Williamson & Lavecchia, L.C. represents victims of defective products. The article below was presented by Tom Williamson to trial lawyers at a seminar on products liability law. Please visit http://www.wllc.com/ for more information about Williamson & Lavecchia, L.C., our attorneys, and our practice areas.

Planes, Trains, and Automobiles, and Pacemakers, and pesticides . . . Federal Preemption in Product Liability Claims

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Congratulations, you just spotted a potential product defect underlying your medical malpractice case. You may now be able to pursue claims and seek damages exceeding those permitted under Virginia's medical malpractice statute. But doesn't the federal government regulate medical devices? Many products which cause injury of our clients are subject to federal regulation and control – automobiles, railroads, drugs and medical devices, etc. The impact of such legislation can be critical. Can you still file suit in state court? Are all of your claims preempted by federal law? Is there a federal private right of action? The answer depends. In the case of preemption, it depends on the specific federal laws and regulations of the product at issue, and which claims you intend to pursue. This essay provides a general overview of some of the federal preemption principles, how specific federal regulations preempt various medical product liability claims, and a brief overview of some other products which are federally regulated.

I. Federal Preemption

The Supremacy Clause of the United States Constitution provides that the "Laws of the United States . . . shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. Accordingly the laws of Congress, including federal regulations made pursuant to the authority of Congress,[1] may supersede state or local laws.[2] Since the 1819 Supreme Court decision of *M'Culloch v. Maryland*,[3] it has been settled that state laws that conflict with federal law are "without effect."[4] While that general statement of law has long been settled, many preemption issues were resolved more recently, and others have not been entirely resolved by the Supreme Court, causing a split among the circuits.

The U.S. Supreme Court has extended federal preemption to common law actions. In *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992), the Supreme Court held that the term "requirement or prohibition" in the Public Health Cigarette Smoking Act of 1969 included common-law duties, and therefore pre-empted certain tort claims against cigarette companies.

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[1] *Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 713 (1985).
[2] *Id.*
[3] 17 U.S. (4 Wheat.) 316, 427, 4 L.Ed. 579 (1819).
[4] *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992).

> Compared to its predecessor in the 1965 Act, the plain language of the pre-emption provision in the 1969 Act is much broader. First, the later Act bars not simply "statement[s]" but rather "requirement[s] or prohibition[s] ... imposed under State law." . . .The phrase "[n]o requirement or prohibition" sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules. As we noted in another context, "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."[5]

That holding was weakened somewhat in *Medtronic v. Lohr* (1996), where a very divided Court in its plurality holding preserved this preemption principle stated in *Cipollone*. The scope of federal preemption of common law claims was again limited in 2002 when the Court held that the Federal Boat Safety Act (FBSA) did not bar common law state actions, based on the provisions of the preemption provision when read with the savings clause.

> Here, the express pre-emption clause in § 10 applies to "a [state or local] law or regulation." 46 U.S.C. § 4306. We think that this language is most naturally read as not encompassing common-law claims for two reasons. First, the article "a" before "law or regulation" implies a discreteness--which is embodied in statutes and regulations--that is not present in the common law. Second, because "a word is known by the company it keeps," *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575, 115 S.Ct. 1061, 131 L.Ed.2d 1 (1995), the terms "law" and "regulation" used together in the pre-emption clause indicate that Congress pre-empted only positive enactments. If "law" were read broadly so as to include the common law, it might also be interpreted to include regulations, which would render the express reference to "regulation" in the pre-emption clause superfluous. The Act's saving clause buttresses this conclusion. See *Geier v. American Honda Motor Co.*, 529 U.S., at 867-868, 120 S.Ct. 1913. It states that "[c]ompliance with this chapter or standards, regulations, or orders prescribed under this chapter does not relieve a person from liability at common law or under State law." § 4311(g). As we held in *Geier*, the "saving clause assumes that there are some significant number of common-law liability cases to save [and t]he language of the pre-emption provision permits a narrow reading that excludes common-law actions."[6]

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[5] *Cipollone* at 518 (quoting *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247, 79 S.Ct. 773, 780, 3 L.Ed.2d 775 (1959)).

[6] *Sprietsma v. Mercury Marine, a Div. of Brunswick Corp*., 537 U.S. 51, 63, 123 S.Ct. 518, 526, 154 L.Ed.2d 466 (2002)

Preemption analysis under the Supremacy Clause starts with the presumption that the historic police powers of the States are not to be superseded by Federal Act unless that is the clear and manifest purpose of Congress.[7] This presumption against preemption is especially weighty in an area of traditional state responsibility such as health and safety. The "health and safety" presumption applies in both express and implied preemption analyses.[8] Thus in determining whether Congress has manifested an intention to preempt, courts are guided by principles of federalism. Where "the regulated conduct touched interests so deeply rooted in local feeling and responsibility, in the absence of compelling congressional direction, the court could not infer that Congress had deprived the States of the power to act."[9] Particularly with respect to the preemption of common law actions, the Supreme Court has instructed,

> A common-law right, even absent a saving clause, is not to be abrogated "unless it be found that the preexisting right is so repugnant to the statute that the survival of such right would in effect deprive the subsequent statute of its efficacy; in other words, render its provisions nugatory."[10]

Conversely, where the issues involved are inherently federal, there is a presumption, or inference that the claims will be preempted.[11]

> Federal preemption arises in one of three ways: express, implied or by conflict.
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> First, when acting within constitutional limits, Congress is empowered to pre-empt state law by so stating in express terms. *Jones v. Rath Packing Co*., 430 U.S. 519, 525 (1977). In the absence of express pre-emptive language, Congress' intent to pre-empt all state law in a particular area may be inferred where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress "left no

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[7] *Id.* (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)); Lucas v. Bio-Lab, Inc., 108 F.Supp.2d 518, 525 (E.D.Va., Aug 07, 2000).

[8] *Phillip Morris, Inc. v. Harshbarger*, 122 F.3d 58, 67 (1st Cir. 1997) (citing *Greenwood Trust Co. v. Commonwealth*, 971 F.2d 818, 823 (1st Cir.1992) ("Even federal statutes that contain express preemption clauses must be viewed through the prism of [the] assumption."); *see also Vango Media, Inc. v. City of New York*, 34 F.3d 68, 72 (2d Cir.1994) (noting that presumption applies "[w]hether preemption under the Supremacy Clause be explicit, or implied under field preemption, or under conflict preemption") (involving preemptive effect of FCLAA over city ordinance respecting tobacco-product advertising)).

[9] *Feikema v. Texaco, Inc*., 16 F.3d 1408, 1413 (4th Cir. Va. 1994) (quoting *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 244 (1959)).

[10] *Id*. Feikema (quoting *Nader v. Allegheny Airlines, Inc.*, 426 U.S. 290, 298, 96 S.Ct. 1978, 1984, 48 L.Ed.2d 643 (1976); *Texas & Pacific R. Co. v. Abilene Cotton Oil Co.*, 204 U.S. 426, 437, 27 S.Ct. 350, 354, 51 L.Ed. 553 (1907)).

[11] *See e.g. Hines v. Davidowitz*, 312 U.S. 52 (1941), where the Court inferred an intent to pre-empt from the dominance of the federal interest in foreign affairs because "the supremacy of the national power in the general field of foreign affairs ... is made clear by the Constitution," *id.* at 401, and the regulation of that field is "intimately blended and intertwined with responsibilities of the national government," *id.* at 66.

> room" for supplementary state regulation. *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947). Pre-emption of a whole field also will be inferred where the field is one in which "the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Ibid*.; *see Hines v. Davidowitz*, 312 U.S. 52 (1941).
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> Even where Congress has not completely displaced state regulation in a specific area, state law is nullified to the extent that it actually conflicts with federal law. Such a conflict arises when "compliance with both federal and state regulations is a physical impossibility," *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143 (1963), or when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, *supra*, 312 U.S. at 67.[12]

A. Express Preemption

Express preemption occurs when a statute or regulation expressly provides that its requirements preempt those of state or local law.[13] Many such statutes contain a savings provision in order to save certain types of claims from preemption, such as common law claims. When determining the preemptive extent of an express pre-emption clause, the court's "task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent."[14] Initially the Court would end its inquiry with its interpretation of the terms of the preemptive provision.

> When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a "reliable indicium of congressional intent with respect to state authority, there is no need to infer congressional intent to pre-empt state laws from the substantive provisions" of the legislation. Such reasoning is a variant of the familiar principle of *expression unius est exclusio alterius:* Congress' enactment of a provision

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[12] *Hillsborough County*, 471 U.S. at 713.

[13] *See e.g. Sprietsma v. Mercury Marine, a Div. of Brunswick Corp.*, 537 U.S. 51, 123 S.Ct. 518, 154 L.Ed.2d 466 (2002)(holding that express preemption clause of Federal Boat Safety Act of 1971, 46 U.S.C. §§ 4301-4311 (FBSA) did not preempt common law tort claims arising out of failure to install propeller guards on boat engine); Jeffers v. Wal-Mart Stores, Inc., 171 F.Supp.2d 617 (S.D. W.Va. 2001)(holding that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136v(b), preempted consumer's state common law negligence, warranty, and strict liability claims against pesticide manufacturer based on labeling issues, but design defect claim was not pre-empted).

[14] *Sprietsma*, 537 U.S. at 62-63 (quoting *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664, 113 S.Ct. 1732, 123 L.Ed.2d 387 (1993)).

> defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted.[15]

Under *Cipollone*, if a federal law had an express preemption clause, the reach of the preemption was determined by the terms of the legislation provision. But in 2000, "[t]he reach of federal preemption was increased with the Supreme Court's decision in *Geier v. American Honda Motor Co.*, 529 U.S. 861, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000).[16] *Geier* held that although a state law is not within the domain expressly preempted, the state law may still be preempted if it conflicts with federal law. Even earlier, in *Medtronic*, the Court suggested that the Court must look beyond the terms of the preemption provision to the context of the legislation, in order to discern the intended preemptive effect of the preemption provision.

> [O]ur analysis of the scope of the statute's pre-emption is guided by our oft-repeated comment, initially made in *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103, 84 S.Ct. 219, 222, 11 L.Ed.2d 179 (1963), that "[t]he purpose of Congress is the ultimate touchstone" in every pre-emption case. As a result, any understanding of the scope of a pre-emption statute must rest primarily on a fair understanding of *congressional purpose."* Congress' intent, of course, primarily is discerned from the language of the pre-emption statute and the "statutory framework" surrounding it. Also relevant, however, is the "structure and purpose of the statute as a whole," as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law.[17]

It is now clear that the presence of an express pre-emption clause does not bar the ordinary working of conflict preemption principles, such that preemption will be implied where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.[18]

B. Conflict Preemption

Where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, federal law prevails.[19] While express pre-emption and field pre-emption are found by reference to congressional intent, conflict pre-emption does not depend upon an expression of legislative intent to pre-empt.[20] As stated

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[15] *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992).
[16] *Dow Chemical Co. v. Ebling ex rel. Ebling*, 753 N.E.2d 633, 637 (Ind. 2001).
[17] Medtronic v. Lohr at 485-86.
[18] See Geier, 529 U.S., at 869, 120 S.Ct. 1913; Freightliner Corp., 514 U.S., at 287, 115 S.Ct. 1483; *Sprietsma.*
[19] *Jeffers v. Wal-Mart Stores, Inc.*, 171 F.Supp.2d 617, 620 (S.D.W.Va. 2001)(citations omitted).
[20] *Id*.

previously, Congress' inclusion of an express pre-emption clause “does not bar the ordinary working of conflict pre-emption principles."[21] The Supreme Court has found “implied conflict pre-emption where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”[22]

> The Court has not previously driven a legal wedge--only a terminological one-- between "conflicts" that prevent or frustrate the accomplishment of a federal objective and "conflicts" that make it "impossible" for private parties to comply with both state and federal law. Rather, it has said that both forms of conflicting state law are "nullified" by the Supremacy Clause, and it has assumed that Congress would not want either kind of conflict. The Court has thus refused to read general "saving" provisions to tolerate actual conflict *both* in cases involving impossibility, *and* in "frustration-of-purpose" cases.[23]

As an illustration, in *Sprietsma, supra*, the Court first analyzed the express preemption and saving provisions of the FSBA, which suggested that the Plaintiff’s common law claims were not preempted. Pursuant to *Geier*, the Court then turned its analysis to whether the state law actually conflicted with the FSBA, requiring preemption. The Court considered the argument that the failure of the Coast Guard to promulgate a requirement suggested an intention to leave the field unregulated, such that a common law duty would conflict.

> Of course, if a state common-law claim directly conflicted with a federal regulation promulgated under the Act, or if it were impossible to comply with any such regulation without incurring liability under state common law, pre-emption would occur.
> . . .
> The Coast Guard has never taken the position that the litigation of state common-law claims relating to an area not yet subject to federal regulation would conflict with "the accomplishment and execution of the full purposes and objectives of Congress.". . . [However] [t]he Illinois Supreme Court concluded "that the Coast Guard's failure to promulgate a propeller guard requirement . . . equates to a ruling that no such regulation is appropriate pursuant to the policy of the FBSA." With regard to policies defined by Congress, we have recognized that "a federal decision to forgo regulation in a given area may imply an authoritative federal determination that the area is best left *un*regulated, and in that event would have as much pre-emptive force as a decision *to* regulate." . . . The Coast Guard's apparent focus was on the lack of any "universally acceptable" propeller guard for "all modes of boat operation." But nothing in its

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[21] *Geier*, 529 U.S., at 869, 120 S.Ct. 1913.
[22] *Sprietsma v. Mercury Marine, a Div. of Brunswick Corp*., 537 U.S. 51, 64, 123 S.Ct. 518, 154 L.Ed.2d 466 (2002)(citations and internal quotations omitted).
[23] *Geier* at 873-74 (emphasis in original)(citations omitted).

> official explanation would be inconsistent with a tort verdict premised on a jury's finding that some type of propeller guard should have been installed on this particular kind of boat equipped with respondent's particular type of motor. Thus, although the Coast Guard's decision not to require propeller guards was undoubtedly intentional and carefully considered, it does not convey an "authoritative" message of a federal policy against propeller guards.[24]

C. Implied Preemption

Implied preemption occurs when Congress, through specific language or its occupation in a field has implied its intent to preempt state law. "Field pre-emption occurs where the scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it."[25] Examples of implied, or field preemption can be found in railroads,[26] oil tankers[27], and military helicopters.[28]

As stated previously, when Congress legislates in an area which has been preserved to the states, such as health or safety, a presumption arises against preemption. However when Congress legislates in an area in which federal concerns predominate, an opposite presumption arises. Nevertheless, as the Supreme Court has made clear, even with a presumption in favor of preemption, state law will only be displaced when it conflicts with a federal law, regulation or objective.

> That the procurement of equipment by the United States is an area of uniquely federal interest does not, however, end the inquiry. That merely establishes a necessary, not a sufficient, condition for the displacement of state law. Displacement will occur only where . . . a "significant conflict" exists between an identifiable "federal policy or interest and the [operation] of state law," or the application of state law would "frustrate specific objectives" of federal legislation. The conflict with federal policy need not be as sharp as that which must exist for ordinary pre-emption when Congress legislates "in a field which the States have traditionally occupied." Or to put the point differently, the fact that the area in question

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[24] *Sprietsma*, 537 U.S. at 64-67, 123 S.Ct. at 527-28 (emphasis in original).

[25] *In re West Virginia Asbestos Litigation*, 215 W.Va. 39, 43, 592 S.E.2d 818, 822 (W.Va. 2003)(quoting *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 98, 112 S.Ct. 2374, 2383, 120 L.Ed.2d 73, 84 (1992)).

[26] See e.g. *In re West Virginia Asbestos Litigation*, 215 W.Va. 39, 43, 592 S.E.2d 818, 822 (W.Va. 2003)(interpreting the Boiler Inspection Act (also called the Locomotive Inspection Act, abbreviated either LIA or BIA), 49 U.S.C. § 20701, *et seq.*, and the Safety Appliance Act at 49 U.S.C. § 20301 *et seq.*).

[27] *See e.g. Ray v. Atlantic Richfield Co.*, 435 U.S. 151, 98 S.Ct. 988, 55 L.Ed.2d 179 (1978)(interpreting the Ports and Waterways Safety Act of 1972).

[28] *Boyle v. United Technologies Corp.*, 487 U.S. 500, 108 S.Ct. 2510, 101 L.Ed.2d 442 (1988).

> *is* one of unique federal concern changes what would otherwise be a conflict that cannot produce pre-emption into one that can. But conflict there must be. [29]

D. Complete Preemption

Closely related to implied preemption is the doctrine of complete preemption. Complete preemption occurs when the "federal policies implicated by a federal statute are sufficiently important as to override the plaintiff's effort to rely on state law."[30] Under federal preemption, the claims become federal in nature such that the action is one over which the federal court will exercise jurisdiction.

"Any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or the defendants, to the district court of the United States for the district and division embracing the place where such action is pending."[31] Pursuant to 28 U.S.C. § 1331, district courts have original jurisdiction over cases "arising under the Constitution, laws, or treaties of the United States."

"It is long settled law that a cause of action arises under federal law only when the plaintiff's well-pleaded complaint raises issues of federal law."[32] The well-pleaded complaint rule enforces the principle that the plaintiff is the master of his complaint and generally permits plaintiffs to "avoid federal jurisdiction by exclusive reliance on state law."[33]

Federal pre-emption is ordinarily a federal defense to the plaintiff's suit. As a defense, it does not appear on the face of a well-pleaded complaint, and, therefore, does not authorize removal to federal court.[34] Complete preemption is an extremely limited exception to the well-pleaded complaint rule that essentially permits a district court to "convert an ordinary state common-law complaint into one stating a federal claim."[35] Under complete preemption, "Congress may so completely pre-empt a particular area that any civil complaint raising this select group of claims is necessarily federal in character."[36]

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[29] *Boyle v. United Technologies Corp*., 487 U.S. 500, 507-508, 108 S.Ct. 2510, 2516, 101 L.Ed.2d 442 (1988).
[30] *Custer v. Sweeney*, 89 F.3d 1156, 1165 (4th Cir.(Va.) 1996).
[31] 28 U.S.C. § 1441(a).
[32] *Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58, 63, 107 S.Ct. 1542, 95 L.Ed.2d 55 (1987).
[33] *Custer v. Sweeney*, 89 F.3d 1156, at 1165 (quoting *Caterpillar, Inc. v. Williams*, 482 U.S.386, 392, 107 S.Ct. 2425, 2429-30, 96 L.Ed.2d 318 (1987)).
[34] *Fullen v. Philips Electronics North America Corp*., 266 F.Supp.2d 471, 474 (N.D.W.Va. 2002).
[35] *Fullen* at 474 (quoting *Caterpillar, Inc. v. Williams*, 482 U.S. 386, 393, 107 S.Ct. 2425, 96 L.Ed.2d 318 (1987)).
[36] *Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58, 63-64, 107 S.Ct. 1542, 95 L.Ed.2d 55 (1987).

Until 1986 only one category of claims met the stringent requirements for complete preemption - labor cases pre-empted by §301 of the Labor Management Relations Act (LMRA), 29 U.S.C. §185.[37] In *Metropolitan Life Ins. Co. v. Taylor,* 481 U.S. 58, 63-64, 107 S.Ct. 1542, 95 L.Ed.2d 55 (1987), the Supreme Court added a second category -- a suit by a beneficiary to recover benefits from an ERISA covered plan falls under § 502(a)(1)(B) of ERISA, which provides an exclusive federal cause of action for resolution of such disputes.[38]

Claims arising from prescription drug use are not completely preempted.[39] The Fourth Circuit has outlined a test to determine whether the complete preemption doctrine is applicable in a given circumstance:

> In applying the complete preemption doctrine, courts generally look first to the preemptive *scope* of the federal statute and second to its preemptive *force.* A statute's preemptive force is measured by the extent to which it precludes state court consideration of claims falling within the statute's preemptive scope.... Only where the federal statute's preemptive scope is sufficiently broad to reach a purported state law claim and its preemptive force is sufficiently powerful to convert that particular claim into a federal claim will the complete preemption doctrine apply.[40]

Complete preemption must be distinguished from cases in which the federal statute has not provided a federal remedy. A common law action may well be preempted by federal law, without a comparable right of action under the federal law. Such preemption will leave a plaintiff without any remedy, but is not a case over which the federal court has jurisdiction under the doctrine of complete preemption.

> The Supreme Court [has] emphasized that the touchstone of complete preemption is "whether Congress intended the federal cause of action" to be "the exclusive cause of action" for the type of claim brought by a plaintiff. In cases of complete preemption, however, it is misleading to say that a state claim has been "preempted" as that word is ordinarily used. In such cases, in actuality, the plaintiff simply has brought a mislabeled federal claim, which may be asserted under some federal statute. Thus, a vital feature of complete preemption is the existence of a federal cause of action that replaces the preempted state cause of action. Where no discernable federal cause of action exists on a plaintiff's claim, there is no complete preemption, for in such cases there is no federal cause of action that Congress intended to be the exclusive remedy for the alleged wrong…..

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[37] *Id*., citing *Avco Corp. v. Machinists*, 390 U.S. 557, 88 S.Ct. 1235, 20 L.Ed.2d 126 (1968), which established complete preemption under such cases.
[38] *Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58, 62-63, 107 S.Ct. 1542, 95 L.Ed.2d 55 (1987).
[39] *McCallister v. Purdue Pharma L.P*., 164 F.Supp.2d 783 (S.D.W.Va. 2001).
[40] *Custer v. Sweeney,* 89 F.3d 1156, 1165 (4th Cir.1996) (internal quotations and citations omitted) (emphasis in original).

> The absence of a federal cause of action says nothing about whether the state claim is preempted in the ordinary sense: it is entirely within the power of Congress to completely eliminate certain remedies by preempting state actions, while providing no substitute federal action. But in such cases, preemption serves only as a federal defense, the barred claims are not completely preempted, and thus not removable to federal court.[41]

II. Preemption of Medical Device Product Liability Claims under MDA

The States have traditionally exercised their police powers to protect the health and safety of their citizens, because health and safety are primarily, and historically matters of local interest.[42] Despite the prominence of the States in matters of public health and safety, in recent decades the Federal Government has played an increasingly significant role. Congress' first significant enactment in the field of public health was the Food and Drug Act of 1906, a broad prohibition against the manufacture or shipment in interstate commerce of any adulterated or misbranded food or drug.[43] In 1938 Congress broadened the coverage of the Food and Drug Act to include misbranded or adulterated medical devices and cosmetics, enacting the Food, Drug, and Cosmetic Act of 1938 (FDCA).[44] As technologies advanced and medicine relied to an increasing degree on a vast array of medical equipment "[f]rom bedpans to brainscans," policymakers and the public became concerned about the increasingly severe injuries that resulted from the failure of such devices. Partly in response to the injuries and deaths caused by the Dalkon Shield in the early 1970's,[45] Congress enacted the Medical Device Amendments of 1976 (MDA).[46]

The Act classifies medical devices in three categories based on the risk that they pose to the public.[47] Devices that present no unreasonable risk of illness or injury are

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[41] *King v. Marriott Intern. Inc*., 337 F.3d 421 (4th Cir. 2003).
[42] *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 719, 105 S.Ct. 2371, 2378, 85 L.Ed.2d 714 (1985).
[43] *Medtronic v. Lohr*, 518 U.S. at 475, 116 S.Ct. at 2246.
[44] *Id*.
[45] *Martin v. American Medical Systems, Inc.*, 116 F.3d 102, 103 (4th Cir. (Va.) 1997).
[46] 90 Stat. 539.
[47] It is quite simple to identify the classification of a specific device, as the regulations are quite detailed. For example, 21 C.F.R. § 880.5075 defines an Elastic bandage as a device consisting of either a long flat strip or a tube of elasticized material that is used to support and compress a part of a patient's body. Such device is classified as Class I and is "exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in Sec. 880.9." 21 C.F.R. § 882.5950 defines an "Artificial Embolization device" as "an object that is placed in a blood vessel to permanently obstruct blood flow to an aneurysm or other vascular malformation, and classifies such devices as "Class III." Class III devices are subject to more stringent requirements of the PMA process or alternatively the § 501k process. These include GDC coils (21 C.F.R. § 882.5950), pacemakers (21 C.F.R. § 870.3610) and penile inflatable implants (21 C.F.R. § 876.3350).[47] If the device in your case is classified as Class III, you must determine whether it came to market pursuant to the "substantial equivalent" requirement of §

designated Class I and are subject only to minimal regulation by "general controls."[48] Devices that are potentially more harmful are designated Class II; although they may be marketed without advance approval, manufacturers of such devices must comply with federal performance regulations known as "special controls."[49] Finally, devices that either present a potential unreasonable risk of illness or injury, or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," are designated Class III.[50] The MDA classifies all devices which do not satisfy the definitions of Class I and II as Class III devices.[51]

A Class III device may be marketed and sold pursuant to the MDA regulations in one of four ways. First, new Class III devices must undergo a comprehensive premarket approval ("PMA") process before marketing.[52] Second, the MDA contains a grandfathering provision which allows pre-1976 devices to remain on the market without FDA approval until the FDA completes the PMA.[53] Thus a device placed into market prior to 1976 need not undergo FDA approval in order to remain on the market. Third, the MDA contains an investigational device exemption ("IDE") for new devices under clinical investigation which allows manufacturers to begin limited marketing of new devices without undergoing the rigorous PMA process.[54] Finally, a Class III device may reach the market without undergoing the PMA procedures if the FDA determines, on the basis of the § 510 process, that the device is "substantially equivalent" to a device already on the market.[55] This final exception all but swallows the rule requiring premarket approval.[56]

510k, or whether the particular device which caused the injury was subjected to premarket approval pursuant to the PMA process. In order to make that determination, visit the FDA website, http://www.fda.gov/cdrh/prodcode.html, and click on search product, type in a basic term, and then search through the products listed. Among the information reported is the classification (I through III) and the submission type (510k or PMA). You can access the 510(k) or PMA database and search each. You can obtain through this website many of the documents relevant to the submission. Others must be obtained through a FOIA request. The database has documents from 1996 forward, according to my search. Finally, you can access a separate portion of the FDA website, http://www.fda.gov/cdrh/index.html, and from there gain access to all documented complaints submitted by the manufacturer or users of the device pursuant to mandatory reporting requirements.

[48] 21 U.S.C. § 360c(a)(1)(A).
[49] 21 U.S.C. § 360c(a)(1)(B).
[50] 21 U.S.C. § 360c(a)(1)(C).
[51] *See Oja v. Howmedica, Inc*., 111 F.3d 782, 786 (10th Cir. 1997).
[52] 21 U.S.C. § 360e.
[53] 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1).
[54] 21 U.S.C. § 360j(g); *see Oja v. Howmedica, Inc*., 111 F.3d 782, 786 (10th Cir. 1997).
[55] 21 U.S.C. § 360e(b)(1)(B).
[56] The House reported in 1990 that 80% of new Class III devices were being introduced to the market through the § 510(k) process and without PMA review. H.R.Rep. No. 101-808, p. 14 (1990). *Medtronic v. Lohr*, 518 U.S. at 477-79, 116 S.Ct. at 2246-47.

The MDA contains an express preemption provision, 21 U.S.C. § 360k[57] which provides in part:

> (a) Except as provided in subsection (b) of this section, no 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.

A. Negligent Design or Manufacture, Breach of Warranty

The Supreme Court has interpreted the express preemption provision of the MDA narrowly, such that it will not preempt state common law claims for negligent design or manufacture,[58] strict liability,[59] or breach of express or implied warranties.[60] In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), a divided Supreme Court held that Plaintiff's claims alleging negligent design, manufacture, assembly, and sale, including failure to warn or properly instruct plaintiff's physicians, and a strict liability count alleging unreasonably dangerous defect, were not preempted by the MDA. Justice Stevens delivered the opinion of the Court, joined by Justices Kennedy, Souter, and Ginsburg; Justice Breyer concurred in the judgment, and in the opinion only as to Parts I, II, III, V, and VII.

The above-stated principles of preemption are helpful in understanding the distinction between the plurality opinions in *Medtronic*. The majority holding in Part V requires the federal regulation be specific to the device in order for it to have preemptive effect over state regulations or common law claims. The opinion reads a specificity requirement into § 360k from the FDA regulations:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.[61]

Thus in order to preempt state law, the federal regulation must be a specific "requirement" pertaining to the particular device. The Court held that the FDA's 510(k) approval of the pacemaker device was not a sufficiently specific requirement which

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[57] Not to be confused with 21 U.S.C. § 360 (k).
[58] *Medtronic v. Lohr, supra*.
[59] *Id*.
[60] *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324, 330 at n.5 (4th Cir. 1996)("Bone Screw II").
[61] 21 C.F.R. § 808.1(d).

actually conflicted with imposition of common law liability requirements. Justice Breyer, joined with the plurality as to Part V of the opinion.

The distinction between the holding of the majority and J. O'Connor's dissent, is whether § 360k is sufficiently ambiguous that the Court was allowed to look to FDA regulations for guidance.[62] The dissenting minority finds § 360k clear and unambiguous, the principle opinion's reliance on FDA regulations unwarranted, and the general manufacturing and labeling requirements sufficiently applicable to the device at issue to preempt plaintiff's common-law claims.

Medtronic extended the analysis of express preemption, stating that the words of preemption must be interpreted in context in order to give effect to Congress's intent.

> MDA's pre-emption provision is highly ambiguous. . . . The words "any [state] requirement" and "any [federal] requirement," for example, do not tell us *which* requirements are at issue, for *every* state requirement that is not identical to even *one* federal requirement is "different from, or in addition to," that single federal requirement; yet, Congress could not have intended that the existence of one single federal rule, say, about a 2-inch hearing aid wire, would pre-empt *every* state law hearing aid rule, even a set of rules related only to the packaging or shipping of hearing aids. Thus, Congress must have intended that courts look elsewhere for help as to just which federal requirements pre-empt just which state requirements, as well as just how they might do so. . . .
> Second, this Court has previously suggested that, in the absence of a clear congressional command as to pre-emption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect. To draw a similar inference here makes sense, and not simply because of the statutory ambiguity. The Food and Drug Administration (FDA) is fully responsible for administering the MDA. See 21 U.S.C. § 393.[63]

In Part IV of the principle opinion, J. Stevens, joined only by Justices Kennedy, Souter, and Ginsburg, further found that in order to be preempted, the state common law requirements must also be "specifically developed 'with respect to' medical devices."

> "Requirement" appears to presume that the State is imposing a specific duty upon the manufacturer, and although we have on prior occasions concluded that a statute pre-empting certain state "requirements" could also pre-empt common-law damages claims, *see Cipollone*, 505 U.S., at 521-522, 112 S.Ct., at 2620, that statute did not sweep nearly as broadly as Medtronic would have us believe that this statute does.
> . . . Medtronic's sweeping interpretation of the statute would require far

[62] *See* 518 U.S. at 412 (O'Connor, J., dissenting).
[63] Medtronic at 505-506 (Breyer, J., concurring)(citations omitted).

> greater interference with state legal remedies, producing a serious intrusion into state sovereignty while simultaneously wiping out the possibility of remedy for the Lohrs' alleged injuries. Given the ambiguities in the statute and the scope of the preclusion that would occur otherwise, we cannot accept Medtronic's argument that by using the term "requirement," Congress clearly signaled its intent to deprive States of any role in protecting consumers from the dangers inherent in many medical devices.[64]
>
> Under Medtronic's view of the statute, Congress effectively precluded state courts from affording state consumers any protection from injuries resulting from a defective medical device. Moreover, because there is no explicit private cause of action against manufacturers contained in the MDA, and no suggestion that the Act created an implied private right of action, Congress would have barred most, if not all relief for persons injured by defective medical devices. Medtronic's construction of § 360k would therefore have the *perverse* effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order "to provide for the safety and effectiveness of medical devices intended for human use."[65]

The majority of the Justices, however, agreed with Medtronic's "perverse" view. A plurality of the Court, led by Justice O'Connor's dissent in which C.J. Rehnquist and Justices Scalia and Thomas joined, and concurred in by Breyer, held that a state common law action can constitute a "requirement" as prohibited in § 360k.[66] Justice Breyer agreed with the dissent that under the controlling precedent, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), "requirement" includes legal requirements arising from state tort actions. "State regulation can be as effectively exerted through an award of damages as through some form of preventive relief."[67]

Combining the two distinct majorities in the *Medtronic* plurality opinion produces the following rule of law:

> In sum, the rule under *Medtronic* is that state common-law causes of action may constitute requirements, but such requirements are preempted only when they conflict with a specific regulation promulgated by the FDA with respect to the particular device in question or a device-specific requirement imposed by the MDA. Accordingly, state-law claims pertaining to medical devices subject only to the general controls imposed

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[64] *Medtronic* at 488-89.
[65] *Medtronic*, 518 U.S. at 487 (emphasis added).
[66] It is noteworthy that the late Chief Justice Rehnquist and Justice O'Connor both participated in the dissent in *Medtronic* which would find such product liability claims preempted under the MDA. The recent appointment of Chief Justice John Roberts, and the potential appointment, as of the date of this essay, of Judge Samuel A. Alito, Jr. for Justice O'Connor's vacancy, will therefore not likely alter the subsequent landscape of preemption under the MDA.
[67] *Medtronic* at 504 (Breyer, J., concurring)(quoting *Cipollone*, 505 U.S. at 521).

by the § 510(k) notification process, GMPs, or labeling requirements are not preempted.[68]

An example of a device in which the FDA has sufficiently regulated to preempt state law claims can be found with the toxic shock syndrome warnings required to be printed on tampon packages.[69] In *Murphy v. Platex*,[70] the court held plaintiff's claims arising from failure to adequately warn were preempted. Had plaintiff been able to show defendant failed to comply with the federal labeling requirements, however, her claim would not have been preempted.[71] Instead, she was forced to assert that despite compliance with the regulations, including three warnings on the package as well as a detailed insert in the box, Playtex failed to comply with Maryland's common law requirements, which were clearly "different from and in addition to" the federal requirements and thereby preempted. Other courts have found failure to warn claims preempted by the FDA's regulations, specific to the particular device, regarding the contents of its warning label.[72]

Under the above reasoning of *Medtronic*, any claims for breach of express or implied warranties would also not be preempted.[73] In *Duvall I*,[74] the Fourth Circuit concluded, prior to *Medtronic*, that plaintiff's breach of express warranty claim was preempted "because Bristol-Meyers had submitted a similar brochure with the materials supporting its § 510(k) notification. Thus, the statements contained in the brochure were mandated by the FDA and could not support an express warranty claim."[75] Duvall I was vacated by the U.S. Supreme Court which directed the court to reconsider its opinion in light of *Medtronic*. On remand, the court notes that "nothing in *Medtronic* calls into question our holding in *Duvall I* that § 360k(a) preempts an express warranty claim to the extent that the claim is based on FDA-mandated labeling, packaging, or advertising."[76] However, the Court in *Duvall II* reversed its prior decision, as "*Medtronic* explicitly holds that neither the § 510(k) notification process nor the general controls on labeling found in 21 C.F.R. part 801 impose requirements on a device sufficient to result in preemption of additional or different state requirements."[77] A manufacturer who voluntarily makes claims about its product will incur *contractual* liability; an obligation freely assumed by contract is not one required by general state law.[78]

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[68] *Duval v. Bristol-Myers Squibb Co.*, 103 F.3d 324, 330 (4th Cir. 1996).
[69] *Duval v. Bristol-Myers Squibb Co.*, 103 F.3d 324 (4th Cir. 1996); see 21 C.F.R. § 801.430.
[70] 69 Fed. Appx. 140 (4th Cir. (Md.) 2003)(unpublished).
[71] *See Murphy*, n. at 143; *Duvall*, supra.
[72] *See e.g. Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001, *cert. denied*, 535 U.S. 1056, 122 S.Ct. 1914, 152 L.Ed.2d 823 (2002))(PMA approval of Simplex including warning label requirements).
[73] *See Duvall*, 103 F.3d 324; *Woods*, 218 F.Supp.2d 802.
[74] 65 F.3d 392, 401 (4th Cir. 1995).
[75] *Duvall II*, 103 F.3d 324, 331.
[76] *Id*. at 332.
[77] *Id.*
[78] *Id.*

At least for products approved under § 510(k), on claims of negligence and breach of warranty, the issue of preemption has been put to rest.[79] Reversing the district court's (E.D. Va.) pre-*Medtronic* grant of summary judgment to defendant, the Fourth Circuit Court noted:

> Martin first attacks the district court's holding that his tort and implied warranty claims are preempted. This issue dominates Martin's brief, but, in its response, American Medical Systems concedes that under the Supreme Court's decision in *Medtronic*, Martin is right: the Medical Device Amendments of 1976 do not preempt his common-law claims. For context's sake, we will briefly describe what this issue *was* all about.[80]

The above-stated rule from *Medtronic* reaches Class I and Class II devices, which are subject only to general FDA regulations, as well as Class III devices subject to 501(k) approval, as the *Medtronic* majority so held. The Court did not determine whether common law claims for injuries sustained as the result of devices marketed under more stringent FDA regulation may be preempted. Other circuits continue to find state common law claims preempted despite *Medtronic*. For example, in *Mitchell v. Collagen*,[81] the Seventh Circuit commented that *Medtronic*'s opinion was ambiguous, and held "state claims based on theories of negligence, strict liability and breach of warranty, 'insofar as these claims threaten to impose different or additional burdens on the defendant,' are preempted." In *Mitchell*, the product at issue had undergone premarket approval, a much more rigorous process requiring a FDA approval of the safety of the device, as opposed to substantial equivalence to a previously marketed device.

Lohr's pacemaker only received 510(k) review, and the *Medtronic* opinion makes that significant in its holding.

> As the court below noted, "the 510(k) process is focused on *equivalence*, not safety." As a result, "substantial equivalence determinations provide little protection to the public.". . . There is no suggestion in either the statutory scheme or the legislative history that the § 510(k) exemption process was intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents. That status quo included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design.[82]

Where a device has been subjected to premarket approval (PMA), several courts have held that premarket approval is a federal regulation specific to the device which

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[79] *See Martin v. American Medical Systems, Inc.*, 116 F.3d 102 (4th Cir. 1997).
[80] *Id.* at 103 (citations omitted)(emphasis added).
[81] 126 F.3d at 912.
[82] *Id.* at 493-94 (citations omitted)(emphasis in original).

preempts certain state common law claims, including the 3rd Circuit,[83] 5th Circuit,[84] 6th Circuit,[85] 7th Circuit,[86] 8th Circuit,[87] and 9th Circuit.[88]

However, the Western District of Virginia rejected that line of cases, instead following the reasoning of the Eleventh Circuit "that the FDA's review and approval of the PMA, by itself, imposes no ascertainable federal requirements."[89]

> The FDA's approval of a PMA does not "provide any indication of what (if any) specific substantive requirements the FDA may have applied to reach that result." The court rejected the defendants' attempts "to convert the FDA's finding and accompanying permission to market its device into the federal government's implied validation of the safety of its device and every step of its manufacture and, then, to use that validation as a shield against liability in tort." This court is persuaded by the Eleventh Circuit's reasoning and concludes that the FDA's conditional approval of Gliatech's PMA is not a specific requirement that preempts state law.[90]

In *Woods v. Gliatech, Inc.*,[91] the device at issue was "a gel-like product for use in surgical back procedures to inhibit post-surgical peridural scar tissue formation." The product, ADCON-L, was conditionally approved under the PMA process, subject to a clinical study. Company employees manipulated the data reported to the FDA. Gliatech also failed to report to the FDA, under MDR reporting requirements, complaints received from surgeons of cerebrospinal fluid leaks caused by its product. The U.S.D.C. denied defendant's motion for summary judgment and allowed plaintiff's claims of negligence and breach of implied warranty to avoid preemption, despite significant federal involvement.[92] When pursuing a product liability case involving a medical device

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[83] *Horn v. Thoratec Corp.*, 376 F.3d 163 (3rd Cir. 2004).

[84] *Martin v. Medtronic, Inc*., 254 F.3d 573 (5th Cir. 2001)(distinguishing *Medtronic* on the grounds that the device at issue, Medtronic's pacemaker Model 4004 had been subjected to PMA which preempted Plantiff's state common law action).

[85] *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000)(finding the FDA's premarket approval of the Model 4004M pacemaker constitutes a specific requirement invoking preemption under § 360k).

[86] *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913 (7th Cir.1997)(quoting *Fry v. Allergan Medical Optics*, 695 A.2d 511 (R.I. 1997)("`[T]he premarket approval process constitutes a specific federal interest as contemplated in *Medtronic* and therefore, the FDA approval served to impose strict FDA requirements upon the defendant.'").

[87] *Brooks v. Howmedica, Inc*., 273 F.3d 785 (8th Cir. 2001)(failure to warn claim preempted).

[88] *Papike v. Tambrands Inc*., 107 F.3d 737 (9th Cir. 1997)(claim for inadequate warning label on tampon preempted).

[89] See *Woods v. Gliatech, Inc.*, 218 F.Supp.2d 802, 808 (W.D. Va. 2002)(quoting *Goodlin v. Medtronic, Inc*., 167 F.3d 1367 (11th Cir. 1999)).

[90] *Id.*

[91] *Id.*

[92]

> In 1996, Gliatech submitted a PMA to the FDA for ADCON-L. . . . In early 2000, the FDA uncovered misconduct . . . with respect to the PMA and the reporting requirements . . . . In January 2001, Gliatech recalled ADCON-L . . . . In April

marketed under premarket approval, great care should be taken to bring the facts within the court's finding in *Woods*.

B. Violations of FDA requirements, Fraud on the FDA, and Misrepresentation

The U.S. Supreme Court recently restricted claims of "fraud-on-the-FDA" in *Buckman Co. v. Plaintiff's Legal Comm.*[93] Plaintiffs in that case alleged that defendant misrepresented its product to the FDA in obtaining 510(k) approval as a substantial equivalent.

> Section 510(k) submissions must include the following: 'Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use,' 21 CFR § 807.87(e)(2000); 'a statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement,' § 807.87(f); 'a statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted,' § 807.87(k); and 'any additional information regarding the device requested by the FDA Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution,' § 807.87(l).[94]

The court initially noted that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied."[95] "Accordingly . . . no presumption against preemption obtains in this case."[96] The court held that state-law fraud-on-the-FDA claims conflict with and are therefore impliedly preempted by federal law. "The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives."[97]

> State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's

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> 2002, the Department of Justice filed an information against Gliatech . . . [which] pled guilty to six counts, including four counts of failure to notify the FDA of reportable events in violation of 21 U.S.C. § 331(q)(1)(B) and 333(a)(1), one count of adulteration of a medical device in violation of 21 USC § 331(k) and 333(a)(1), and one count of submitting a materially false and misleading report regarding a medical device in violation of 21 U.S.C. § 331(a)(2).

Woods at 803 and 804.

[93] 531 U.S. 341 (2001).

[94] *Buckman* at 345-46.

[95] *Id.* at 347.

[96] *Id.*

[97] *Id.* at 348.

> judgment and objectives. . . . [F]raud-on-the-FDA claims could cause the Administration's reporting requirements to deter off-label use despite the fact that the FDCA expressly disclaims any intent to directly regulate the practice of medicine. . . [F]raud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court, [providing] incentive to submit a deluge of information that the Administration neither wants nor needs. . .[98]

Buckman is self-limiting in two key respects, however. First, the opinion does not consider whether these claims are subject to express preemption under 21 U.S.C. § 360k.[99] Second, the Court distinguishes plaintiffs' claims from those in *Silkwood v. Kerr-McGee Corp.*[100] and *Medtronic* where claims based on state tort principles were not preempted. "In the present case, the fraud claims exist solely by virtue of the FDCA disclosure requirements. . . . [P]laintiffs . . . would not be relying on traditional state tort law. . . . On the contrary, the existence of these federal enactments is a critical element in their case."[101]

While the Court suggested in *Medtronic* that to the extent plaintiff's claims of negligent manufacturing and labeling were founded upon breach of federal regulation requirements, they would not be preempted.[102] "The presence of a damages remedy does not amount to the additional or different 'requirement' that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing requirements under federal law."[103] However *Medtronic* did not "purport to allow private plaintiffs to sue directly for violations of a federal statute in the absence of a separate underlying cause of action. They merely hold that such causes of action as previously existed under state law were not preempted by the FDCA and Medical Device Amendments."[104]

Subsequent cases narrow *Buckman*'s application based on the limiting factors noted in the Supreme Court's opinion.

> [T]he only claim set forth in *Buckman* . . . was that certain information had been misrepresented to the FDA . . . . There is nothing in *Buckman* to suggest that the plaintiffs in that case alleged other grounds for relief, such as fraud on the medical community or that the product was defective and unreasonably dangerous. . . . the only theory preempted is that resting

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[98] *Id*. at 350-51.
[99] *Id.,* n.2 at 348.
[100] 464 U.S. 238 (1984).
[101] *Id.* at 352-53.
[102] *Medtronic* at 495 ("it is clear that the Lohrs' allegations may include claims that Medtronic has, to the extent that they exist, violated FDA regulations").
[103] *Medtronic* at 495.
[104] *In re Orthopedic Bone Screw Products Liability,*193 F.3d 781 (3rd Cir. 1999)("Bone Screw II").

> exclusively on the fact that the federal agency was itself the victim of the fraud.[105]

Distinguishing the facts and claims, *Globetti* found: "Defendant owed separate duties beyond simply full and fair disclosure to the FDA, duties not to market a defective and unreasonably dangerous product, not to misrepresent or suppress the facts needed by *physicians and consumers* to assess the safety of the product, and to adequately warn of known risks associated with it. These duties existed irrespective of the FDCA."[106] In *Woods, infra*, the U.S.D.C. in Roanoke distinguished *Buckman*, and allowed plaintiff's claims against the defendant who manipulated data reported to the FDA and failed to report incidents regarding its product.

> [M]any courts distinguish "fraud on the FDA" from state fraud claims alleging fraud against the public generally where no reference to any federal regulation or directive is made or required. In this case, Woods' fraud claim is based on material misrepresentations to "consumers and users and patients" and not on misrepresentations to the FDA. It, therefore, avoids the concerns identified in *Buckman*.[107]

It is critical when framing the complaint to properly allege the misrepresentations as being directed at the public rather than the FDA. *Gilleon v. Medtronic USA, Inc.*,[108] is instructive in this regard. In that case Medtronic asserted that plaintiffs' claims, including assertions that defendants "delayed in providing information to the FDA regarding five ruptures that occurred during the clinical studies," were actually 'fraud on the FDA' claims. The court declined defendant's invitation to re-characterize plaintiff's claim. "[T]he fraud, negligent misrepresentation, and fraud by concealment claims each allege that misrepresentations were made (or true facts concealed from) the general public, physicians, the patient-plaintiffs and plaintiffs' physicians."

Webster v. Pacesetter, Inc.,[109] on the other hand, illustrates what to avoid.

> Plaintiffs cannot bootstrap their arguments regarding defendant's alleged failure to report and to investigate adverse incidents to the FDA into a defective warning case.
> . . .
> Plaintiffs argue that if defendant had adhered to MDA requirements regarding record- keeping, adverse incident reporting, investigation, monitoring and complaint file maintenance, the 1388TC lead would have been recalled or placed on alert notice and plaintiff would not have been

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[105] *Globetti v. Sandoz Pharmaceutical Corp.*, 2001 WL 419160 at *1 (N.D. Ala. March 5, 2001).
[106] *Id.* at *2 (emphasis in original).
[107] *Woods*, 218 F.Supp.2d 802, 809-810.
[108] 2002 WL 31300694 at *6 (N.D. Cal. 2002).
[109] 259 F.Supp.2d 27 (D.D.C. 2003).

injured. This is precisely the type of claim barred by the Supreme Court [in *Buckman*].[110]

III. Specific Legislation Affecting other Products

a. Medical Drugs and Vaccines

Unlike the clarity with which the U.S. Supreme Court has spoken to the preemption of medical devices, there is no pivotal Supreme Court case defining preemption in the field of prescription or non-prescription drugs. It is generally accepted that the FDA will not preempt state law negligence claims related to prescription medication. "FDA regulations of prescription drugs are generally viewed as setting *minimum* standards, both as to design and warning."[111]

Non-prescription drugs, on the other hand, are controlled by the Food and Drug Administration Modernization Act of 1997 (Modernization Act).[112] Section 379r(a) of the Act establishes the preemptive effective of federal regulation of non-prescription drugs; it states in part: "[N]o State or political subdivision of a State may establish or

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[110] *Id.* at 36 and 39.

[111] *Rite Aid Corp. v. Levy-Gray,* 162 Md.App. 673, 876 A.2d 115 (2005)(quoting *Graham v. Wyeth Laboratories*, 906 F.2d 1399 (10th Cir.), cert. denied, 498 U.S. 981, 111 S.Ct. 511, 112 L.Ed.2d 523 (1990)) and citing: "*Brochu v. Ortho Pharmaceutical Corp.,* 642 F.2d 652 (1st Cir.1981) [(design defect)]; *Salmon v. Parke-Davis & Co.* [*Parke, Davis & Co.*], 520 F.2d 1359 (4th Cir.1975) [(failure to warn)]; ... *MacGillivray v. Lederle Laboratories,* 667 F.Supp. 743, 746 (D. N.Mex.1987) [(defective design)]; *Toner v. Lederle Laboratories,* 112 Idaho 328, 732 P.2d 297, 311 n. 12 (1987) ('FDA certification represents only the FDA's opinion, albeit an informed one, of the safety and efficacy of the drug. Regrettably, drugs occasionally prove not so safe as the FDA first believed.') [(defective condition)]; *Wooderson v. Ortho Pharmaceutical Corp.,* 235 Kan. 387, 681 P.2d 1038, *cert. denied,* 469 U.S. 965, 105 S.Ct. 365, 83 L.Ed.2d 301 (1984) [(failure to warn)]; *Feldman v. Lederle Laboratories,* 97 N.J. 429, 479 A.2d 374 (1984) [(failure to warn)]; *Barson v. E.R. Squibb & Sons, Inc.,* 682 P.2d 832, 836 (Utah 1984) [(breach of warranty; failure to warn)]; ***702***Ferrigno v. Eli Lilly & Co.,* 175 N.J.Super. 551, 420 A.2d 1305 (1980) [(breach of warranty; failure to warn; design defect)]; *Bristol-Myers v. Gonzales,* 548 S.W.2d 416 (Tex.Civ.App.1976) [(failure to warn)]; *McEwen v. Ortho Pharmaceutical Corp.,* 270 Or. 375, 528 P.2d 522 (1974) [(failure to warn)]; *Stevens v. Parke-Davis & Co.* [*Parke, Davis & Co.*], 9 Cal.3d 51, 107 Cal.Rptr. 45, 53, 507 P.2d 653, 661 (1973) [(failure to warn)];*Tobin v. Astra Pharmaceutical Prods., Inc.,* 993 F.2d 528, 536-38 (6th Cir.) (defective design), *cert. denied,* 510 U.S. 914, 114 S.Ct. 304, 126 L.Ed.2d 252 (1993); *Hurley v. Lederle Laboratories Div. of Am. Cyanamid Co.,* 863 F.2d 1173, 1176-77 (5th Cir.1989) (failure to warn and defective design); *Abbot v. American Cyanamid Co.,* 844 F.2d 1108, 1110-14 (4th Cir.) (failure to warn and defective design), *cert. denied,* 488 U.S. 908, 109 S.Ct. 260, 102 L.Ed.2d 248 (1988); *Morris v. Parke, Davis & Co.,* 667 F.Supp. 1332, 1339-40 (C.D.Cal.1987) (defective design); *Shackil v. Lederle Laboratories,* 116 N.J. 155, 561 A.2d 511, 527 (1989) (defective design); *MacDonald v. Ortho Pharmaceutical Corp.,* 394 Mass. 131, 475 N.E.2d 65, 70-71 (failure to warn), *cert. denied,* 474 U.S. 920, 106 S.Ct. 250, 88 L.Ed.2d 258 (1985).

[112] Pub.L. No. 105-115.

continue in effect any requirement.... (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter...." The Modernization Act, however, contains a savings clause section 379r(d)(2), that provides: "This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997."[113] The issue in *Dowall* was whether the Act preempted Plaintiff's state law failure to warn claim arising from Defendant's labeling of nicotine gum and patch. The Court held that the Modernization Act preempted Plaintiff's claim based on an actual conflict.[114]

The Public Health Service Act (PHSA)[115] and the Federal Food, Drug, and Cosmetic Act (FDCA)[116] do not preempt claims for defective design and warning arising from vaccines.[117] "The overwhelming majority of courts considering federal preemption of state law as regards vaccines have found no preemption."[118]

> The FDA's regulation of prescription drugs and biological products is comprehensive. The DPT vaccine is a prescription biological product subject to the provisions of the FDCA, the PHSA, and regulations promulgated thereunder. The FDA regulations encompass the licensing, production, testing, distribution, labeling, review and approval of all drugs and biologicals. . . .
> Preemption does not follow immediately from the comprehensive federal regulation of prescription biological products. Every subject that merits congressional legislation is, by definition, a subject of national concern. That cannot mean, however, that every federal statute ousts all related state law.[119]

b. Planes

While Congress has also legislated in the field of aviation, it is generally understood that a state law civil action in tort will not be preempted.[120] "Private tort actions based on common-law negligence or fraud ... are not pre-empted."[121]

> The Federal Aviation Act of 1958 ("the FAA") empowered the Civil Aeronautics Board to regulate the interstate airline industry. Although the

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[113] *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal.4th 910, 88 P.3d 1 (Cal. 2004).
[114] *Id*.
[115] 42 U.S.C. § § 201-300.
[116] 21 U.S.C. § § 301-392.
[117] *Abbot by Abbot v. American Cyanamid Co*., 844 F.2d 1108 (4th Cir.(Va.) 1988).
[118] *Abbott*, 844 F.2d at 1112, at n.1.
[119] *Abbott* at 1112.
[120] *See Delta Airlines v. Cook*, 816 N.E.2d 448 (Ind.App. 2004), opinion vacated, *sub. nom. Atlantic Coast Airlines v. Cook*, 831 N.E.2d 748 (Ind. May 26, 2005) (TABLE).
[121] *American Airlines, Inc. v. Wolens*, 513 U.S. 219,235-36, 115 S.Ct. 817, 130 L.Ed.2d 715 (1995)(Stevens, J., concurring in part and dissenting in part).

> FAA authorized the Board both to regulate fares and to take administrative action against deceptive trade practices, the federal legislation originally contained no clause preempting state regulation. The FAA contained a "saving clause" which provided: "Nothing contained in this chapter shall in any way abridge or alter the remedies now existing at common law or by statute, but the provisions of this chapter are in addition to such remedies."[122] In 1978, Congress enacted the ADA, which largely deregulated domestic air transport. The ADA includes a preemption clause, which provides: "A State ... may not enact or enforce a law, regulation, or other provision having the force and effect of law related to a price, route, or service of an air carrier." 49 U.S.C. § 1305(a)(1) (current version at 49 U.S.C. § 41713). The ADA also contains a saving clause, [49 U.S.C. § 40120(c),] which provides that "a remedy under this part is in addition to any other remedies provided by law."[123]

The United States Supreme Court has twice addressed the scope of Section 1305(a)(1), first in *Morales v. Trans World Airlines, Inc*., 504 U.S. 374, 112 S.Ct. 2031, 119 L.Ed.2d 157 (1992), and then in *American Airlines, Inc. v. Wolens*, 513 U.S. 219, 115 S.Ct. 817, 130 L.Ed.2d 715 (1995). . . .In both *Morales* and *Wolens*, the Supreme Court took great pains to articulate the boundaries of the preemption, indicating that the ADA would not preempt most state law tort claims.[124]

The issue of preemption often does not even arise in this area. For example, in *Ridge v. Cessna Aircraft Co*.,[125] plaintiff successfully pursued a wrongful death action arising from a design defect in North Carolina state court. There was no discussion of preemption in the reported opinion affirming the verdict.

c. Trains

State law tort claims against manufacturers of parts or components of railroad locomotives are preempted by federal law under the Locomotive Boiler Inspection Act, 49 U.S.C. § 20701.[126] In *W.Va. Asbestos* railroad employees filed a mass tort suit against the railroad operator and manufacturers of equipment used in railroad operations for injuries resulting from exposure to asbestos. "Railroad law is unique in the breadth, degree, and comprehensiveness of federal oversight and involvement."[127]

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[122] 49 U.S.C. § 1506 (current version at 49 U.S.C. § 40120(c)).

[123] *Delta Airlines v. Cook*, 816 N.E.2d 448, 453-54 (Ind.App. 2004), opinion vacated, *sub. nom. Atlantic Coast Airlines v. Cook*, 831 N.E.2d 748 (Ind. May 26, 2005). (TABLE).

[124] *Id*. at 454 (citing *Wolens*, 513 U.S. at 230-33, 115 S.Ct. 817; *Morales*, 504 U.S. at 390, 112 S.Ct. 2031).

[125] 117 F.3d 126 (4th Cir. 1997).

[126] *In re West Virginia Asbestos Litigation*, 215 W.Va. 39, 592 S.E.2d 818 (W.Va. 2003).

[127] *Id* at 41, 592 S.E.2d at 820.

> In 1893, Congress passed the first of what we now call the Safety Appliance Acts, followed in 1911 by the Boiler Inspection Act (also called the Locomotive Boiler Inspection Act . . . LIA or BIA). The Boiler Inspection Act can now be found at 49 U.S.C. § 20701, et seq., and the Safety Appliance Act at 49 U.S.C. § 20301 et seq. Together these Acts standardized the safety requirements for many aspects of railroad operation, including brakes, lights, grab bars, coupling devices, pressure relief devices, and other such items.[128]

Because of the extensive regulation of the field, the Court found plaintiff's claims preempted under implied, or field preemption.

> In spite of the strong presumption against federal preemption . . . an overwhelming body of case law persuades us that, through passage of the Boiler Inspection Act, Congress has occupied the field of railroad safety so pervasively that plaintiffs' claims against the defendants are preempted.[129]

In addition to the Boiler Inspection Act, Congress passed the Federal Railroad Safety Act (FRSA)[130] in 1970, "to promote safety in every area of railroad operations and reduce railroad-related accidents and incidents."[131] The FRSA contains an express pre-emption provision, which states:

> Laws, regulations, and orders related to railroad safety shall be nationally uniform to the extent practicable. A State may adopt or continue in force a law, regulation, or order related to railroad safety until the Secretary of Transportation prescribes a regulation or issues an order covering the subject matter of the State requirement."[132]

In *Norfolk Southern Ry. Co. v. Shanklin*[133] the Supreme Court held that Plaintiff's failure to warn claim at a railroad crossing was preempted by the regulations addressing adequacy of warning devices installed under Federal Railway-Highway Crossings Program, because these regulations apply to all warning devices actually installed with federal funds and the state transportation department used federal funds for the signs' installation.[134]

> Three years after passing the FRSA, Congress enacted the Highway Safety Act of 1973, § 203, 87 Stat. 283, which, among other things, created the Federal Railway-Highway Crossings Program (Crossings Program), see

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[128] *Id* at 42, 592 S.E.2d at 821.
[129] *Id*. at 43, 592 S.E.2d at 822.
[130] 49 U.S.C. § 20101.
[131] *Norfolk Southern Ry. Co. v. Shanklin*, 529 U.S. 344, 120 S.Ct. 1467 (2000).
[132] 49 U.S.C. § 20106.
[133] 529 U.S. 344, 120 S.Ct. 1467 (2000).
[134] *See also Major v. CSX Transp*., 278 F.Supp.2d 597 (D.Md. 2003).

> 23 U.S.C. § 130. That program makes funds available to States for the "cost of construction of projects for the elimination of hazards of railway-highway crossings."
> In *CSX Transp., Inc. v. Easterwood,*[135]. . . we explained that the language of the FRSA's pre-emption provision dictates that, to pre-empt state law, the federal regulation must "cover" the same subject matter, and not merely " 'touch upon' or 'relate to' that subject matter." Thus, "pre-emption will lie only if the federal regulations substantially subsume the subject matter of the relevant state law."[136] Applying this standard, we concluded that the regulations contained in 23 C.F.R. pt. 924 (1999), which "establish the general terms of the bargain between the Federal and State Governments" for the Crossings Program, are not pre-emptive. With respect to §§ 646.214(b)(3) and (4), however, we reached a different conclusion. Because those regulations "establish requirements as to the installation of particular warning devices," we held that "when they are applicable, state tort law is pre-empted." . . .
> In *Easterwood* itself, we ultimately concluded that the plaintiff's state tort claim was not pre-empted. As here, the plaintiff brought a wrongful death action alleging that the railroad had not maintained adequate warning devices at a particular grade crossing. We held that §§ 646.214(b)(3) and (4) were not applicable because the warning devices for which federal funds had been obtained were never actually installed at the crossing where the accident occurred. Nonetheless, we made clear that, when they do apply, §§ 646.214(b)(3) and (4) "cover the subject matter of state law which, like the tort law on which respondent relies, seeks to impose an independent duty on a railroad to identify and/or repair dangerous crossings."[137]

d. Automobiles

Congress legislated in the field of automobile safety with the National Traffic and Motor Vehicle Safety Act of 1966.[138] Pursuant to its authority granted under the Act, the Department of Transportation passed standard, FMVSS 208, which required auto manufacturers to equip some but not all of their 1987 vehicles with passive restraints. In *Geier v. American Honda Motor Co.,*[139] the Supreme Court held that the Act, taken together with FMVSS 208, preempted Plaintiff's state common-law tort action alleging that the auto manufacturer, who was in compliance with the standard, should nonetheless have equipped a 1987 automobile with airbags. Although the Act contains an express preemption provision and savings clause, the Court in *Geier* stated that when analyzing the extent of preemption, the presence of a preemption provision and savings clause did not end the court's inquiry into the extent to which Congress intended to preempt state

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[135] 507 U.S. 658, 113 S.Ct. 1732, 123 L.Ed.2d 387 (1993).
[136] *Easterwood, supra*, at 664, 113 S.Ct. 1732.
[137] *Norfolk Southern Ry. Co. v. Shanklin*, 529 U.S. at 352-53, 120 S.Ct. at 1473-74.
[138] 80 Stat. 718, 15 U.S.C. §1381 et seq. (1988 ed.).
[139] 529 U.S. 861, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000).

claims. Thus even if the Act did not by its express terms manifest an intent to preempt state claims, the claims could nonetheless be preempted where they conflict with federal law.

The preemption provision in the FMVSA provides:

> Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment[,] any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard.[140]

The Act contains a savings clause at 15 U.S.C. § 1397(k) which preserves state common-law actions. It states that compliance with a federal safety standard does not exempt any person from any liability under common law.

> Nothing in the language of the saving clause suggests an intent to save state-law tort actions that conflict with federal regulations. The words "[c]ompliance" and "does not exempt," sound as if they simply bar a special kind of defense, namely, a defense that compliance with a federal standard automatically exempts a defendant from state law, whether the Federal Government meant that standard to be an absolute requirement or only a minimum one.[141]

Similarly claims for negligence and strict liability even though styled as a design defect claim were impliedly pre-empted when based on the theory that Hyundai exercised an option granted under FMVSS 208 and installed in the Sonata an automatic shoulder belt system with a "Type 1" manual lap belt.[142] "Wrong choice" lawsuits are preempted under *Geier*.[143] A claim for negligent design should remain viable when it can be established.[144] However the Eleventh Circuit found a plaintiff's claims that a 1994 Mazda Protege's manual lap belt had been defectively designed and that Mazda had negligently failed to warn consumers that the Protege was dangerous unless the manual lap belt was worn were preempted.[145]

Fraud on the NHTSA, unlike Fraud on the FDA, remains viable, at least according to one court.[146]

> Defendant relies on *Buckman* for the contention that the fraud on NHTSA claim will inevitably conflict with the Federal Motor Vehicle Safety Act.

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[140] 15 U.S.C. § 1392(d) (1988 ed.).
[141] *Geier* at 870.
[142] *Kendall v. Hyundai Motor Co*., 2000 WL 34013265 (D.S.C., Nov 20, 2000)(citing *Geier, supra*).
[143] *Moser v. Ford Motor Co*., 2001 WL 936346 (N.D.W.Va., Feb 02, 2001)(NO. CIV. A. 197CV194).
[144] *See Moser, supra*; *King v. Ford Motor Co*., 209 F.3d 886 (6th Cir.2000).
[145] *See James v. Mazda Motor Corp*., 222 F.3d 1323, 1324 (11th Cir.2000)).
[146] *Hernandez v. Ford Motor Co*., 2005 WL 1830660 (S.D.Tex., Aug 02, 2005) (NO. C.A. C-04-319).

The *Buckman* Court addressed a "fraud on the FDA" claim and whether this was preempted by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360e.

The Federal Motor Vehicle Safety Act contains a savings clause. Compliance with consumer product safety rules or other rules or orders under this chapter shall not relieve any person from liability at common law or under State statutory law to any other person." 15 U.S.C. § 2074(a). The Supreme Court held that the Safety Act does not preempt state statutory and common law claims and that existence of "[t]he saving clause assumes there are some significant number of common-law liability cases to save." *Geier*, 529 U.S. at 867. The Food, Drug, and Cosmetic Act, however, contains no savings clause protecting the ability to bring claims under state statutes and common law. Therefore, *Buckman* is distinguishable.

IV. Conclusion

There is a wealth of federal legislation of planes, trains, automobiles, medical devices, cell phones, pesticides . . . . Plaintiff's product liability claims must always be analyzed under the specific laws affecting the product in order to determine if the laws and regulations conflict with the theories of state law necessary to support plaintiff's allegations. In every instance, Plaintiff should start with a review of the applicable legislation, starting with broad legislation, followed by more careful consideration of the relevant federal regulations. If the facts support an allegation that Defendant was negligent in the design or manufacture of the product, was the design or manufacture expressly approved as safe by the FDA, NHTSA, etc. In a failure to warn case, are the regulations governing labeling specific to the device, and did the defendant comply with the regulations precisely. The preemption issue has been well developed under legislation of medical devices, but the law is product-specific, and preemption should be considered in every product case when formulating the theories of recovery.