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Recent mass tort developments

A review of developments in the law of mass torts in 2012

Toxic Torts – Component Parts Doctrine

•***O'Neil v. Crane Co. et al.*** (Jan. 12, 2012) 53 Cal.4th 335

Facts: Plaintiff served on navy vessel for two years in the 1960s, during which time he was exposed to airborne asbestos fibers, including as a result of work performed on asbestos-containing equipment. (*Id.* at 345.) Defendants manufactured and sold asbestos-containing valves and pumps that were used on the vessels. These valves and pumps had internal gaskets and packing (used as sealants) that contained asbestos when they were originally installed on the vessel. In the 1940s, they also were used in conjunction with external asbestos-containing products, such as insulation. Plaintiff alleges to have been exposed to both sources of asbestos. Defendants' pumps and valves that contained internal asbestos (in the form of packing and gaskets) when they were originally installed on the vessel were replaced by those of other manufacturers before plaintiff's exposure. (*Ibid.)*

Held: Defendants are not strictly liable for plaintiff's injury because (1) any design defect in defendant's products was not a legal cause of injury to O'Neil, and (2) defendants had no duty to warn of risks arising from other manufacturers' products. (*Id.* at 348.) The Court's reasoning centered on two primary findings: defendants did not manufacture or sell the external asbestos to which plaintiff was exposed, nor did defendants manufacture or sell the actual internal asbestos to which plaintiff was exposed. (*Id.* at 347-53.)

Moreover, defendants' valves and pumps did not *require* that asbestos be incorporated into them for them to operate, nor did defendants mandate that the external asbestos-containing products be used with their valves and pumps. Accordingly, that a consumer would be exposed to asbestos through use of the pumps and valves was merely foreseeable, and the Court believed mere foreseeability is an insufficient justification for the imposition of strict liability outside the stream of commerce. (*Id.* at 350.) In sum, " . . . where the hazard arises entirely from another product, and the defendant's product does not create or contribute to that hazard, liability is not appropriate." (*Id*. at 361-62.)

1. Thus, *O'Neil* sets forth a **general rule**: a product manufacturer generally may not be held strictly liable for harm caused by another manufacturer's product. (*Id.* at 362.)
2. There are **two exceptions** to this rule: (1) if the defendant's own product contributed substantially to the harm, or (2) if the defendant participated substantially in creating a harmful combined use of the products, liability may be appropriate. (*Ibid*)

•***O'Neil* applied**: ***Bettencourt v. Hennessy Industries, Inc.*** (May 4, 2012) 205 Cal.App.4th, 1103

Facts: Plaintiffs worked with defendant's brake shoe grinding machine to grind brake shoe linings for use in automobiles, light trucks and commercial trucks. (*Id.* at 1108.) The brake shoe linings themselves contained asbestos, the fibers of which were released into the air during the grinding process and inhaled by plaintiffs, causing subsequent injury. (*Ibid*.) The court granted defendant's motion for judgment on the pleadings and plaintiffs requested leave to amend their complaint. Trial court granted the former and denied the latter. (*Id.* at 1110.)

Held: Although defendant did not manufacture or sell the asbestos-containing brake shoe linings, defendant's brake shoe grinding machine was solely intended and used for the grinding of asbestos-containing brake shoe linings. Accordingly, plaintiffs alleged sufficient strict liability and negligence causes of action. (*Id.* at 1117-18.) Plaintiffs' allegations, then, fall within the first *O'Neil* exception, that defendant's grinding machine contributed substantially to plaintiff's injury. Trial court judgment reversed; plaintiffs' leave to amend complaint granted. (*Ibid.)*

•***O'Neil* applied and *Bettencourt* distinguished**: *Barker v. Hennessy Industries, Inc*. (May 22, 2012) 206 Cal.App.4th 140

Facts: Plaintiff used defendant's brake shoe arcing machine and brake drum machines to work on various asbestos-containing products in an automotive repair shop. These machines were useful on non-asbestos products as well as asbestos-containing products. Defendant moved for summary judgment, arguing that it cannot be held liable for another's dangerous product, even if it is foreseeable that its product (the machine) will be used in conjunction with asbestos-containing products. (*Id.* at 144-45.)

Held: Because the shoe arcing machine and brake drum machine were not intended to be used nor required to be used solely on asbestos-containing products (as opposed to *Bettencourt*), plaintiffs established that it was merely foreseeable that defendant's machines would be used on asbestos-containing products. This, as set forth in *O'Neil*, is an inadequate justification for the imposition of strict liability outside the stream of commerce (i.e., a component). Defendant's motion for summary judgment granted. (*Id.* at 145.)

Loss of consortium

•***Vanhooser v. Hennessy Industries Inc.*** (June 1, 2012) 206 Cal.App.4th 921

Facts: Decedent was exposed to asbestos throughout the 1960s, 1970s as well as from 1988 to 1990. Plaintiff married decedent in 1991 or 1992. (*Id.* at 926.)

Held: Trial court held that spouse has a valid loss-of-consortium claim even if consortium with spouse developed after (or long after) exposure to the toxin in question. LASC Judge Emilie Elias certified her ruling to the court of appeals, which affirmed, stating that injury in cases of latent illnesses, such as asbestos-related

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diseases, occurs upon diagnosis or when symptoms of an asbestos-related disease appear. (See *id*. at 930.) "It is illogical to conclude [otherwise]." (*Ibid.)*

Although the first element of the loss of consortium cause of action is the existence of a marriage at the time of plaintiff's injury, for purposes of loss of consortium, injury doesn't occur at the time of exposure, but at the time the spouse discovers or should reasonably have discovered he suffers from a compensable injury. (See *id.* at 928.)

Pleadings/toxic products

•***Jones et al. v. ConocoPhillips et al.*** (Aug. 30, 2011) 198 Cal.App.4th 1187

Facts: Plaintiffs filed a complaint alleging exposure to toxins contained in defendants' products but did not identify which specific toxins were contained in each. Defendants demurred. (*Id.* at 1192-93.)

Held: Plaintiffs' complaint need not identify the specific toxins contained in the hazardous product(s) that caused alleged injury. Plaintiffs can maintain products liability action by identifying the specific products that caused the injury, *without* identifying the specific toxins within those products. (See *id.* at 1195.) Trial court erred in sustaining defendants' demurrers.

Attorney work product

•***Cotio v. Superior Court*** (Cal., June 25, 2012) 278 P.3d, 860

Facts: A 13-year-old boy drowned in the Tuolumne River in Modesto, California; six juveniles witnessed the drowning. (*Id.* at 863.) Decedent's mother filed a wrongful death complaint naming, inter alia, the City of Modesto ("Modesto") and the State of California ("the state") as defendants. (*Ibid.*) After Modesto noticed depositions for five of the six witnesses, the state interviewed four of those witnesses *at the direction of the state's counsel*. (*Ibid.*) (emphasis added.) Later, in its supplemental interrogatories, plaintiff sought (1) the names, addresses, and telephone numbers of those four witnesses (interrogatory "No. 12.3") and (2) the audio recordings obtained by the state in the interviews. (*Id.* at 864.)

The state objected to the request, to which plaintiff filed a motion to compel an answer. (*Ibid.*) The state opposed the motion, arguing that recorded witness statements are entitled to absolute work-product protection and that No. 12.3 is entitled to qualified work-product protection. (*Ibid.*) The trial court denied plaintiff's motion to compel[1], and held as a matter of law that the recorded witness interviews were entitled to absolute work-product protection and that the information concerning the identities of the witnesses was entitled to qualified work-product protection. The Court of Appeal reversed, and the Supreme Court granted review. (*Ibid.*)

The applicable statute is Code of Civil Procedure section 2018.030:

> (a) A writing that reflects an attorney's impressions, conclusions, opinions, or legal research or theories is not discoverable under any circumstances.
>
> (b) The work product of an attorney, other than a writing described in subdivision (a), is not discoverable unless the court determines that denial of discovery will unfairly prejudice the party seeking discovery in preparing that party's claim or defense or will result in an injustice.

Subdivision (a) refers to absolute work product protection; subdivision (b) refers to qualified work product protection (*Id.* at 863.) The term "writing" includes any form of recorded information, including audio recordings. (Code Civ. Proc., § 2018.030(c).)

Issues: What work product protection, if any, should be accorded to (1) the recordings of witness interviews conducted by defendant's counsel's investigators and (2) information concerning the identity of witnesses from whom defendant's counsel has obtained statements? (*Id.* at 863.)

Held: (1) The recorded witness statements are entitled, as a matter of law, to at least qualified work-product protection.[2] The statements may be entitled to absolute protection if defendant can show that disclosure would reveal its "attorney's impressions, conclusions, opinions, or legal research or theories." If not, then the recording may be subject to discovery if plaintiff can show that "denial of discovery will unfairly prejudice [her] claim . . . or will result in an injustice," thus defeating qualified work-product protection. Further, (2) information concerning the identity of the witnesses is entitled neither to absolute nor qualified work-product protection as a matter of law. To invoke the privilege, defendant must make a showing that the disclosure of the information would reveal the attorney's tactics, impressions, or evaluation of the case (absolute privilege) or would result in opposing counsel taking undue advantage of the attorney's industry or efforts (qualified privilege). (*Ibid.*)

Witness Interview Statements: As to its first holding, the Court reasoned that witness interview statements could disclose an attorney's strategy and evaluation of which issues he/she deems important, and which issues he/she does not. (*Id.* at 869.) For instance, "[l]ines of inquiry that an attorney chooses to pursue through follow-up questions may be especially revealing." (*Ibid.*) The witness's answers to questions, even if the attorney's questions are redacted, may be especially revealing as well. (See *id.*) In these instances, the witness statement will be entitled to absolute work-product protection. On the other hand, explained the Court, witness statements procured by an attorney will not always reveal an attorney's thought process. (*Id.* at 869. In this instance, the witness statement will become entitled to qualified work-product protection. (*Ibid.*) Whether or not witness statements will be entitled to absolute work-product protection will ultimately, then, be decided on a case-by-case basis. (*Ibid.*)

Essentially, this holding gives the objecting party an opportunity to persuade the Court that the witness statements it procured somehow reveal "attorney's impressions, conclusions, opinions, or legal research or theories," thereby entitling the witness statement to absolute work product protection. (See *id.* at 863.) If the objecting party is not successful in doing so, the witness statement is automatically entitled to qualified work-product protection. At this point, the party seeking production may attempt to demonstrate that denying discovery of the witness statement would be unfairly prejudicial, thereby vitiating the qualified work-product protection. (*Ibid*.) However, if the seeking party is not successful in doing so, the witness statement will remain undiscoverable, protected as qualified work product. (*Ibid.*)

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Witness Identities: As to its second holding, the Court set forth its rationale in the form of examples. To be sure, information concerning the identities of witnesses interviewed by opposing counsel is usually discoverable (*Id.* at 874); however, some such information may reveal an "attorney's impression of the case," thus entitling it to absolute work-product protection. (*Id.* at 873.) "Take, for example, a bus accident involving 50 surviving passengers and an allegation that the driver fell asleep at the wheel. If an attorney for one of the passengers took recorded statements from only 10 individuals, disclosure of the list may well indicate the attorney's evaluation or conclusion as to which witnesses were in the best position to see the cause of the accident." (*Ibid.*) Such a list, the Court explained, could be entitled to absolute work-product protection. (*Ibid.*)

If the objecting party does not sufficiently show such information to be entitled to absolute work-product protection, it may still be entitled to qualified work-product protection if it reflects the attorney's "industry and effort in selecting which witnesses to ask for a record statement." (*Ibid.*) In continuing with the bus accident example, the Court mused, "perhaps the attorney devoted significant effort to tracking down bus tickets and passenger logs in order to determine which passengers sat in which seats, and then decided to take recorded statements from the 10 passengers closest to the driver. Even without obtaining the witness statements themselves, the [defendant's] lawyer would gain valuable information by free-riding on the attorney's identification of the most salient witnesses." (*Ibid.*) This would be an example of qualified work-product protection.

Essentially, with respect to witness identities, an objecting party may be entitled to work-product protection "if it can make a preliminary and foundational showing that answering the interrogatory would reveal the attorney's tactics, impressions, or evaluations of the case (absolute protection), or would result in opposing counsel taking undue advantage of the attorney's industry efforts (qualified protection)." (*Id.* at 874.)

Conclusion: Judgment of the Court of Appeal reversed and case remanded for further proceedings, consistent with the Court's opinion.

Pharmaceuticals – brand-name manufacturers & federal pre-emption

•***Johnson & Johnson v. Superior Court*** (Jan. 20, 2011) 192 Cal.App.4th 757

Holding: The burden is on manufacturers to ensure their drug labeling is adequate at all times, regardless of FDA approval of existing labeling. (*Id.* at 767.)

Facts: A 15-year-old suffered a severe skin injury after taking Motrin. The manufacturer did not warn of this specific adverse reaction to the drug. Defendant brand-name drug manufacturer filed motion for summary adjudication on the issue of punitive damages. (*Id*. at 760.)

Court's analysis: If a drug manufacturer knows of the connection between its product and a risk, but does not submit a supplemental warning application (via the "Changes Being Affected" (CBE) provision of the Code of Federal Regulations § 314.70(c)(6), allowing drug manufacturers to modify their labels without preliminary agency approval) then there is a triable issue of fact as to whether the manufacturer's previous FDA-approved label could evidence despicable conduct, and thus liability for punitive damages. (*Ibid.*)

Accordingly, unless the manufacturer defendant can show clear evidence that the FDA would not have approved the change to the drug label via the supplemental application, then the manufacturer *could* have complied with both federal and state law by modifying the label pre-FDA approval. (*Id.* at 763.) (The manufacturer could have complied with federal law by submitting the supplemental application and immediately changing its warning upon the FDA's receipt of that application, while simultaneously complying with stricter state failure-to-warn standards.) As noted in the decision, if foreign drug labels for the same generic drug (ibuprofen, e.g.) include the warning at issue, this evidences that the FDA would have approved the new label, and defeats defendants' argument that FDA would have rejected it. (See *id.* at 766.)

Impact on consumers: In California, brand-name drug manufacturers now have another compelling reason to continually update drug labels, even after initial approval by the FDA. This opinion is ultimately highly beneficial to consumers, as brand-name drug manufacturers will not only be unable to rely on federal pre-emption as an affirmative defense to their failures to warn consumers, but will also face severe financial punishment for not doing so. In sum, an FDA approval does not indicate the be-all and end-all be warning label by any stretch, and brand-name manufacturers ought to continually look to foreign equivalents of their particular drugs' warnings to make sure they are sufficiently warning consumers.

Pharmaceuticals – generic manufacturers & federal pre-emption

•***Gaeta v. Perrigo Pharmaceuticals Co***. (9th Circuit, Jan. 24, 2011) 630 F. 3d, 1225

Holding: The state law duty to warn for a generic drug was not preempted by federal law. (*Id.* at 1239.)

Facts: A child took over-the-counter generic ibuprofen and suffered injury, requiring the amputation of certain tissue in his fingers and toes. Though factually similar to Johnson, the court here focused on the issue of pre-emption (not discussed in Johnson) as opposed to punitive damages. Defendant Perrigo filed a motion for summary judgment, arguing that a claim against a generic manufacturer of drugs for failure to warn is preempted. The court held that it is not.

Court's analysis: The state law duty to warn by an appropriate label on the generic ibuprofen drug is not preempted by federal law. Compliance with both state and federal law was not "impossible." Additional warnings would not stand as an obstacle to the accomplishment of purposes and objectives of the MDA (Medical Device Amendments).

Perrigo, as manufacturer of the generic ibuprofen, had three options that would have allowed it to comply with both federal regulations on generic drugs, and state law-duties: **(1)** the CBE approval process mentioned in *Johnson*, **(2)** the "prior approval" process (similar to the CBE process, but requires actual approval by the FDA rather than mere receipt of the application) or **(3)** the generic manufacturer can request that the FDA send "Dear Doctor" warning letters to health-care professionals. Again (like *Johnson*), had Perrigo presented clear evidence that the FDA would have rejected the specific

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hepatotoxicity warnings, then its motion for summary judgment would likely have been granted due to federal pre-emption. (*Id.* at 1239.)

Impact on consumers: This decision would have been highly beneficial to generic drug consumers, as it would allow state law causes of action to be brought against generic drug manufacturers. However, it was vacated and remanded on October 31, 2011, due to the recent U.S. Supreme Court case of *Pliva Inc. v. Mensing*.

Pharmaceuticals – generic manufacturers vs. brand-name manufacturers & federal pre-emption

• ***Gaeta v. Perrigo Pharmaceuticals Co.*** (9th Circuit, Jan. 24, 2011) 630 F. 3d, 1225

Holding: Claims against *brand-name* drug manufacturers are not preempted by federal law but claims against *generic* drug manufacturers are preempted.

Facts: In separate suits, two plaintiffs sued generic drug manufacturers for injuries resulting from their use of a generic drug, metoclopramide, as opposed to the brand-name counterpart ("Reglan") that the two plaintiffs were actually prescribed. Both manufacturers argued federal pre-emption and lost in the Courts of Appeal. The U.S. Supreme Court consolidated the cases and found the following:

Court's analysis: Pursuant to FDA regulations, generic manufacturers' warning labels need only mirror those of their corresponding brand-name drug labels. Generic drug warnings, in other words, must be "equivalent" to the brand-name drug label that it has duplicated. Accordingly, while a brand-name drug manufacturer is responsible for the continual update of its warnings (*Johnson*, e.g.), the generic drug manufacturer duplicating that drug is only responsible for ensuring that its warning label is the ***same*** as the brand name's. The CBE process then, is unavailable to the generic manufacturer until the brand-name manufacturer utilizes it. "Dear Doctor" letters are likewise not available, as such letters are considered "labels" in and of themselves. (*Id.* at 2574-77.)

According to the above analysis, there is impossibility here. The generic drug manufacturer could not have updated its warning label without conflicting with either federal or state law. Indeed, by unilaterally altering their labels, the manufacturers would have violated federal law, as generic drugs are required by the FDA to have the ***same*** warning label as their counterpart brand-name drug labels. Thus, federal law would permit the generic manufacturers to comply with the stricter state law labeling requirements if, and only if, the FDA and the brand-name manufacturer changed the brand-name label to do the same. In sum, state law imposed a duty on the generic manufacturers to change their labels, and federal law barred them from doing so. Therefore, plaintiffs' tort claims are pre-empted by the Supremacy Clause. (*Id.* at 2577-81.)

Impact on consumers: The Supreme Court has made it very clear that a consumer's claim for failure-to-warn against a generic drug manufacturer will be pre-empted by federal law, while those against a brand-name manufacturer will not be. As suggested by the dissent, this distinction does appear rather arbitrary. Regardless, this holding will inevitably lead to harm for those consumers who can only afford/prefer to purchase the generic versions of the brand-name medication prescribed to them. (Generic drugs dominate the market. (*Id.* at 2584.)

(**Note:** Although it is not expressly clear in the *Pliva* opinion whether only prescription drugs are affected here; because *Gaeta* was vacated as a result of *Pliva*, it appears that *Pliva* applies to all drugs, prescription as well as over-the-counter.)

Smart phones' medical devices & the conflict with federal pre-emption

Summary: A recent influx of mobile medical "applications," such as those available on the iPhone or Android Smartphones, have prompted the FDA to issue a July 19, 2011 "draft guidance" seeking input as to how the agency will regulate those applications that "present the greatest risk to patients when they don't work as intended."[3] Essentially, some of these applications fall into the FDA's definition of a "medical device," and are thus subject to the same (sometimes very stringent) regulations, potentially including: premarket approval, proper labeling, tracking of devices and postmarket surveillance.

Some of these applications, or "devices," are actually used to diagnose or treat medical conditions. The FDA-issued draft guidance lists 34 types of mobile phone applications as "mobile medical apps," including those that analyze medical data, screen patients for blood transfusions or control other medical devices etc. Other medical applications on the market today include blood pressure monitors, glucose meters, eyeglass prescription readers and ultrasounds.[4]

The issue is complex, not only due to the widespread access to the rapidly growing mobile application market, but also in determining which applications actually fall within the definition of a "medical device." Whether a mobile phone application is a "medical device" depends on whether the application was ***intended*** for specified medical purposes. This can be very difficult to discern, especially considering the many steps and parties involved in the manufacture of the application. However, the FDA seems to be focused on those who create and control the application's software itself.[5]

On June 20, 2012, the U.S. Congress passed a bill allowing the FDA to regulate medical devices on Smartphones, but this legislation will not manifest itself for months. The bill requests that a strategy for a risk-based regulatory framework be posted by the secretary of Health and Human Services within 18 months.[6] Accordingly, there is still uncertainty as to how the FDA will actually go about regulating this seemingly relentless new market, one certainly not accustomed to oversight by this previously unrelated agency.

Impact on consumers: By implication, it appears that at least some of the smart phone applications that are to be regulated by the FDA will eventually be subject to pre-emption by federal law. For instance, if a mobile medical application misdiagnoses a consumer's symptoms or reports an erroneous glucose level that leads to an injury, this device may not be subject to state tort law if the mobile application's prior FDA regulation passes the Riegel Pre-emption test in California.[7] Should this occur, a consumer's state law claims will likely not survive a manufacturer's motion for summary judgment. Though it is unlikely that the FDA will

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even categorize any mobile medical applications as class III (due to the high-risk nature of class III devices – replacement heart valves, a pacemaker, e.g.), it is certainly possible that several Smartphone applications may be termed as class II (pregnancy test kits, e.g.), a class inherently less risky than class III, and thus likelier to stem from a mobile platform.

A recent 9th Circuit decision held for federal pre-emption for a class II device because it passed the Riegel Test. This suggests that future class II mobile medical applications may also be subject to federal pre-emption as well. (*Dengelmann v. Advanced Medical Optics, Inc*. (2011) 659 F.3d 835.) Considering the number of Smart-phone users, and the incredible growth of this market, the FDA may need to reconsider whether the Medical Devices Amendments[8] ought to be further amended to specifically include smart phone medical devices.

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[1] The state used the content of one of the four witnesses' recorded interviews while questioning that witness during a deposition. The trial court and Supreme Court held this to be a waiver of the work-product privilege, and it is not at issue here. At issue are the other three recorded interviews.

[2] This holding disapproves substantial appellate precedent, including: *Fellows v. Superior Court* (1980) 108 Cal.App.3d 55, *People v. Williams* (1979) 93 Cal.App.3d 40, *Rodriguez v. McDonnell Douglas Corp*. (1978) 87 Cal.App.3d 626, *Kadelbach v. Amaral* (1973) 31 Cal.App.3d 814.

[3] *FDA NEWS RELEASE*, U.S. Food and Drug Administration (Jul. 18, 2012), http://www.fda.gov/ News Events/Newsroom/PressAnnouncements/ucm263340.htm.

[4] *Smartphones and tablets as medical devices*, phoneArena.com (Jul. 18, 2012), http://www.phonearena.com /news/ Smartphones-and-tablets-as-medical-devices_id21791/.

[5] *Is Your Smart Phone an FDA Regulated Medical Device? –FDA Announces Plans to Regulate "Mobil Medical Applications,"* Mondaq.com (Jul. 18, 2012), http://www.mondaq.com/unitedstates/x/141970/Healthcare+Food+Drugs+Law/Is+Your+Smart+Phone+An+FDA Regulated+Medical+Device+FDA+Announces+Plans +To+Regulate+Mobile+Medical+Applications.

[6] *Congress passes bill allowing FDA to regulate smartphone apps*, Yahoo! News, (Jul. 18, 2012), http://news.yahoo.com/congress-passes-bill-allowing-fda-regulate-smartphone-apps-002106746.html.

[7] Riegel Test for pre-emption: federal law preempts if (1) federal government established requirements applicable to defendants' [device(s)] and (2) if the common law claims are based on state requirements with respect to that device that are "different from, or in addition to" the federal requirements, and that relate to safety/effectiveness. *Robinson v. Endovascular Technologies, Inc*., 190 Cal.Rptr.3d 158.

[8] The Medical Device Amendments (MDA) preempt state law claims that impose requirements that are "different from, or in addition to, any requirements" already set forth by the FDA and that "which relate directly to the safety or effectiveness of the device." 21 U.S.C. § 360k(a). Accordingly, any device that has already been subject to FDA approval is essentially immune from any state law claims, as the FDA has impliedly set forth safety requirements that directly relate to the safety of the device. *McGuan v. Endovascular Technologies, Inc*., 182 Cal.App.4th, 974 (2010) (holding that a class III medical device already given pre-market approval by the FDA was not subject to state law claims, and that such claims are pre-empted by federal law via the MDA.)