PARALLEL STATE DUTIES: NINTH CIRCUIT CLASS ACTIONS PREMISED ON VIOLATIONS OF FDCA REPORTING REQUIREMENTS

*Connor Karen**

Recent Ninth Circuit cases relating to violations of reporting requirements imposed by the Federal Food, Drug and Cosmetic Act ("FDCA") present new possibilities for plaintiffs' attorneys in consumer cases. While multidistrict or "mass tort" litigation has always been possible in this area of law, the Ninth Circuit, in its most recent cases clarifying the scope of potential liability arising from violations of the FDCA's reporting requirements, has opened the door for a new theory of liability that allows for a new wave of consumer class action litigation.[1]

I. Regulatory Background

The FDCA Medical Device Amendments of 1976 established three classes of medical devices: Class I (General Controls), Class II (Performance Standards), and Class III (Premarket Approval).[2] Class I devices are the least dangerous and therefore least strictly regulated, while Class III devices are the most strictly regulated due to the potential dangers they present.[3] The FDCA's implementing regulations require that the FDA respond to petitions by citizens for changes to health policy, including reclassification of medical devices, within 180 days.[4] Since the implementation of the Citizen Petition process, a number of petitions have been submitted requesting that the FDA reclassify or ban medical devices that seem to present an unreasonable risk of illness or injury. Prominent examples include Citizen Petitions to reclassify or ban hip

* JD Candidate, UC Davis School of Law, Class of 2017.
[1] *See* McClellan v. I-Flow Corp., 776 F.3d 1035 (9th Cir. 2015); Stengel v. Medtronic, Inc., 704 F.3d 1224 (9th Cir. 2013).
[2] 21 U.S.C. § 360c (2012).
[3] *Id.* § 360c(a)(1)(C); Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 343 (2001).
[4] 21 C.F.R. § 10.30(e)(2).

resurfacing systems,[5] electroconvulsive therapy devices,[6] intravenous hydroxyethyl starch solutions intended to treat low blood volume,[7] and implantable birth control devices made of nickel,[8] due to significant amounts of adverse events resulting from use of these devices.

II. Developments in Case Law

Previous cases brought on behalf of consumers alleging injury resulting from FDA-regulated devices have taken the form of either multidistrict litigation ("mass torts") or individual actions.[9] However, the Ninth Circuit, in expanding on Supreme Court precedent, has recently decided two cases that suggest the feasibility of class action litigation as a more direct remedy.[10] The governing Supreme Court cases on violations of FDCA reporting requirements are *Medtronic, Inc. v. Lohr*,[11] *Buckman v. Plaintiffs' Legal Committee*,[12] and *Riegel v. Medtronic, Inc.*[13]

In *Lohr*, a class III pacemaker accessed the market through the 510(k) process as a product "substantially similar" to a pre-Amendments device, meaning it was subject to less restrictive market approval requirements than those typically applied to Class III devices.[14] The plaintiff was injured when her pacemaker failed, and sued under Florida common law for

[5] JEFFREY G. ROBERTS, CITIZEN PETITION OF OCT. 29, 2005, https://www.fda.gov/ohrms/dockets/dockets/05p0440/05p-0440-cp00001-01-vol1.pdf.
[6] JONATHAN W. EMORD ET AL., CITIZEN PETITION OF AUG. 24, 2016, http://emord.com/blawg/wp-content/uploads/2016/08/1-ECT-Citizen-Petition.pdf.
[7] YOLANDA GIRALDO ET AL., CITIZEN PETITION OF FEB. 8, 2017, http://www.citizen.org/documents/2358.pdf.
[8] MARCUS J. SUSEN & JUSTIN PARAFINCZUK, CITIZEN PETITION OF FEB. 20, 2015, https://www.regulations.gov/document?D=FDA-2015-P-0569-0001&source=govdelivery.
[9] *See, e.g.*, *In re* Reglan Litig., 142 A.3d 725 (N.J. 2016) (mass tort); *see also* Riegel v. Medtronic, Inc., 552 U.S. 312 (2008) (individual action).
[10] *See* McClellan v. I-Flow Corp., 776 F.3d 1035 (9th Cir. 2015); Stengel v. Medtronic, Inc., 704 F.3d 1224 (9th Cir. 2013).
[11] 518 U.S. 470 (1996).
[12] 531 U.S. 341 (2001).
[13] 552 U.S. 312 (2008).
[14] *See* 21 U.S.C. § 360c.

negligence and strict product liability.[15] The Court held that state law claims regarding safety and efficacy reporting for medical devices are only pre-empted under the Amendments if they impose requirements different from, or in addition to, the FDCA's data reporting and labeling requirements, or requirements unrelated to the safety and effectiveness of the device.[16] The Court held that the plaintiffs' state law claims were not pre-empted by the FDA's regulatory regime, because the alleged state duties ran "parallel to" the federal reporting requirements rather than imposing any additional or different requirement.[17]

Lohr contrasts with *Buckman*, in which the Court illustrated the limits to state law claims premised on violations of FDCA reporting requirements.[18] In *Buckman*, plaintiffs alleged injuries resulting from implantation of Class III orthopedic bone screws. The manufacturers of the bone screws hired a consultant to handle their FDCA reporting requirements. Alleging that the consultant made affirmative misrepresentations to the FDA during the premarket approval process, plaintiffs claimed that the FDA would not have granted the bone screws access to the market had these misrepresentations not been made.[19] The Court characterized plaintiff's claim as "state law fraud-on-the-FDA" arising "solely by virtue of the FDCA reporting requirements."[20] As such, plaintiff's claims were pre-empted by the FDA's regulatory regime.[21] The main deficiency in the claims pled by the plaintiffs in *Buckman* seems to be the fact that they

[15] *Lohr*, 518 U.S. at 481.
[16] *Id.* at 500.
[17] *Id.* at 501.
[18] Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001).
[19] *Id.* at 343.
[20] *Id.* at 353.
[21] *Id.* at 353 ("[W]e think this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme.").

sued directly for violation of FDCA reporting requirements and did not plead any "parallel" state-law duty of reasonable care.[22]

The Ninth Circuit seems to have recognized a window of liability between *Lohr* and *Buckman*, and clarified the theory of parallel state duty liability first in the 2013 case of *Stengel v. Medtronic*,[23] followed by the 2015 case of *McClellan v. I-Flow Corp.*[24] In *Stengel*, plaintiffs sued Medtronic Inc. for injuries allegedly resulting from spinal implantation of a pump and catheter manufactured by the company.[25] Plaintiffs brought numerous state common law claims, alleging that the manufacturers of the Class III pump and catheter failed to warn the FDA that the device "may have contributed to a death or serious injury" after the device had received premarket approval.[26] Defendants argued that plaintiffs' claims were pre-empted. The Ninth Circuit, *en banc*, followed the Supreme Court ruling in *Lohr* by holding that state law tort claims premised on violations of FDCA reporting requirements are not pre-empted as long as the reporting duties alleged under the state law claims run "parallel to" federal reporting requirements.[27]

The Ninth Circuit further elucidated the scope of potential liability in this area in *McClellan v. I-Flow Corp.*[28] The *McClellan* court suggested a specific theory of liability for plaintiffs to pursue when bringing state law "parallel duty" cases premised on violations of

[22] *Cf.* Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008) (holding that a state law claim imposed duties "different from, or in addition to" the federal reporting requirements, and therefore was pre-empted).
[23] Stengel v. Medtronic Inc., 704 F.3d 1224, 1228 (9th Cir. 2013) ("[Section 360k] does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act." (citing 21 C.F.R. § 808.1(d))).
[24] 776 F.3d 1035 (9th Cir. 2015).
[25] *Stengel*, 704 F.3d 1226-27.
[26] *Id.* at 1225-27.
[27] *Id.* at 1228-29.
[28] *McClellan*, 776 F.3d 1035.

FDCA reporting requirements.[29] In *McClellan,* the plaintiff sued the manufacturers of a "continuous infusion pump device" intended to administer painkillers, alleging that its use caused chondrolysis of the shoulder and complete shoulder immobility.[30] The plaintiff brought state law claims for negligent failure to warn and strict liability, alleging that the product was unreasonably dangerous due to a lack of adequate warnings.[31]

The district court, referring to the reporting requirements of the FDCA, instructed the jury at trial to "consider federal law discussed at trial."[32] The jury found for defendants, and plaintiffs appealed to the Ninth Circuit.[33] Remarkably, the Ninth Circuit held that failing to provide to the jury a negligence per se instruction with precise reference to the statutes at issue was prejudicial error. It held this way specifically because of the strength of the negligence per se doctrine in the context of FDCA reporting requirement violations.[34]

This is noteworthy for multiple reasons. First, it appears to be the only mention by circuit courts of the negligence per se doctrine's applicability in cases premised on violations of the FDCA reporting requirements.

Second, the *McClellan* court seems to have explicitly approved the use of the negligence per se doctrine for a *failure to warn claim,* in which the requirements alleged to have been violated were the "parallel state law duties" described by *Stengel* and *Lohr* — not the FDCA reporting requirements directly, as in *Buckman.* Although failure to warn is not comprised of the same elements as ordinary negligence, the court in *McClellan* nevertheless expressly approved

[29] *Id.* at 1041 ("[T]he instruction given was far weaker than the requested *negligence per se* instruction." (emphasis added)).
[30] *Id.* at 1037.
[31] *Id.* at 1037.
[32] *Id.* at 1041.
[33] *Id.* at 1038.
[34] *Id.* at 1041.

application of the negligence per se doctrine in the context of a failure to warn claim.[35] The holding in *McClellan* seems to indicate that the Ninth Circuit is willing to entertain some substantive flexibility in order to facilitate claims premised on violations of FDCA reporting requirements.

Third, application of the negligence per se doctrine seems to render these potential cases much easier to win for plaintiffs. The negligence per se doctrine allows plaintiffs to argue that duty and breach of duty, for purposes of state common law, are automatically shown where a defendant has breached a statutory (or regulatory) duty. Therefore, under these cases, all that needs to be shown for plaintiffs to win is (1) applicability of one of the numerous reporting requirements of the FDCA; (2) violation of that reporting requirement; and (3) that the violation of that reporting requirement caused, proximately and directly, the harm suffered by plaintiffs. Moreover, the court in *McClellan* took care to address some of the arguments that defendants are likely to make in cases where the plaintiff brings a tort claim against a manufacturer and alleges state law duties parallel to federal reporting requirements.[36]

III. Forecasting Future Litigation

These cases seem to hint at a new and largely untapped area of consumer litigation in which plaintiffs harmed by a particular product sue the manufacturers under state common law theories of liability. Rather than bringing claims that "arise solely by virtue of the FDCA reporting requirements," these plaintiffs would allege theories of liability like negligence or failure to warn that are "premised on a violation of FDCA reporting requirements" and which

[35] *Id.* at 1041.
[36] *Id.* at 1041 ("The appellees would have us conclude that any use of federal law to establish a standard of care is an attempt to enforce the underlying federal provisions, but we do not accept that proposition."); *id.* ("[Defendants'] attempts to characterize McClellan's claims as torts in form only are poorly explained and unpersuasive.").

impose state duties "parallel to federal reporting requirements."[37] The cases of *Stengel* and *McClellan* state clearly that a damages remedy for such claims is appropriate and that these state common law claims are not pre-empted by the FDA's regulatory regime if pled correctly.[38] Further, *McClellan* suggests a powerful theory of liability — negligence per se — for plaintiffs to use for these potential claims. Perhaps what is most remarkable is the clarity with which the court delivers this message; it is almost as if the Ninth Circuit made a concerted effort to tell plaintiffs' litigators that their services are needed.

Given the clear line of attack made available under *Stengel* and *McClellan*, as well as the Ninth Circuit's demonstrated willingness to entertain a certain amount of substantive flexibility with respect to the negligence per se doctrine,[39] the Ninth Circuit seems to be facilitating a new wave of litigation over consumer injury resulting from inadequate FDCA reporting.

One might wonder whether the Ninth Circuit might be willing to bend procedurally as well. Negligence per se claims premised on violation of FDCA reporting requirements seem well suited for class action litigation. Putative classes of plaintiffs all suffering similar types of injury resulting from drugs or medical devices, where the manufacturer of such drugs or devices failed to comply with an FDCA reporting requirement, may now satisfy the class certification requirements of Rule 23 of the Federal Rules of Civil Procedure.

Under the doctrine of negligence per se, violation of a statute or regulatory duty automatically proves duty and breach of duty for the purposes of a negligence claim.[40] Therefore,

[37] *Preemption Cases After the* Riegel *Decision*, 2 FOOD & DRUG ADMIN. § 26:68 (2016).
[38] *McClellan*, 776 F.3d 1035; Stengel v. Medtronic, 704 F.3d 1224 (9th Cir. 2013).
[39] *See McClellan*, 776 F.3d 1035.
[40] *See* RESTATEMENT OF TORTS (THIRD) § 14 (2010).

duty and breach of duty in these hypothetical class actions may be satisfied on a common basis by proving that a manufacturer violated a reporting requirement of the FDCA.[41]

Moreover, in cases premised on violations of FDCA reporting requirements, plaintiffs would likely argue that the device or drug at issue would not have reached the consumer in its dangerous form if defendants had complied with federal reporting requirements. Should courts accept this argument, then the element of actual causation or causation-in-fact in a negligence claim is satisfied on a common basis as well, as a court would not have to look into the individual circumstances of the plaintiffs in resolving causation-in-fact.[42] Negligence per se in this context therefore jumps a large hurdle for class certification purposes that many other claims fail to clear: actual causation.[43]

Proximate causation between use of the drug or device in question and a plaintiff's injury still presents individual questions which may threaten certification in the context of traditional opt-out class actions.[44] A savvy plaintiff's attorney may clear this hurdle by defining the putative class strategically and bifurcating into separate claims for liability and damages, since damages would present individual issues.[45] Such a strategy may allow for resolution of liability through class proceedings while leaving the individual issues of damages resulting from the drug or device to be determined through multidistrict litigation, or "mass tort" proceedings.[46] The party

---

[41] *See* FED. R. CIV. P. 23(a)(2), (b)(3).
[42] Rather, under *McClellan*, the dispositive issue appears to be whether the device or drug would have been available to consumers in its dangerous form had the manufacturer complied with FDCA requirements. This issue is determinable on a class-wide, rather than individual, basis.
[43] *See, e.g.*, Poulos v. Caesars World, Inc., 379 F.3d 654, 666 (9th Cir. 2004) (denying certification of a putative class in a civil RICO mail fraud claim because "individualized reliance issues related to plaintiffs' knowledge, motivations, and expectations bear heavily on the causation analysis").
[44] *See* FED. R. CIV. P. 23; *see also* Mazur v. eBay, Inc., 257 F.R.D. 563 (N.D. Cal. 2009) (denying class certification on the grounds that proximate cause presented individual issues which predominated over common questions).
[45] *Mazur*, 257 F.R.D. at 570-71 (implying that proximate cause is properly analyzed in the damages phase rather than the liability phase of a lawsuit).
[46] *See* M2 Software, Inc., v. Madacy Ent., 421 F.3d 1073, 1088 (9th Cir. 2005) (upholding district court's decision to bifurcate proximate and causation-in-fact where doing so avoided jury confusion and prejudice to the defendants);

seeking bifurcation bears the burden of demonstrating that it is justified given the facts of the case.[47]

If a court takes issue with the traditional opt-out class approach, an "opt-in" class action may be appropriate for this type of claim.[48] This is because these cases are likely to present generally high, yet variable, damages awards, as well as individualized circumstances of injury.[49] Based on the tone of *McClellan* and *Stengel*, the Ninth Circuit may be willing to entertain the use of opt-in consumer class actions in the context of injuries caused by violations of FDCA reporting requirements. The opt-in method would be an effective way to address plaintiffs for whom relief is sorely needed due to severe injuries, while saving time and judicial resources by leaving out plaintiffs who do not have much of an interest in the outcome of the suit due to the minimal nature of their injuries.[50]

IV. Conclusion and Implications

McClellan and *Stengel* opened the door for a particularly impactful brand of plaintiffs' tort and product liability litigation with the potential to bolster the FDCA reporting requirements and ensure the safety and efficacy of products that pass through the FDA's regulatory regime.

Although the recent cases in the Ninth Circuit allow for a more aggressive approach to state law "parallel duty" claims in the form of class actions, the Fairness in Class Action Litigation Act of 2017 threatens to put a moratorium on class actions in federal court for the

see also Rutherford v. Owens-Illinois, Inc., 941 P.2d 1203, 1207-08 (Cal. 1997) ("In the first damages phase of trial, the jury was to determine, as to each plaintiff, whether exposure to asbestos was a proximate cause of injury . . . .").
[47] *See, e.g.*, Spectra-Physics Lasers, Inc. v. Uniphase Corp., 144 F.R.D. 99, 101 (N.D. Cal. 1992).
[48] *See* Scott Dodson, *An Opt-in Option for Class Actions*, 115 MICH. L. REV. 171, 187-89 (2016).
[49] *Id.* at 188 ("[P]erhaps the claims' high value and individualized nature of proof suggests deference to claimant autonomy.").
[50] *See id.* at 203.

foreseeable future.[51] The Act would require that, as a prerequisite for class certification, plaintiffs' counsel make an affirmative showing through strong evidence that each individual member of the putative class suffered the same type and scope of injury.[52] The Act imposes a menacingly high bar for class certification, and would drastically reduce the number of class actions in federal courts. Moreover, because the question of whether a defendant violated the reporting requirements of the FDCA is likely a federal question,[53] the Act, if passed, would likely preclude the aforementioned litigation made possible by *Lohr, McClellan* and *Stengel*. As a result, plaintiffs' litigators should act quickly if they intend to bring such cases premised on violations of FDCA reporting requirements, so as not to miss the window of opportunity that closes upon passage of the Act.

[51] *See* Fairness in Class Action Litigation and Furthering Asbestos Claim Transparency Act, H.R. 985, 115th Cong. (2017–2018).
[52] *Id.*
[53] *See* 28 U.S.C. § 1331.