDA, Conklin's failure-to-warn claim, at bottom, is an attempt to enforce a federal law requirement. That claim is impliedly preempted under the MDA. *Id.*; *see also Mink*, 860 F.3d at 1330 (finding failure-to-warn claim based on manufacturer's failure to submit adverse event reports to the FDA impliedly preempted because such "duty is owed to the FDA," and that liability theory "is not one that state tort law has traditionally occupied"); *Marsh v. Genentech, Inc.*, 693 F.3d 546, 552–54 (6th Cir. 2012) (same, stating that the "alleged wrong was perpetrated upon" the FDA and applying state's immunity law to affirm dismissal of claim); *In re Medtronic, Inc.*, 623 F.3d at 1205–06 (same, finding such "claims are simply an attempt by private parties to enforce the MDA, claims foreclosed by § 337(a) as construed in *Buckman*"); *cf. Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 769, 774–75 (5th Cir. 2011) ("[a]ssuming that a failure to warn claim may be pursued" under state law based on manufacturer's failure to submit adverse event reports to the FDA, finding no implied preemption because the claim is based on an "underlying" and "recognized state tort claim").

VI.

¶30 Conklin relies on the court of appeals' opinion and *Stengel* to support a contrary conclusion. In finding no preemption of Conklin's failure-to-warn claim, the court of appeals embraced *Stengel*'s "premise that a manufacturer's continuing duty to warn of dangers discovered after sale in Arizona can be satisfied by warning a third party such as the FDA." *Conklin*, 244 Ariz. at 146 ¶ 22. The court agreed with *Stengel* that "Arizona law contemplates that a warning to the FDA could satisfy Medtronic's general duty of reasonable care to warn," reasoning that "the FDA, in turn, could have notified Mr. Conklin's doctor, thus discharging Medtronic's duty." *Id.* (citing *Watts*, 239 Ariz.

at 24 ¶¶ 13–14). Although the court of appeals observed that Conklin's failure-to-warn claim is based on "Medtronic's violation of the federal duty to report post-PMA adverse events to the FDA," *id.* ¶ 23, the court determined that the claim "is not impliedly preempted" because he is "not suing to enforce the FDCA, but to recover under Arizona state law for Medtronic's alleged failure to warn of dangers discovered after sale," *id.* ¶ 24.

¶31 We disagree with *Stengel* and consequently with the court of appeals' reasoning and conclusion in this case. In *Stengel*, the Ninth Circuit held that the MDA did not expressly or impliedly preempt the plaintiffs' Arizona common law failure-to-warn claim based on Medtronic's alleged failure to submit adverse event reports to the FDA. 704 F.3d at 1226, 1233. That holding, however, was based on the unsupported premises that "Arizona law contemplates a warning to a third party such as the FDA" and that, "[u]nder Arizona law, a warning to a third party satisfies a manufacturer's duty if, given the nature of the warning and the relationship of the third party, there is 'reasonable assurance that the information will reach those whose safety depends on their having it.'" *Id.* at 1233 (quoting *Anguiano v. E.I. DuPont de Nemours & Co.*, 808 F. Supp. 719, 723 (D. Ariz. 1992)). Neither premise comports with Arizona law. Arizona law would recognize a claim for a failure to provide an adequate warning to the patient directly or through certain third parties (including health care providers), but established law does not recognize a claim merely for failing to provide something like adverse event reports (which may not qualify as "warnings" under Arizona law) to a government agency that has no obligation to relay the information to the patient.

¶32 Because *Stengel* incorrectly recited and applied Arizona law, we decline to follow it. *See Andrade v. City of Phoenix*, 692 F.2d 557, 559 (9th Cir. 1982) ("The courts of a state alone can define the authoritative meaning of state law."); *Planning Grp. of Scottsdale, L.L.C. v. Lake Mathews Mineral Props., Ltd.*, 226 Ariz. 262, 267 ¶ 22 (2011) (noting that Ninth Circuit decisions "are not binding on this Court"). As discussed above, our case law contemplates that a medical device manufacturer may satisfy its duty to warn *consumers* by properly warning a third party, such as a learned intermediary. *Watts*, 239 Ariz. at 22 ¶ 1. But the FDA is not a learned intermediary or other relevant third party in that analysis. And we are not aware of any case that supports the proposition that a manufacturer is independently required under Arizona law to warn a *governmental regulatory body*.

¶33 Conklin's other cited cases are inapposite or unpersuasive. *Anguiano* (the district court case on which *Stengel* relied) involved a materially distinguishable issue and does not support the proposition that Arizona law imposes a duty on a manufacturer to warn the FDA or even that a manufacturer may satisfy its duty to warn consumers by warning the FDA. 808 F. Supp. at 726–27. *Coleman v. Medtronic, Inc.* largely hinged on *Stengel*'s reasoning, with which we disagree, that "state law [failure-to-warn] claims based on failure to file adverse event reports with the FDA are not subject to preemption."

167 Cal. Rptr. 3d 300, 311 (Ct. App. 2014). And *Fiore v. Collagen Corp.* addressed only a claim of express preemption under 21 U.S.C. § 360k(a), adopted a minority view espoused by the Ninth Circuit, and in any event likely does not survive *Riegel*. 187 Ariz. 400 (App. 1996).

VII.

¶34 The superior court's judgment dismissing this action with prejudice is affirmed. We vacate paragraphs 1, 18 through 25, and 28 through 31 of the court of appeals' opinion, as well as any other statements relating to Conklin's failure-to-warn claim that are inconsistent with this opinion.