SHARED SOVEREIGN IMMUNITY AS AN ALTERNATIVE TO FEDERAL PREEMPTION: AN ESSAY ON THE ATTRIBUTION OF RESPONSIBILITY FOR HARM TO OTHERS

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I. INTRODUCTION

In 1992, the Supreme Court handed down a plurality decision in Cipollone v. Liggett Group, Inc. That decision, together with a series of subsequent cases dealing with the federal preemption of state tort law, served to reverse a long-standing judicial approach to federal preemption under which claims of express preemption had been summarily rejected. These more recent decisions have been criticized by many and, in fact, have been characterized by myself and others as examples of pro-business judicial activism seeking to impose tort reform from the bench. Yet, for all that is objectionable about the Court’s approach in these cases, often there is also something intuitively appealing about the results attained.

This Article will argue that, notwithstanding numerous judicial assertions to the contrary, the results reached in many of these cases have little, if anything, to do with congressional intent. Instead, the decisions are better understood in terms of implied immunity or shared sovereign immunity and represent a strikingly clear application of a long-standing principle of tort law—a principle that insists that responsibility for harm will not be attributed to an individual where the

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individual’s ability to have chosen an alternative course of action was impaired by another who was in a position of authority and thus able to dictate conduct. In other words, where one could not have acted otherwise without risking legal sanction, tort law may not be used to penalize the compliant conduct.  

The importance of the underlying principle is readily apparent in other areas of tort law as well. The Products Liability Restatement’s insistence on the availability of a “reasonable alternative design” as the primary test of defectiveness in (non-drug) product design cases is one obvious example, but there are also many other less obvious applications of the principle.

At this point, it should probably be noted that the underlying premise that tort liability is commonly viewed as a form of punishment or at least attribution of responsibility for wrongdoing is nothing new, although the apparently casual implicit acceptance of this notion by the United States Supreme Court, the federal judiciary, and many state courts is somewhat surprising given that courts and legal scholars have long denied tort law’s punitive role. In contrast, social scientists—primarily psychologists and sociologists—have recognized the obvious parallel between tort and crime and dealt with both as variations on the same assignment of responsibility theme, pretty much as a matter of self-evident truth.

Using Cipollone as a starting point, Part II of this Article will review the decision, note the essential problem, and briefly sketch the reason for the attractiveness of the outcome. Part III takes up the social science attribution literature both as background and to explain why coercion or duress plays such a key role in tort law and forms the pivotal issue in the preemption cases. Part IV illustrates just how the coercion argument has been applied, particularly when the government is the source of coercion, while Part V uses it to lay out an alternative and more coherent approach to those products liability cases presently being decided under the fiction of congressional intent.

5. See infra notes 63-74 and accompanying text.
7. See infra text accompanying notes 63-76, 89-92, 106-08.
8. With the exception of punitive damages, of course.
9. See, e.g., Robert F. Kidd & Mary K. Utne, Reactions to Inequity: A Prospective on the Role of Attributions, 2 LAW & HUM. BEHAV. 301, 304 (1978) (noting equity theorists’ application of their model to tort and criminal law and citing examples); see also Jeannine A. Gailey & Matthew T. Lee, An Integrated Model of Attribution of Responsibility for Wrongdoing in Organizations, 68 SOC. PSYCHOL. Q. 338, 340 (2005) (explaining the application of their model to tort, crime, and informal social sanction, and distinguishing them on the basis of a “burden-of-proof continuum”).
II. THE MODEL CASE—CIPOLLONE

Ignoring, for the moment, how the case could (and should) have been decided, it is useful to examine the approach taken by the Court in Cipollone v. Liggett Group, Inc.10 The underlying products liability lawsuit was brought by a smoker of cigarettes marketed by the defendants. Among the many counts, the plaintiff alleged that the cigarettes were defective because of the defendants’ failure to warn “about the hazards of smoking.”11 Of course, in fact the cigarettes did carry a warning. As required by the Federal Cigarette Labeling and Advertising Act of 196512 (the “Act”) and the 1969 amendment to the Act,13 cigarettes marketed between 1966 and 1969 warned that smoking “May Be Hazardous to Your Health,”14 while those marketed in conformity to the 1969 amendment warned that cigarette smoking “Is Dangerous.”15 These warnings, however, were alleged to have been inadequate.16 In response, the defendants pled that the suit was preempted by federal law.17

Thus, the decision of the case was made to turn on whether and to what extent Congress intended to preclude state common-law tort litigation when it enacted the Act. Responding to that issue, the Court focused on the preemption language of the statute.18 The Act provided:

(a) No statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any cigarette package.
(b) No statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.19

When the Act was amended in 1969, the language was changed somewhat to read:

(b) No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or

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11. Id. at 508 (plurality opinion).
16. 505 U.S. at 509 (plurality opinion).
17. Id. at 510.
18. Id. at 514-15 (quoting the language of the Act and the 1969 amendment).
promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.\textsuperscript{20}

Analyzing the original language of the Act, a plurality of the Court concluded that it was not intended to preempt state lawsuits, but “merely prohibited state and federal rulemaking bodies from mandating particular cautionary statements on cigarette labels”\textsuperscript{21} and the simple fact that “Congress requires a particular warning label does not automatically pre-empt a regulatory field.”\textsuperscript{22} In other words, the restriction applied only to state legislatures and regulatory bodies, not to courts.\textsuperscript{23} The 1969 amendment’s language of no “requirement[] or prohibition[],” on the other hand, was viewed as “much broader,”\textsuperscript{24} prohibiting not only positive enactments by the states, but certain state common-law lawsuits as well.\textsuperscript{25} Counts that were based, not on the mandated warning, but on other conduct not compelled by the statute—the creation and subsequent breach of express warranty and fraudulent misrepresentation, for example—were allowed to proceed.\textsuperscript{26}

The Court stressed that, because the preemption doctrine rests entirely upon congressional intent, the presence of an express preemption provision precluded the possibility of finding implied preemption—either on the basis of conflicts between state and federal law or on the basis of a congressional intent to occupy the field. The Court stated:

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 \textit{expressio unius est exclusio alterius}: Congress’ enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted.\textsuperscript{27}

\begin{itemize}
\item \textsuperscript{21} 505 U.S. at 518 (plurality opinion).
\item \textsuperscript{22} \textit{Id}.
\item \textsuperscript{23} \textit{Id.} at 518-19.
\item \textsuperscript{24} \textit{Id.} at 520.
\item \textsuperscript{25} \textit{Id.} at 521.
\item \textsuperscript{26} \textit{Id.} at 523-29.
\item \textsuperscript{27} \textit{Id.} at 517 (quoting Malone v. White Motor Corp., 435 U.S. 497, 505 (1978); Cal. Fed. Sav. & Loan Ass’n v. Guerra, 479 U.S. 272, 282 (1987)).
\end{itemize}
There were at least two major problems with the decision, however. First, the Court was attempting to get an awful lot of interpretive mileage out of what appears to be a very minor alteration in the language of the 1965 preemption provision. Certainly the change from “[n]o statement relating to smoking and health shall be required” to “[n]o requirement or prohibition based on smoking and health shall be imposed under State law” is not self-evidently reflective of a congressional intent to broaden the scope of preemption to encompass state common-law tort suits. In fact, when the Third Circuit Court of Appeals considered that precise issue, it had concluded that no significant change had been intended 28 and the parties themselves took the position “that the 1969 Act did not materially alter the pre-emptive scope of federal law.”29 Second, if the issue is one of legislative intent, as it necessarily must be under the Court’s analysis, there is virtually no extrinsic evidence that supports the conclusion that Congress somehow had such a result in its collective mind when it enacted the law. In fact, the legislative history of the Act and the state of preemption jurisprudence at the time that the 1969 amendment was enacted makes it difficult to believe that the preemptive interpretation given by the Court was congressionally foreseen, let alone intended.30

29. Cipollone, 505 U.S. at 520 (plurality opinion).
30. See Cipollone, 789 F.2d at 185-86. Because we are constrained by the presumption against preemption, we cannot say that the language of section 1334 clearly encompasses state common law. We find support for this determination in Congress’s failure to include state common law explicitly within section 1334, as it has in numerous other statutes. Indeed, in the absence of a preemption provision encompassing state common law, the Supreme Court has relied generally on principles of implied preemption in evaluating whether a statutory scheme preempts state common law.


The legislative history of the Cigarette Act and the subsequent amending legislation, however, discuss this preemption provision in terms of state and local regulations. Congress was silent on the question of whether section 1334 was intended to extend to state tort law. Accordingly, the legislative history indicates that Congress intended to preempt state and local regulation, but provides no dispositive evidence as to whether Congress intended its labeling scheme to preempt state tort liability. Several Congressmen thought that consumers would still be able to bring tort actions against the tobacco companies in the aftermath of the Cigarette Act. However, these few statements do not provide enough evidence from which to infer congressional intent.

Id. (footnotes omitted).
On the other hand, the idea that it would have been grossly unfair to have held the manufacturers civilly liable for having not placed a stronger, more explicit warning on the cigarette packages or in their advertising when they were expressly prohibited from doing so by the congressional mandate of the Act has a distinct intuitive appeal, and this is particularly so if the imposition of tort liability is seen as punishment for wrongdoing. After all, if the defendants are being blamed for having inflicted harm (and ultimately death), it seems entirely appropriate for them to object on the basis that they had no choice—the precise language of the warning was dictated by the legislation and the defendants were compelled to abide by the statutory command.

Of course, punishment or even attribution of responsibility has not always been viewed as a necessary or even proper function of tort law. Only a few decades ago, during the height of judicial acceptance of strict liability theory, the imposition of tort liability was widely regarded as non-punitive—requiring the payment of compensation simply served to increase the cost of doing business in order to accomplish various instrumentalist goals. Thus, for example, in *Ferebee v. Chevron Chemical Co.*, the court rejected the defendant’s federal preemption argument, explaining:

In this case, a Maryland jury found that the [Environmental Protection Agency ("EPA")] approved label did not sufficiently guard against certain injuries. Even if Chevron could not alter the label, Maryland could decide that, as between a manufacturer and an injured party, the manufacturer ought to bear the cost of compensating for those injuries that could have been prevented with a more detailed label than that approved by the EPA. That is, Maryland can be conceived of as having decided that, if it must abide by EPA’s determination that a label is adequate, Maryland will nonetheless require manufacturers to bear the risk of any injuries that could have been prevented had Maryland been allowed to require a more detailed label or had Chevron persuaded EPA that a more comprehensive label was needed. The verdict itself does not command Chevron to alter its label—the verdict merely tells Chevron that, if it chooses to continue selling paraquat in Maryland, it may have to compensate for some of the resulting injuries. That may in some sense impose a burden on the sale of paraquat in Maryland, but it is not equivalent to a direct regulatory command that Chevron change its label. Chevron can comply with both federal and state law by

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31. Mrs. Cipollone filed the original lawsuit in 1983. She died from lung cancer in 1984 and her husband then filed an amended complaint shortly before his own death. *Cipollone*, 504 U.S. at 509 (plurality opinion).
32. 736 F.2d 1529, 1539 (D.C. Cir. 1984).
continuing to use the EPA-approved label and by simultaneously paying damages to successful tort plaintiffs such as Mr. Ferebee.33

With the widespread rejection of strict liability theory in more recent years, however, courts have come to view the imposition of tort liability as punitive, thus squarely raising the fairness issues that, though dismissed in earlier times, appear critical in understanding the decision in Cipollone and the subsequent preemption cases.

III. THE SOCIAL SCIENCE “ATTRIBUTION” LITERATURE

To understand the importance of the view that tort law is viewed as punitive, it is useful to briefly review some of the social science “attribution” literature. For the past fifty years or so, psychologists and, to a somewhat lesser extent, sociologists and anthropologists, have sought to identify those factors deemed important in the decision to attribute responsibility or blame to an individual who has caused another to suffer some loss or injury.34 While the relative importance of the factors, the order in which children integrate each into their framework for moral decisionmaking, and the empirical methodology used to test for the factors’ existence and relative importance remain open to debate, something approaching consensus exists as to the identification of the requisite factors themselves. Thus, for example, it is generally agreed that the existence of a causal connection between one person’s act and another’s harm is a necessary but not sufficient condition for a judgment that blame is to be attributed.35 In fact, studies involving children

33. Id. at 1541; see also Mazur v. Merck & Co., 742 F. Supp. 239, 248 (E.D. Pa. 1990) (reasoning that state tort law supplemented federal regulation of vaccines since “the specter of damage actions may provide manufacturers with added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement.” (quoting Ferebee, 736 F.2d at 1541-42)).

34. See John M. Darley & Thomas R. Shultz, Moral Rules: Their Content and Acquisition, 41 ANN. REV. PSYCHOL. 525, 526-32, 538 (1990) (reviewing the literature from 1932 to 1990); see also JEAN PIAGET, THE MORAL JUDGMENT OF THE CHILD 100-01, 109-12 (Marjorie Gabain trans., 1965) (discussing children’s acquisition of moral values). The origin of the modern field of attribution of responsibility for harm, however, is usually credited to Heider. See FRITZ HEIDER, THE PSYCHOLOGY OF INTERPERSONAL RELATIONS 15-17 (1958) (discussing the factors of the mind that are attributed to a person’s perception of harmful acts).


[An initial perception of harm doing is followed by a decision about how the harm was caused. If a particular person’s actions are seen as not constituting a necessary condition for the harm, that actor is judged not to have caused the harm, and the judgment process is terminated for that actor, who is held neither morally responsible nor punishable. In contrast, if a particular person’s action is viewed as a necessary condition for the harm,
provide evidence that by age five children know “that judgments of punishment presuppose[] judgments of moral responsibility and that moral responsibility judgments presuppose causal judgments.”

When coupled with causation, the actor’s intention, in the sense of acting for the purpose of bringing about a specific consequence, is generally agreed to be sufficient, although studies often reveal the existence of the familiar legal problem of determining or agreeing upon what counts as a relevant consequence. Thus, although the modern American view of battery as an intentional tort (distinct from the older English view of trespass as requiring intentional or unintentional direct touching of another) is more than a hundred years old, courts continue to disagree whether the defendant need only act for the purpose of touching or must act for the purpose of harmfully or offensively touching. In the absence of intent (however defined), negligence or recklessness, characterizations that are dependent on the extent to which harm was foreseeable or foreseen, will suffice.

Id. (citation omitted).

36. Darley & Shultz, supra note 34, at 535.
37. Id. at 533-36.
39. RESTATEMENT (SECOND) OF TORTS §§ 13, 18 (1965) (defining harmful battery and offensive battery, respectively).
40. See W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 6, at 29-30 (5th ed. 1984) (noting “[t]here is still some occasional confusion, and some talk of a negligent ‘assault and battery,’ but in general these terms are restricted to cases of intent” (footnotes omitted)).
41. Compare White v. Univ. of Idaho, 797 P.2d 108, 109 (Idaho 1990) (“[T]he Court of Appeals concluded that Professor Neher did in fact commit a battery, reasoning that under Idaho law the intent required for the commission of a battery is simply the intent to cause an unpermitted contact not an intent that the contact be harmful or offensive. We agree . . . .”), with White v. Muniz, 999 P.2d 814, 818 (Colo. 2000) (holding that “the law of Colorado requires the jury to conclude that the defendant both intended the contact and intended it to be harmful or offensive”).
42. Although there is no disagreement on the point that “negligence” requires reasonably foreseeable harm, there is considerable disagreement on the proper definition of “recklessness.” Compare RESTATEMENT (SECOND) OF TORTS § 500, at 58’ (“The actor’s conduct is in reckless disregard of the safety of another if he does an act or intentionally fails to do an act which it is his duty to the other to do, knowing or having reason to know of facts which would lead a reasonable man to realize, not only that his conduct creates an unreasonable risk of physical harm to another, but also that such risk is substantially greater than that which is necessary to make his conduct negligent.”), with RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 2, at 18 (Proposed Final Draft 2005) (“A person acts recklessly in engaging in conduct if: (a) the person knows of the risk of harm created by the conduct or knows facts that make the risk obvious to another in the person’s situation, and (b) the precaution that would eliminate or reduce the risk
Not surprisingly, the actor’s motive—whether one acted altruistically or to bestow a benefit on oneself in the sense of acting out of spite or malice, for example—is judged as highly relevant, particularly by children, but by adults as well. Other underlying reasons for acting that might be characterized as “motive”—to protect oneself (self-defense, or private necessity) or to protect others (defense of others, or public necessity)—are also important, although analytically, they typically serve as excuses or justifications offered to negate or ameliorate the blame that might otherwise be attributed.

There is some disagreement regarding the importance of the extent of harm. While some older studies seemed to link attribution of blame and severity of injury, the methodology by which those conclusions involve burdens that are so slight relative to the magnitude of the risk as to render the person’s failure to adopt the precaution a demonstration of the person’s indifference to the risk.”

43. See Shultz et al., supra note 35, at 177 (stating that “if the person’s harm-producing action is deemed either intentional or negligent, the actor is held morally responsible (blameworthy) and the process continues”); see also Darley & Shultz, supra note 34, at 531-33 (discussing the literature on intent and foreseeability); J.G. Hook, Heider’s Foreseeability Level of Responsibility Attribution: Does It Come After Intentionality?, 60 CHILD DEV. 1212, 1216 (1989) (arguing that children first attribute responsibility for intentional harm and only later develop an understanding of foreseeability).

44. See Tjeert Olthof et al., Personal Responsibility Antecedents of Anger and Blame Reactions in Children, 60 CHILD DEV. 1328, 1329, 1335 (1989) (noting that earlier studies “show that motive acceptability influences even 3-year-old children’s evaluations, and this criterion increases in importance up to the age of 8 to 9 years” and concluding from their experiments that “the presence of bad motives outweighs the perpetrator’s lack of intent in causing the harm” (citation omitted)).

45. See Sally Lloyd-Bostock, The Ordinary Man, and the Psychology of Attributing Causes and Responsibility, 42 MOD. L. REV. 143, 155 (1979) (noting that it has been suggested that the failure to control for motive may account for inconsistencies in psychological experimentation); see also Martin A. Kotler, Motivation and Tort Law: Acting for Economic Gain as a Suspect Motive, 41 VAND. L. REV. 63, 68 (1988) (arguing that the perceived motivation of the actors has played an extensive role in the development of tort doctrine).

46. See Darley & Shultz, supra note 34, at 533-34 (“Excuses are offered when one admits to having caused harm, but does not accept responsibility for it. . . . If such an excuse is accepted, the act was not immoral and the question of blame does not arise. A justification comes into play, on the other hand, when the actor accepts moral responsibility for the harm but denies that it was a bad thing to do, thereby avoiding blame . . . .”). For a discussion on the distinction between justifications and excuses, see generally Kent Greenawalt, Distinguishing Justifications from Excuses, 49 LAW & CONTEMP. PROBS. 89 (1986).

47. See Charles A. Lowe & Frederic J. Medway, Effects of Valence, Severity, and Relevance on Responsibility and Dispositional Attribution, 44 J. PERSONALITY 518, 527-29, 533-34 (1976); Frederic J. Medway & Charles A. Lowe, Effects of Outcome Valence and Severity on Attribution of Responsibility, 36 PSYCHOL. REP. 239, 243 (1975); see also Darley & Shultz, supra note 34, at 534 (noting additional studies); Richard L. Gorsuch & Craig S. Smith, Attritions of Responsibility to God: An Interaction of Religious Beliefs and Outcomes, 22 J. SCI. STUD. RELIGION 340, 344-46 (1983) (examining the Lowe-Medway hypothesis in light of subjects’ religious convictions); Elaine Walster, Assignment of Responsibility for an Accident, 3 J. PERSONALITY & SOC. PSYCHOL. 73, 78-
were generated has been questioned. Although there does not appear to have been much research on the subject, one might also hypothesize that the type of harm might be significant either as a function of severity—personal injury is more serious and deserving of blame than property damage—or as a function of foreseeability.

Additionally, volition is certainly a necessary condition, although the waters are somewhat muddied by the fact that social scientists often refer to it as “intention.” At the very least, however, there does not appear to be any reason to believe that truly involuntary physical movements—those which occur while one is asleep or while one is having a seizure, for example—will trigger blame. To the foregoing factors, generated primarily by experimental psychologists, sociologists (most notably Hamilton) have added the actor’s social status and others’ expectations regarding his or her behavior in light of that social status. This additional factor adds significant complexity to the problem. Not only must one consider what the actor did and why the actor behaved that way, but one must also consider who is doing the judging and what his or her perception of the conduct, in light of his or her expectations, will be. In any case, a theory of attribution must necessarily account for not only what was done and why, but by whom and whether it is acceptable or not according to the person making the judgment attributing blame.

79 (1966) (hypothesizing that people attribute responsibility to others to protect themselves from having to acknowledge that they might be victims of random events and that this tendency will increase with severity of harm).


49. See Grueneich, supra note 38, at 33-34 (noting the lack of research on the importance of the nature of the consequences and suggesting that its importance may be linked to whether the outcome was intentionally or accidentally produced).

50. See, e.g., id. at 31 (discussing intentional and unintentional actions).

51. See Mark D. Alicke, Culpable Control and the Psychology of Blame, 126 PSYCHOL. BULL. 556, 558 (2000) (explaining that the author’s central premise “reflects the assumption that observers’ proclivity to blame . . . is conflated with their assessments of personal control”).


54. Russell Veitch & Anthony Piccione, The Role of Attitude Similarity in the Attribution Process, 41 SOC. PSYCHOL. 165, 165-66 (1978) (“The person attributing responsibility may selectively focus on certain aspects of events while ignoring others. This selectivity may be a
Nevertheless, the situation is not quite as bad as suggested by the late Arthur Leff when he characterized the experience of reading some anthropological literature as “falling into a tub of still-warm taffy.”

Although the attribution of responsibility may be dependent on a host of factors whose relative importance varies with the particular circumstances surrounding the occurrence and the subsequent assessment of it, it is commonly accepted that an actor’s freedom of choice is an essential prerequisite. In fact, the foregoing statement is essentially definitional. Absent the choice to act other than one has, one’s conduct cannot be deemed volitional at all. Thus, consider, for example, the implications of an extreme version of predestination. If one is not a free agent, in some sense, responsibility is an impossibility.

Assuming free agency, however, the question of responsibility becomes meaningful. When the existence of choice becomes questionable because the actor was responding to duress or coercion, the nature, extent, and source of the coercive power that is exercised to compel behavior and the harm-causing individual’s response to that coercion will largely account for the degree to which we will attribute blame—that is, conclude that the harm-causing actor was a wrongdoer. In other words, the acceptability of a claim that one was just following orders depends on who was giving the orders, the relationship between the coercer and coerced, the perceived consequences of disobedience to the actor, and the foreseen or foreseeable consequences to others if the actor obeys.

In the context of assigning criminal responsibility, there is a large body of literature dealing with the legal and moral significance of an
actor having obeyed a command of one in authority. Whether examining
the Nazi atrocities of the 1930s and 1940s or Mai Lai in 1968 or, more
recently, Abu Ghraib and Guantanamo, the issue of the presence of
cocorion, and the existence and extent of personal responsibility in the
face of that coercion, has been a recurring theme. The same issues,
however, albeit in far less dramatic form with fewer and less severe
consequences, permeate the field of civil liability—both in tort and
contract law.

In tort cases, there is significant debate concerning the meaning of
“cocorion” (or “duress”) and just where it fits into the analysis.57 An
actor who is, in some sense, coerced to act—say, by having a gun put to
his or her head—might claim that conduct made in response to cocorion
does not (or should not) count as being an act at all. Under this view, the
actor’s volition has been so severely compromised by the presentation of
unacceptable choices that even characterizing the resulting conduct as an
“act” is inappropriate. It is closer to an involuntary muscle spasm. On
the other hand, one might plausibly argue that conduct performed in
compliance to a coercive threat is still an act, but the fact that it was
cocorced should be taken into account either to excuse the conduct or to
justify it.58

For our purposes here, however, the precise characterization is
unimportant as long as it is recognized that one can be confronted with a
set of circumstances that affect choice in such a manner that it would be
deemed unfair to hold the actor responsible for the resulting
consequences. John Lawrence Hill explained:

The traditional theory views cocorion as an overcoming of the will of
the victim such that the resulting action is viewed as unfree,
involuntary, or against one’s will. Thus, defenders of the traditional
account tend to conceptualize cocorion as a type of excuse, rather than
as a justification, because the underlying rationale for the defense is
that the cocorced actor is not responsible for her act. . . .

In contrast to the traditional theory, moralized accounts of cocorion
maintain that legal claims predicated upon duress are at least partially a
function of normative judgments about the nature of the situation and
the right of the victim to respond in a certain way. In other words, a
claim of cocorion is not simply a legal conclusion drawn from empirical

57. Greenawalt, supra note 46, at 96.
58. See supra note 46 and accompanying text; see also Alicke, supra note 51, at 557
(explaining that Shaver viewed the existence or lack of acceptable excuses or justifications as the
basis of distinguishing “moral responsibility” and “blame” (citing KELLY G. SHAVER, THE
ATRIBUTION OF BLAME: CAUSALITY, RESPONSIBILITY, AND BLAMEWORTHINESS 67 (1985)).
premises concerning the psychological state of the actor—i.e., that the actor did not act voluntarily—as with the traditional theory. Rather, the determination that a particular case is coercive may flow from antecedent moral convictions that the putatively coerced actor possessed a kind of moral privilege to yield to the threat, or that no person should have to resist a similar threat. In sum, the defender of a moralized theory of coercion need not maintain that coerced acts are qualitatively different, with respect to the standpoint of the psychological state of the victim of coercion, from uncoerced acts. All that is absolutely necessary for the moralized account is to maintain that the victim’s predicament is morally different from that of the uncoerced actor—that it would not be fair to hold the victim of coercion responsible for his act irrespective of whether the coerced act is “voluntary.”\footnote{59}

Moreover, in cases where the coercion takes the form of a legal mandate backed by the sanctioning power of a governmental entity, penalizing the actor for the consequences that result from compliance with the statutory, regulatory, or judicial order may also be viewed as unfair. The legal cliché dusted off for such occasions typically alludes to the court’s unwillingness to see a party placed between Scylla and Charybdis.

IV. APPLICATION OF THE SCYLLA-CHARYBDIS ARGUMENT

A. In General

In Greek mythology, Charybdis was a whirlpool-creating sea monster that inhabited one side of a narrow strait, and Scylla was a six-headed sea monster that inhabited the other side of the strait.\footnote{60} Sailors seeking to avoid the whirlpools of Charybdis were thus compelled to come within the reach of (and become a meal for) Scylla.\footnote{61} In other words, the allusion being employed refers to being placed in the unenviable situation where one is confronted with two equally bad choices. Courts have used the allusion to characterize many disparate types of cases. For example, a California appellate court rejected a claim

\footnote{60. HOMER, THE ODYSSEY 273-74 (Robert Fagles, trans.) (1996).}
\footnote{61. Id. at 274-75, 278-79; see also WEBSTER’S NEW WORLD DICTIONARY OF THE AMERICAN LANGUAGE 1313 (David B. Guralnik et al. eds., 1968) (“[B]etween Scylla and Charybdis, facing difficulty or danger on either hand; between two perils or evils, neither of which can be evaded without risking the other.”).}
of ineffective assistance of counsel in a case where unfavorable testimony was given by a witness who had been called to testify at the client’s insistence, contrary to the attorney’s advice. The court noted:

To label defense counsel’s conduct in this case “incompetent” is to take this abused theory into the stratosphere of legal abstraction: it has never been clearer that the decision under attack was not defense counsel’s. The court, defense counsel, and [the defendant] himself took pains to memorialize that fact. And claims such as [defendant’s] place defense counsel between Scylla and Charybdis: if counsel had overruled [defendant’s] decision to call [the witness] we would certainly be faced with the claim that counsel had deprived his client of an essential defense, since [Defendant] had expected [the witness] to give favorable testimony on entrapment.\(^62\)

The allusion is also sometimes used to characterize a type of unconscionability, that which exists where a party is offered an ostensible choice, but under circumstances where one of the choices is simply not a realistic option—though it would be more accurate to describe it as a “Hobson’s choice.”\(^63\) Thus, for example, where a credit card issuer demanded that an existing customer either agree to the addition of a mandatory arbitration clause or immediately cancel the card and pay off the balance, the court refused to enforce the arbitration clause, noting that “when placed between Scylla and Charybdis, the practical result is the consumer has no choice at all and is forced to ‘agree’ to the modification.”\(^64\)

More commonly, however, it is used as the basis for the creation of a common-law immunity from liability where the liability would arise from the performance of conduct that is mandated by a court order, positive enactment, or government contract. Thus, for example, in DeVargas v. Mason & Hanger-Silas Mason Co.\(^{65}\) a case involving § 1983\(^66\) and Bivens\(^67\) claims against a private company that provided security services for Los Alamos National Laboratory (“LANL”) under a

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63. See WEBSTER’S NEW WORLD DICTIONARY OF THE AMERICAN LANGUAGE, supra note 61, at 690 (“Hobson’s choice, [after Thomas Hobson (d. 1631), of Cambridge, England, who owned livery stables and let horses in strict order according to their position near the door], a choice of taking what is offered or nothing at all.”); see also infra note 74.
65. 844 F.2d 714 (10th Cir. 1988).
contract with the federal government, the court held that the defendant possessed a qualified immunity from liability. The court explained:

In the instant case, the private party defendants are not alleged to have conspired with a government official to act beyond the boundaries of the law, or to have acted pursuant to an unconstitutional law which permits, but does not require, their conduct. Here, as the district court found, the private defendants reasonably thought that their contract with a government body required them to act in a certain manner. The private parties’ contract with LANL required Mason & Hanger to provide security forces for the laboratory, and to do so in accordance with DOE regulations, including IMD 6102.

The type of case before us presents the strongest arguments for extending qualified immunity to private party defendants. First, the governmental authority involved requires private defendants to act as they do. Indeed, were they to act otherwise they would likely be liable for breach of contract to the governmental body with whom they contracted. Not to allow immunity here places defendants between Scylla and Charybdis—potentially liable either to plaintiffs for obeying the contract, or to governmental bodies for breaching it.

Although the Supreme Court’s rejection of private party immunity in Wyatt v. Cole has cast some doubt over the doctrine, the narrowness of the holding in that case has allowed at least some circuits to continue to recognize private party immunity where a defendant was compelled to perform the acts that form the basis of the plaintiff’s claim. For example, in Sherman v. Four County Counseling Center, the court concluded that “Wyatt does not bar, and public policy requires qualified immunity be extended to [the defendant]” where the defendant was following a court order or statutory command. Distinguishing other situations, the court stated:

Like the First Circuit, we distinguish this case from those in which private parties “voluntarily engaged in illegal activities in the advancement of their own self-interest.” We refuse to give private hospitals the Hobson’s choice of obeying a court’s order directing discretionary medical treatment, and facing liability for the resulting medical judgment, or refusing to make a medical judgment, and

68. DeVargas, 844 F.2d at 715-16.
69. Id. at 721-22.
70. Id. (footnote omitted).
72. 987 F.2d 397 (7th Cir. 1993).
73. Id. at 405.
exposing hospital staff and patients to the risk of harm posed by a potentially violent mental patient.74

Along the same lines, in Eagon v. City of Elk City,75 the Tenth Circuit, following post-Wyatt cases in the Seventh and Eleventh Circuits, declared the rule “‘that a private individual who performs a government function pursuant to a state order or request is entitled to qualified immunity if a state official would have been entitled to such immunity had he performed the function himself.’”76

B. Application to Products Liability Cases

1. Definition of “Defect”

Although somewhat beyond the scope of this Article, it is worth noting that the intuition that one should not be held liable in the absence of choice77 has assumed a place at the very core of modern products liability doctrine. Section 2 of the Products Liability Restatement provides:

A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product:

(a) contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product;

(b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption

74. Id. at 406 (quoting Felix de Santana v. Velez, 956 F.2d 16, 20 (1st Cir. 1992)); see also Rodriques v. Furtado, 950 F.2d 805, 815 (1st Cir. 1991) (holding that a physician sued for performing a cavity search was entitled to qualified immunity where he was “pressed into service by the State”).

75. 72 F.3d 1480 (10th Cir. 1996).

76. Id. at 1489 (quoting Warner v. Grand County, 57 F.3d 962, 967 (10th Cir. 1995)).

77. This intuition also finds support in the attribution literature. See, e.g., Daniel McGillis, Attribution and the Law: Convergences Between Legal and Psychological Concepts, 2 LAW & HUM. BEHAV. 289, 294 (1978) (noting that an earlier study found that “people typically assess an action of another in light of potential alternative actions” (citing Edward E. Jones & Keith E. Davis, From Acts to Dispositions: The Attribution Process in Person Perception, in 2 ADVANCES IN EXPERIMENTAL SOCIAL PSYCHOLOGY 219, 222-23 (Leonard Berkowitz ed., 1965))).
of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe;

(c) is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.78

Although manufacturing defects exist simply because the product fails to meet the manufacturer’s own specifications,79 the existence of both design defects and warning defects is made to turn on whether the manufacturer could have acted in a way other than it actually did.80 Thus, design defects exist only when there was “a reasonable alternative design,”81 and warning defects exist when there was an unreasonable failure to warn or instruct or when better warnings or instructions should have been provided.82 As the comments note, “manufacturers may persuasively ask to be judged by a normative behavior standard to which it is reasonably possible for manufacturers to conform.”83

2. The Government Contractor “Defense”

Prior to the Supreme Court’s decision in Boyle v. United Technologies Corp.,84 the treatment of those manufacturers that created products under a contract with the federal government was unsettled. The issue had been considered by no fewer than six circuit courts of appeals85 and many more federal district and state courts.86 Although

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79. Id. cmt. c, at 18.
80. Id. cmt. a, at 15-16.
81. Id. § 2(b), at 14.
82. Id. § 2(c), at 14.
83. Id. cmt. a, at 17.
85. See Tozer v. LTV Corp., 792 F.2d 403, 407-09 (4th Cir. 1986); Shaw v. Grumman Aerospace Corp., 778 F.2d 736, 746 (11th Cir. 1985); Bynum v. FMC Corp., 770 F.2d 556, 566 (5th Cir. 1985); In re Air Crash Disaster at Mannheim F.R.G. on Sept. 11, 1982, 769 F.2d 115, 122-23 (3d Cir. 1985); Tillett v. J.I. Case Co., 756 F.2d 591, 596-97 (7th Cir. 1985); McKay v. Rockwell Intl’ Corp., 704 F.2d 444, 451 (9th Cir. 1983).
private party immunity was usually found to exist,\textsuperscript{87} significant disagreement existed as to the proper basis of the immunity and its proper scope. Probably a majority of cases took the position that the contractor was immune from liability only when the plaintiff was injured while on active duty in the military—that is, in those cases where the government was immune under the \textit{Feres-Stencel} doctrine.\textsuperscript{88}

In any case, many courts agreed that there was a sound basis for immunizing a government contractor under certain circumstances. For example, in \textit{Johnston v. United States},\textsuperscript{89} the court explained:

\begin{quote}
\textit{[T]he government contract defense . . . applies only where the product in question has been manufactured pursuant to a contract with the government. This defense has been characterized as one that “allows the contractor to ‘share’ the government’s immunity from suit on grounds of public policy,” and is potentially applicable in a wide variety of tort actions. Like the contract specification defense, the government contract defense only applies where the injury-causing aspect of the product was mandated by the contract.}\textsuperscript{90}
\end{quote}

\textit{\ldots [One] rationale for the government contract defense is that it would be inequitable to impose liability on a contractor for a defect in a product he was forced by the government to make. As the \textit{Agent Orange} court put it:

Where, as here, manufacturers claim to have been compelled by federal law to produce a weapon of war without ability to negotiate specifications, contract price or terms, the potential for unfairly imposing liability becomes great. Without the government contract defense a manufacturer capable of producing military goods for government use would face the untenable position of choosing between severe penalties for failing to supply products necessary to conduct a war, and producing what the government

\begin{itemize}
  \item \textsuperscript{87} But see Nobriga v. Raybestos-Manhattan, Inc., 683 P.2d 389, 392 (Haw. 1984) (rejecting immunity in cases involving asbestos).
  \item \textsuperscript{88} Under \textit{Feres v. United States}, 340 U.S. 135, 146 (1950), the federal government is immune from tort liability when the plaintiff was on active duty in the military and the injury arose out of an incident relating to that active duty. See, e.g., \textit{Tozer}, 792 F.2d at 408-09; \textit{McKay}, 704 F.2d at 451. Moreover, under \textit{Stencel Aero Engineering Corp. v. United States}, 431 U.S. 666, 673-74 (1977), defendants who are held liable to persons who could not sue the government under \textit{Feres} are precluded from bringing indemnity claims against the government.
  \item \textsuperscript{89} 568 F. Supp. 351 (D. Kan. 1983).
  \item \textsuperscript{90} \textit{Id.} at 356 (citations omitted). The “contract specification defense” is based on the premise that it is not negligent for a contractor to follow plans prepared by another unless the contractor knows or has reason to know of the excessive danger created by the plans. See \textsc{Restatement (Second) of Torts} § 289(b), at 41, § 389 cmt. e, illus. 1, at 313, § 404 cmt. a, at 364-65 (1965).\end{itemize}
requires but at a contract price that makes no provision for the need to insure against potential liability for design flaws in the government’s plans.  

There is no doubt that this spectre of inequity is a powerful justification for the government contract defense, although it is not a completely sufficient rationale: in some situations the manufacturer might know that a design was dangerous and defective when the government did not, and it would not be sound policy to allow the manufacturer to nevertheless produce with impunity, without at least requiring him to share his knowledge with the government.  

The facts giving rise to Boyle are fairly illustrative of the issues presented. Boyle, a Marine helicopter pilot, was killed when his helicopter, manufactured by the defendant, crashed into the ocean. Although he survived the initial crash, because the door opened out (rather than in), the water pressure prevented him from opening the door and escaping, thus resulting in his death by drowning. His father brought suit, alleging that the helicopter was defective by reason of its design. Suit could not be successfully brought against the federal government since, among other reasons, Boyle was a member of the armed forces who was injured in an incident arising out of that service and was thus barred by Feres. The issue before the Court was whether the defendant, as the party who manufactured the product under contract with the federal government, could share in the government’s sovereign immunity.  

In a five-to-four decision written by Justice Scalia, the Court held that it could, provided certain conditions were satisfied:  

Liability for design defects in military equipment cannot be imposed, pursuant to state law, when (1) the United States approved reasonably precise specifications; (2) the equipment conformed to those specifications; and (3) the supplier warned the United States about the dangers in the use of the equipment that were known to the supplier but not to the United States.  

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91. Id. at 357 (quoting In re Agent Orange Prod. Litig., 506 F. Supp. 762, 794 (E.D.N.Y. 1980) (citations omitted)).  
92. Id. at 357-58 (citations omitted).  
94. Id. at 502-03.  
95. Id.  
98. Id. at 512.
In reaching that conclusion, the Court reasoned that “the procurement of equipment by the United States is an area of uniquely federal interest,” and, therefore, a proper subject for an expansion of federal common law. However, merely identifying it as such “does not . . . end the inquiry. . . . Displacement [of state law] 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.”

Although the lower court reached its decision essentially by expanding the Feres doctrine to encompass suits against contractors as well, in Boyle the conflict that the Court identified was that between the imposition of state common-law liability on those who contract with the government and the discretionary act immunity available to the government under the Federal Tort Claims Act (“FTCA”), specifically, 28 U.S.C. § 2680(a). That section provides that an action cannot be brought against the government based “upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or employee of the Government, whether or not the discretion involved be abused.”

The Court reasoned:

There is . . . a statutory provision that demonstrates the potential for, and suggests the outlines of, “significant conflict” between federal interests and state law in the context of Government procurement. In the FTCA, Congress authorized damages to be recovered against the United States for harm caused by the negligent or wrongful conduct of Government employees, to the extent that a private person would be liable under the law of the place where the conduct occurred. It excepted from this consent to suit, however, [suit based upon discretionary acts of government under § 2680(a)].

. . . And we are further of the view that permitting “second-guessing” of these judgments through state tort suits against contractors would produce the same effect sought to be avoided by the FTCA exemption. The financial burden of judgments against the contractors would ultimately be passed through, substantially if not

99. Id. at 507.
100. Id.
101. Id. (citations omitted).
102. Id. at 509-10.
103. Id. at 510-11.
totally, to the United States itself, since defense contractors will predictably raise their prices to cover, or to insure against, contingent liability for the Government-ordered designs. To put the point differently: It makes little sense to insulate the Government against financial liability for the judgment that a particular feature of military equipment is necessary when the Government produces the equipment itself, but not when it contracts for the production. In sum, we are of the view that state law which holds Government contractors liable for design defects in military equipment does in some circumstances present a “significant conflict” with federal policy and must be displaced.\textsuperscript{105}

Apart from the policy considerations emphasized by the Court, however, there is another factor that the Court could have stressed, and probably should have. Once the contractor has fully disclosed all known risks, the final design decision is the government’s. Even if the engineers employed by United Technologies thought that outward opening doors were the product of an incredibly foolish design decision, ultimately there was little real choice involved. Assuming the government could not be persuaded to alter the design, the company’s only alternative courses of action were to build it as the government wanted, or walk away from the project, possibly incurring liability for breach. And the latter course, while noble, is hardly a realistic option for a company dependent on military contracts.

In short, it would simply have been unfair to assign blame to the contractor under the circumstances presented by the case, and, as noted above, the fairness rationale had been squarely addressed by some of the lower courts that had previously considered the issue.\textsuperscript{106} In turn, the fairness claim is linked to the defendant’s freedom of choice and thus it was common for courts to at least consider the element of compulsion, which clearly permeates much of the reasoning. One court observed that “the government contract defense has been most successfully asserted by government contractors who were required to produce products in compliance with military specifications,”\textsuperscript{107} citing, among others, a New Jersey case that held that liability could not be imposed on a vehicle manufacturer based on a lack of seat belts or a roll bar where the vehicle

\textsuperscript{105.} Boyle, 487 U.S. at 511-12 (citations and footnote omitted).

\textsuperscript{106.} See supra note 92 and accompanying text; see also Bynum v. FMC Corp., 770 F.2d 556, 566 (5th Cir. 1985) (quoting In re Agent Orange Prod. Liab. Litig., 506 F. Supp. 762, 794 (E.D.N.Y. 1980)).

\textsuperscript{107.} In re All Maine Asbestos Litig., 575 F. Supp. 1375, 1377-78 (D. Me. 1983) (citing numerous cases as examples).
was manufactured for the military under specifications that did not permit the installation of these safety features.\footnote{108}

3. Two Narrow Exceptions

If, as argued here, it is the defendant’s lack of choice that compels the finding of implied immunity, that same principle causes one to consider the possibility of circumstances under which immunity should not be available. As previously noted in passing, defendants who are subjected to coercion in a sense still have something of a choice to make, even if the theoretical options are all bad ones.\footnote{109} Being eaten by Scylla is not much of an option, but there is still some element of choice involved. In determining how bad a particular choice may be, one must consider the various foreseen and foreseeable consequences that will follow. Thus, it was observed earlier that it is unrealistic to ask a military contractor, for example, to walk away from a contract simply because of disagreement over the wisdom of some aspect of the design upon which the government is insistent.\footnote{110}

Nevertheless, it is at least possible that some design or warning options are, to use the language of the \textit{Products Liability Restatement}, so “manifestly unreasonable” that a defendant should be held responsible for simply agreeing to market a product that includes a particular design feature or, perhaps, for marketing the product at all.\footnote{111}

To illustrate, the comments to the \textit{Products Liability Restatement} use the example of an exploding cigar capable of generating sufficient force to cause personal injury to the victim of a practical joke as a case where liability for defective design might be found, notwithstanding the lack of a reasonable alternative design.\footnote{112} Along the same lines, one can imagine a medical device or pharmaceutical that is simply too dangerous to market, notwithstanding the existence of a mandate issued by the Food and Drug Administration (“FDA”) (assuming FDA approval is, in fact, a “mandate”).\footnote{113}

Consider, for example, the following illustration from the \textit{Products Liability Restatement}:

\begin{itemize}
\item 109. \textit{See supra} notes 56-59 and accompanying text.
\item 110. \textit{See supra} text accompanying note 106-08.
\item 111. \textit{Restatement (Third) of Torts: Products Liability} § 2 cmt. e, at 21-22 (1998).
\item 112. \textit{Id.} cmt. e, illus. 5, at 22.
\item 113. \textit{See infra} text accompanying notes 173-77,180-81.
\end{itemize}
1. ABC Pharmaceuticals manufactures and distributes D, a prescription drug intended to prolong pregnancy and thus to reduce the risks associated with premature birth. Patricia, six months pregnant with a history of irregular heart beats, was given D during a hospital stay in connection with her pregnancy. As a result, she suffered heart failure and required open-heart surgery. In Patricia’s action against ABC, her expert testifies that, notwithstanding FDA approval of D five years prior to Patricia’s taking the drug, credible studies published two years prior to Patricia’s taking the drug concluded that D does not prolong pregnancy for any class of patients. Notwithstanding a finding by the trier of fact that ABC gave adequate warnings to the prescribing physician regarding the serious risks of heart failure in patients with a history of irregular heart beats, the trier of fact can find that reasonably informed health-care providers would not prescribe D for any class of patients, thus rendering ABC subject to liability.\footnote{RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. f, illus. 1, at 150 (1998). The illustration was apparently based on Tobin v. Astra Pharmaceutical Products, Inc., 993 F.2d 528, 540 (6th Cir. 1993). See also George W. Conk, The True Test: Alternative Safer Designs for Drugs and Medical Devices in a Patent-Constrained Market, 49 UCLA L. REV. 737, 743 (2001) (criticizing the Restatement approach to the problem and noting that the drug in question “is manifestly unreasonable in design even in the absence of an alternative design”); Michael D. Green, Prescription Drugs, Alternative Designs, and the Restatement (Third): Preliminary Reflections, 30 SETON HALL L. REV. 207, 227 (1999) (discussing the possibility of “categorical liability” for drugs, which would entail “a determination of definitiveness is permitted based on the inherent risks that a product poses without proof of any alternative design. Such liability might be based on a judgment that a product’s risks outweigh its benefits, and, therefore, the manufacturer should not be marketing the product because it is too dangerous, or, at a minimum, all harms caused by the product should be imposed on the manufacturer”).}

The foregoing illustration hints at a second exception to the immunity suggested here. Product manufacturers frequently are actively involved in the process of producing legislation and regulations that affect their various industries. Sometimes the process by which the industry provides information is quite transparent. Sometimes, however, it is, shall we say, something less than that. Moreover, at various times, as well as in various contexts, it has been claimed that a variety of industries have sought to intentionally mislead federal regulators by affirmatively misrepresenting or concealing facts, or by failing to disclose.

For roughly ten years spanning 1990 to 2000, a number of lawsuits were filed against products manufacturers in which it was claimed that they had defrauded regulatory agencies into approving the proposed design of products and/or the warnings that were to accompany them.\footnote{See, e.g., In re Orthopedic Bone Screw Prods. Liab. Litig., 159 F.3d 817, 820 (3d Cir. 1998), rev’d sub nom. Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341 (2001); Michael v.
In 2001, however, in *Buckman Co. v. Plaintiffs’ Legal Committee*, a case involving allegations of “fraud-on-the-FDA” in obtaining FDA approval of a particular type of orthopedic bone screw, the Court held that:

[T]he plaintiffs’ state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted 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. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law.

A concurring opinion written by Justice Stevens, joined by Justice Thomas, disagreed with the majority’s preemption analysis, but noted the difficulties in proving that the fraud caused the harm complained of in light of the fact that even after the truth came to light, the FDA did not act to remove the product from the market.

Fraud, however, may play a different role than that asserted by the plaintiff and addressed by the Court. If, as I will explain, the manufacturers’ exculpation should be based not on the fiction of congressional intent, but on the unfairness that would result to a product manufacturer when the conduct which is alleged to be tortious is, in fact, mandated by law, the defendant’s immunity from liability should be forfeited where it can be shown that it wrongfully participated in the crafting of the very mandate it now seeks to use as a shield.


117. *Id.* at 348 (footnote omitted); *see also* Jean Macchiaroli Eggen, *The Normalization of Product Preemption Doctrine*, 57 Ala. L. Rev. 725, 753 (2006) (“In *Buckman*, the important role of state tort law in product cases was overshadowed by the overriding federal interests reflected in the federal enforcement scheme. Chief Justice Rehnquist was concerned that allowing the state fraud claims would interfere with the federal interest of allowing a federal agency to police its own process, particularly where the duties underlying the common law remedies directly involved the relationship of the manufacturer to the federal agency.” (footnote omitted)).


119. *See supra* text accompanying notes 65-74, 91, 105-08.
V. RECONSIDERING THE “PREEMPTION DECISIONS”

A. Shared Sovereign Immunity

Many of the federal preemption cases involve factual situations that, in some sense, can be viewed as arising out of tortious misconduct by the federal government. Consider again, for example, the case underlying the suit in Cipollone v. Liggett Group, Inc. In that case, the defendants’ claim of federal preemption was based on the Act, which prohibited the sale of cigarettes unless the package contained the following language: “Caution: Cigarette Smoking May Be Hazardous to Your Health.” In 1969, the Act was amended to strengthen the “may be hazardous” language to “Is Dangerous.” The plaintiff’s lawsuit was based in part on a failure to warn theory, claiming that the federally mandated warning on the cigarette packages was inadequate. In other words, although the defendants were private parties, in essence the lawsuit was a claim that Congress was negligent in enacting legislation that mandated an insufficiently strong warning.

Of course, suit could not be brought against Congress for passing a bad law. Prior to the enactment of the FTCA in 1946, such an action could not be brought against the government unless the government waived sovereign immunity. The enactment of the FTCA partially abrogated sovereign immunity, but not to the extent that would expose the federal government to potential tort liability for enacting a bad law. In Dalehite v. United States, the Court, referring to the discretionary act exception to the waiver of sovereign immunity, explained:

The legislative history indicates that while Congress desired to waive the Government’s immunity from actions for injuries to person and property occasioned by the tortious conduct of its agents acting within their scope of business, it was not contemplated that the government

124. Cipollone, 505 U.S. at 509 (plurality opinion).
125. 28 U.S.C. § 2674 (2000) (providing that the United States may be held liable “in the same manner and to the same extent as a private individual under like circumstances”).
126. The history and private bill process utilized prior to the enactment of the FTCA is discussed in Dalehite v. United States, 346 U.S. 15, 24-28 (1953).
127. Id.
should be subject to liability arising from acts of a governmental nature or function. Section 2680(a) draws this distinction.128

Given that Congress was immune from liability for having mandated the particular label warnings specified in the Act and in its 1969 amendment, the question was really whether the cigarette manufacturers should have been permitted to share in the governmental immunity when they complied with the governmental mandate.129

In other words, there were in fact two very separate and distinct bases for arguing that federal law displaces state law presented in *Cipollone*, and the Court chose the wrong one. Based on the issues as framed by the parties, of course, the Court focused on the preemption language of the Act and its 1969 amendment, which, in fact, probably evidenced no congressional intent to bar state common-law lawsuits.130 On the other hand, the Court could have focused on the conflict between the discretionary acts immunity of 28 U.S.C. § 2680(a), which served to immunize Congress from liability for passing a bad law,131 and the state law that potentially served to impose liability on those who were compelled to comply with that law. As in *Boyle*, it is this conflict that provided the basis for extending sovereign immunity to the defendants because the important federal interest in having congressional mandates obeyed would be undercut by the imposition of state civil liability on those who must comply. Under a legal system that views the imposition of tort liability as a sanction for wrongdoing, any other result would be viewed as grossly unfair.

Of course, the extent to which the labeling requirements at issue in *Cipollone* limited the defendants’ choices makes the case particularly clear. Nevertheless, the extent of choice that could have been exercised by the defendants in light of the particular legislative or regulatory command, though not explicitly articulated in those terms, often appears to be the deciding principle, not only in *Cipollone*, but in most of the products liability preemption cases.

**B. The Post-Cipollone Preemption Decisions**

With one notable exception, the Court has found preemption in those cases in which the product manufacturer was compelled by a specific legislative or regulatory command to act in the manner which

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128. *Id.* at 27-28 (footnotes omitted).
130. *See supra* notes 28-30 and accompanying text.
subsequently is alleged to have been tortious, but has declined to do so in those cases where the federal legislation or regulation would have permitted the manufacturer to have done more.

For example, in *Riegel v. Medtronic, Inc.*, 132 in finding preemption under the Medical Device Amendment (“MDA”) to the Food, Drug, and Cosmetic Act, 133 the majority specifically noted that “[o]nce a device has received premarket approval [“PMA”], the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness.” 134 In other words, although the device manufacturer obviously participated in the PMA process, once the agency acted by granting approval, it is at least arguable that the defendant had no choice but to manufacture and label the product as approved. However, it is important to note that the factual question of whether FDA approval constitutes a mandate compelling compliance has emerged as a critical and hotly contested issue in those cases where a drug is alleged to be defective by reason of its design or the warnings that accompany it. 135

On the other hand, *Bates v. Dow Agrosciences, LLC* 136 was a case that involved a claim of preemption under § 136v(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”). 137 That section provided: “Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.” 138 In the course of refusing to find preemption, the Court explicitly stressed that FIFRA did not constrain the defendant’s freedom of action. 139 Although the case was remanded to allow a lower court to determine whether a failure to warn claim was being asserted, 140 at least as to “breach of express warranty, fraud, violation of the Texas DTPA [Deceptive Trade Practices-Consumer Protection Act], strict liability (including defective design and defective manufacture), and negligent testing,” 141 the Court noted:

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135. *See infra* text accompanying notes 174-78 and 181-82.
137. *Id.* at 434; *see also* 7 U.S.C. §§ 136-136y (2006).
139. *See Bates*, 544 U.S. at 445 (“A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.”).
140. *Id.* at 442 n.15.
141. *Id.*
Rules that require manufacturers to design reasonably safe products, to use due care in conducting appropriate testing of their products, to market products free of manufacturing defects, and to honor their express warranties or other contractual commitments plainly do not qualify as requirements for “labeling or packaging.” None of these common-law rules requires that manufacturers label or package their products in any particular way. Thus, petitioners’ claims for defective design, defective manufacture, negligent testing, and breach of express warranty are not pre-empted.

To be sure, Dow’s express warranty was located on Strongarm’s label. But a cause of action on an express warranty asks only that a manufacturer make good on the contractual commitment that it voluntarily undertook by placing that warranty on its product. Because this common-law rule does not require the manufacturer to make an express warranty, or in the event that the manufacturer elects to do so, to say anything in particular in that warranty, the rule does not impose a requirement “for labeling or packaging.”

Although in both Riegel and Bates the Court conducted an extensive analysis of the preemption language in the MDA and FIFRA in reaching its respective decisions, those analyses, particularly concerning the MDA, are not only open to serious question but, more importantly, unnecessary to the decision of those cases. As in Cipollone, the real issue was shared sovereign immunity and, under that approach, only if the defendant was truly faced with the options of marketing the product as approved or withdrawing it from the market altogether would shared sovereign immunity be appropriate.

142. Id. at 444-45 (citation and footnotes omitted).
144. See, e.g., Riegel, 128 S. Ct. at 1014-15 (Ginsburg, J., dissenting):

Congress enacted the MDA “to provide for the safety and effectiveness of medical devices intended for human use.” A series of high-profile medical device failures that caused extensive injuries and loss of life propelled adoption of the MDA. Conspicuous among these failures was the Dalkon Shield intrauterine device, used by approximately 2.2 million women in the United States between 1970 and 1974. Aggressively promoted as a safe and effective form of birth control, the Dalkon Shield had been linked to 16 deaths and 25 miscarriages by the middle of 1975. By early 1976, “more than 500 lawsuits seeking compensatory and punitive damages totaling more than $400 million” had been filed. Given the publicity attending the Dalkon Shield litigation and Congress’ awareness of the suits at the time the MDA was under consideration, I find informative the absence of any sign of a legislative design to preempt state common-law tort actions.

Id. (citations and footnotes omitted); see also Robert S. Adler & Richard A. Mann, Preemption and Medical Devices: The Courts Run Amok, 59 Mo. L. Rev. 895, 930 (1994) (arguing that congressional silence regarding any intent to preempt state tort litigation is evidence that preemption was not intended).
C. Geier

The only Supreme Court case that is neither justifiable under any traditional preemption doctrine, nor explicable by reference to the shared sovereign immunity or fairness based on freedom of choice principles, is the Court’s 2000 decision in Geier v. American Honda Motor Co., and, in the final analysis, the decision in that case is difficult to defend.

As noted earlier, courts have held that preemption may either be express or implied. Express preemption may be found when the legislative intent to preempt is “explicitly stated in the statute’s language or implicitly contained in its structure and purpose.” Implied preemption, on the other hand, may take one of two forms. So-called “field preemption” may be found “if federal law so thoroughly occupies a legislative field ‘as to make reasonable the inference that Congress left no room for the States to supplement it.’” Alternatively, state law may be preempted in cases of a conflict between state and federal law.

Underlying the notion of implied conflict preemption is the assertion, often implicit, that Congress intended, in some rather undefined way, to preclude the possibility of inconsistencies between federal law and policy, on the one hand, and state law and policy, on the other. However, the inference of such congressional intent is often pure fiction, not only unsupported by any objective basis for believing it to be true, but sometimes directly contradicted by the available evidence. That was the situation in Geier.

Eight years earlier, in Cipollone, the Court had claimed that the presence of an express preemption provision “provides a ‘reliable

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146. See supra note 30.
149. Id. at 516.
150. See Geier for an explanation:
   This policy [of uniform standards] by itself favors pre-emption of state tort suits, for the rules of law that judges and juries create or apply in such suits may themselves similarly create uncertainty and even conflict, say, when different juries in different States reach different decisions on similar facts.
   On the other hand, the saving clause reflects a congressional determination that occasional nonuniformity is a small price to pay for a system in which juries not only create, but also enforce, safety standards, while simultaneously providing necessary compensation to victims. That policy by itself disfavors pre-emption, at least some of the time.

Id. at 871.
indicium of congressional intent”151 and thus “‘there is no need to infer congressional intent to pre-empt state laws from the substantive provisions’ of the legislation.”152 Nevertheless, although the National Traffic and Motor Vehicle Safety Act (“NTMVSA”) contained a provision that rather clearly asserted that compliance with safety standards promulgated pursuant to the NTVMSA was not to “exempt any person from any liability under common law,”153 the Geier Court engaged in a lengthy and often convoluted analysis in order to find implied (conflict) preemption.154

At issue was a federal regulation promulgated by the Department of Transportation (“DOT”) dealing with passive restraint systems for automobiles. The regulation, the 1984 version of Federal Motor Vehicle Safety Standard (“FMVSS”) 208, gave manufacturers a number of choices. As the Court explained:

[T]hat standard deliberately sought variety—a mix of several different passive restraint systems. It did so by setting a performance requirement for passive restraint devices and allowing manufacturers to choose among different passive restraint mechanisms, such as airbags, automatic belts, or other passive restraint technologies to satisfy that requirement. And DOT explained why FMVSS 208 sought the mix of devices that it expected its performance standard to produce. DOT wrote that it had rejected a proposed FMVSS 208 “all airbag” standard because of safety concerns (perceived or real) associated with airbags, which concerns threatened a “backlash” more easily overcome “if airbags” were “not the only way of complying.” It added that a mix of devices would help develop data on comparative effectiveness, would allow the industry time to overcome the safety problems and the high production costs associated with airbags, and would facilitate the development of alternative, cheaper, and safer passive restraint systems.155

Mr. Geier was injured in an accident involving a 1987 Honda Accord.156 The vehicle was equipped with lap and shoulder belts, which were being utilized at the time of the crash.157 The vehicle was lacking airbags, and the theories of liability under state law in the suit that

151. 505 U.S. at 517 (plurality opinion) (quoting Malone v. White Motor Corp., 435 U.S. 497, 505 (1978)).
152. Id. (quoting Cal. Fed. Sav. & Loan Ass’n v. Guerra, 479 U.S. 272, 282 (1987)).
155. Id. at 878-79 (internal citations omitted).
156. Id. at 865.
157. Id.
ensued were that the vehicle was defective because it lacked airbags and Honda was negligent for not equipping the vehicle with airbags.\footnote{158} Reasoning that “no airbag” lawsuits could not be reconciled with a federal regulation that expressly endorsed the use of passive restraint systems other than airbags, Justice Breyer, writing for the majority, concluded that the state lawsuit was preempted.\footnote{159}

As a matter of policy, of course, the majority’s position is certainly understandable, as is that of many tort reform advocates who have argued for the enactment of state legislation establishing a statutory compliance defense in products liability cases generally.\footnote{160} However, the claim that this was what Congress intended when the NTMVSA was enacted stands unsupported since the law itself clearly states otherwise,\footnote{161} and, in fact, as the dissent in \textit{Geier} complained, the use of fictionalized congressional intent gives “unelected federal judges \textit{carte blanche} to use federal law as a means of imposing their own ideas of tort reform on the States.”\footnote{162}

\footnote{158. \textit{Id.}}\footnote{159. \textit{Id.} at 874.}\footnote{160. See generally Michael D. Green, \textit{Statutory Compliance and Tort Liability: Examining the Strongest Case}, 30 U. MICH. J. L. REFORM 461 (1997) (discussing the pros and cons of establishing a statutory compliance defense for pharmaceutical products liability litigation).}\footnote{161. See Susan Raeker-Jordan, \textit{The Pre-emption Presumption That Never Was: Pre-emption Doctrine Swallows the Rule}, 40 ARIZ. L. REV. 1379, 1448 (1998).} The final Senate report is significant in its explanation of the Safety Act’s meaning and its effect on state law. The report first recognized the need for uniformity throughout the country because of the mass production and high volume nature of automobile manufacturing and then noted that state standards are pre-empted only if they differ from the applicable federal standard. More importantly, though, the report proceeded to qualify the pre-emption. It stated: “[m]oreover, the Federal minimum safety standards need not be interpreted as restricting State common-law standards of care. Compliance with such standards would thus not necessarily shield any person from product liability at common law.” The intent of Congress, as seen in this passage, was to achieve regulatory uniformity as a subsidiary objective; once a minimum level of safety was established under the federal scheme, the states were free to impose liability on a manufacturer for defective products that caused injuries.

Also important is the Safety Act’s implicit distinction between state statutes or regulations, forms of direct regulation promulgated by state machinery, and common-law damage actions; in the Senate report passage, Congress discussed the two types of regulation and the pre-emption of only one of them, state “standards.” The evidence from legislative history confirms what appears to be the plain language of the statute.

\footnote{162. \textit{Geier}, 529 U.S. at 894 (Stevens, J., dissenting).}
Nevertheless, it is clear that the existence of some types of conflict between federal law and state tort liability should provide the basis for a defense. The basis for such a defense, however, arises out of fairness considerations, quite apart from any question of congressional intent. In this regard, it is necessary to distinguish two very different forms of conflict that may arise between state and federal law and policy. The first type of conflict between state and federal law involves the situation where the defendant literally cannot comply with both. Thus, the Court had previously noted: “[W]e must ask whether or not the Federal and State Statutes are in ‘irreconcilable conflict.’ [This would be the case,) for example, if the federal law said, ‘you must sell insurance,’ while the state law said, ‘you may not.’”

The former represents a clear illustration of the Scylla-Charybdis dilemma, the existence of which has been found, in analogous cases, to be an adequate basis for immunizing a defendant from liability. The second situation in which conflicts are said to arise exists when “state law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”

The former represents a clear illustration of the Scylla-Charybdis dilemma, the existence of which has been found, in analogous cases, to be an adequate basis for immunizing a defendant from liability. The latter, however, does not, for the simple reason that a defendant is not deprived of choice; that is, the defendant is not compelled to act in a way that subsequently forms the basis for civil liability. It may well be true, of course, that inconsistency between federal policy goals and state tort liability may be the product of foolish lawmaking or the enactment of inconsistent legislative policy choices, but this, by itself, does not justify judicial intervention on the basis of either congressional intent or fairness. This was the situation presented in Geier. Neither the NTMVSA nor the regulation promulgated by DOT under its delegated rule-making authority can be said to have compelled Honda to choose

164. Hillsborough County, Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985) (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)). It is important to note, however, that in Geier, the Court explicitly refused to make a distinction between “impossibility” and “obstacle” conflict preemption. The Court stated:

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.

Geier, 529 U.S. at 873-74 (citations omitted).
165. See supra text accompanying notes 65-76, 89-108.
the design at issue—that is, some restraint system other than airbags. In
the absence of compulsion, the fairness justification advanced here for
finding shared sovereign immunity cannot be defended.166

Moreover, there is an additional reason that a claim of shared
sovereign immunity is untenable in the context of Geier. While it is true,
of course, that the promulgation of FMVSS 208 could not expose the
DOT to state tort liability given the discretionary acts immunity
 provision of § 2680(a), any inference that a private party should be
entitled to share in that immunity is rebutted by the terms of the savings
clause that expressly permitted state tort law suits against private
parties.167 While the claim of shared immunity was available, even
compelling, in cases like Boyle or Cipollone, it is utterly inconsistent
with the respective roles of the judiciary and legislative branches for the
Court to imply such a doctrine in the face of an express congressional
declaration that it is not to exist. Thus, in effect, the savings clause
becomes a congressional statement that immunity is not to be shared.

D. FDA Approval

In a series of recent state and federal cases, courts have struggled
with the question of whether drug manufacturers should be protected
from tort liability in cases where a particular drug, whose design and
label had been approved by the FDA, is alleged to have been defective
by reason of design or, more commonly, inadequate warning.168 As one
would expect, the decisions ostensibly seek to interpret and apply (or
distinguish) the Geier decision. What is interesting, however, is that
once one looks beyond the analyses necessitated by Geier, it becomes
apparent that the decisions actually turn on the implied immunity
question discussed here.

166. Unless one wishes to openly acknowledge the Court to be a political policy-making
institution, a view that creates all kinds of legitimacy issues concerning an unelected judiciary’s role
in a system committed to majoritarian politics. Although the “counter-majoritarian difficulty” is
beyond the scope of this Article, it has been the subject of numerous scholarly articles and books.
ALEXANDER M. BICKEL, THE LEAST DANGEROUS BRANCH: THE SUPREME COURT AT THE BAR OF
POLITICS 16 (1962) (coining the phrase “counter-majoritarian difficulty”); see also Symposium, The
167. See supra text accompanying notes 99-105.
168. See generally Colacicco v. Apotex, Inc., 521 F.3d 253 (3rd Cir. 2008); Mason v.
SmithKline Beecham Corp., 546 F. Supp. 2d 618 (C.D. Ill. 2008); Mensing v. Wyeth, Inc., 562 F.
2008); In re Vioxx Prods. Liab. Litig., 501 F. Supp. 2d 776 (E.D. La. 2007); McDarby v. Merck &
cert. granted, 128 S. Ct. 1118 (2008).
Consider, for example, Colacicco v. Apotex, Inc., a recent split-panel decision out of the Third Circuit. The case arose out of the drug companies’ failure to warn of the alleged risk of suicide among adults taking selective serotonin reuptake inhibitors (“SSRIs”). While the majority claimed to find preemption using a Geier-type of analysis, the opinions of both the majority and dissent focused on whether the defendant drug manufacturers could have done anything other than manufacture the drug with the FDA-approved label (which did not warn of a suicide risk for adult users). The plaintiffs made two important arguments:

First, they argue that nothing less than the FDA’s explicit rejection of a drug manufacturer’s request to add a contested warning to its drug labeling should suffice to establish conflict preemption. Second, they contend that the pharmaceutical companies failed to provide the FDA with sufficient information for it to make a valid decision regarding the necessity of a suicidality warning.

In other words, the first claim was that the defendants were not locked into the earlier FDA approval of the warning that did not mention adult suicide. Under the FDA’s procedures, the companies could have tried to get the FDA to change the warning, but failed to do so. In response, writing for the majority, Judge Sloviter stressed that attempts to get the FDA to change the warning would have been futile, noting that “[t]he FDA clearly and publicly stated its position prior to the prescriptions and deaths at issue here.” In fact, the holding was specifically limited to those cases “in which the FDA has publicly rejected the need for a warning that plaintiffs argue state law requires.” Moreover, the majority opinion notes:

[The FDA] has repeatedly rejected the scientific basis for the warnings that [the plaintiffs] argue should have been included in the labeling. The FDA has actively monitored the possible association between SSRIs and suicide for nearly twenty years, and has concluded that the

170. Id. at 256.
171. Id. at 264-69, 274-75.
172. Id. at 268-76, 278-84.
173. Id. at 272.
174. Id. at 268.
175. Id. at 271.
176. Id. at 271-72.
suicide warnings desired by plaintiffs are without scientific basis and would therefore be false and misleading.177

The dissent too focused on the question of whether the defendants were powerless to change the command of the regulatory body, arguing, in effect, that the defendants were free to ignore the FDA mandate without any real risk of sanction. Judge Ambro wrote:

None of the drug manufacturers in these cases attempted to enhance a warning and received an FDA sanction in response. The majority opinion correctly states that hypothetical conflicts can give rise to conflict preemption. But the hypothetical in question must be convincing for us to allow this. The conflict the defendants raise relies, at its heart, on the FDA punishing drug manufacturers for over-warning. But a heightened warning would likely have its source in new information that the FDA had not previously known. Thus, I find it hard to believe that, if a drug manufacturer augmented its warning in response to or in anticipation of a state tort lawsuit, the FDA would sanction the manufacturer for over-warning consumers under 21 U.S.C. §§ 331(a)-(b) and 352(a).

Indeed, drug manufacturers have authority to strengthen warnings without advance permission from the FDA. The plain language of 21 C.F.R. § 314.70 permits unilateral additions to warnings, subject to subsequent FDA approval: 

\[\text{[T]he holder of an approved application may commence distribution of the drug product involved upon receipt by the agency of a supplement for the change,} \]

including such changes as “add[ing] or strengthen[ing] a contraindication, warning, precaution, or adverse reaction.”178

The plaintiffs’ second important argument urges the court to find an exception from what is, in essence, a grant of immunity, based on the defendants’ alleged failure to disclose sufficient information to the FDA regarding the risk of adult suicide.179 As noted earlier, if the FDA approval (or mandate) was based on the defendants’ concealment or non-disclosure of the relevant risk, the defendants ought not to be able to share in the agency’s tort immunity.180

Considering the same issue, the Vermont Supreme Court declined to find “preemption” in \textit{Levine v. Wyeth}.181 As in \textit{Colacicco}, the decision

177. Id. at 269 (footnote omitted).
178. Id. at 282 (Ambro, J., dissenting) (alteration in original) (quoting 21 C.F.R. § 314.70(c)(6), (c)(6)(iii)(A) (2007)).
179. See supra note 173 and accompanying text.
180. See supra notes 118-19 and accompanying text.
turned on the extent to which the defendant was obligated to use the
FDA-approved warning. The court asserted:

Section 314.70(c) creates a specific procedure allowing drug
manufacturers to change labels that are insufficient to protect
consumers, despite their approval by the FDA. “The FDA’s approved
label . . . can therefore be said to set the minimum labeling
requirement, and not necessarily the ultimate label where a
manufacturer improves the label to promote greater safety.” While
specific federal labeling requirements and state common-law duties
might otherwise leave drug manufacturers with conflicting obligations,
§ 314.70(c) allows manufacturers to avoid state failure-to-warn claims
without violating federal law. (“[I]t is apparent that prior FDA
approval need not be obtained, nor will a product be deemed
mislabeled, if the manufacturer voluntarily or even unilaterally
strengthens the approved warnings, precautions or potential adverse
reactions upon the label pursuant to 21 C.F.R. § 314.70(c)(6)(iii)(A).”).
There is thus no conflict between federal labeling requirements and
state failure-to-warn claims. Section 314.70(c) allows, and arguably
encourages, manufacturers to add and strengthen warnings that, despite
FDA approval, are insufficient to protect consumers. State tort claims
simply give these manufacturers a concrete incentive to take this action
as quickly as possible.182

Since the Supreme Court has granted certiorari in Levine,183 the
preemption question, if the cases actually present one, remains very
much up in the air. However, the outcome should be made to turn on the
extent to which pharmaceutical companies were compelled to
manufacture and label drugs in a manner that complies with previously
granted FDA approval and how that approval came about, not whether
state tort liability is, for other reasons, a good idea.

VI. CONCLUSION

The Supreme Court has been remaking the “preemption doctrine”
in products liability cases for a few decades now. That the Court chose
to deal with these cases on the basis of fictional congressional intent can
only be regarded as unfortunate. It is unfortunate because it seems so
unlikely that anyone really believes that the will of Congress is driving

182. Id. at 185-86 (alteration in original) (quoting McNellis ex rel. DeAngelis v. Pfizer, Inc.,
No. 05-1286, 2005 WL 3752269, at *5, rev’d sub nom. Colacicco v. Apotex, Inc., 521 F.3d 253,
276 (3d Cir. 2008)).
183. Oral argument was heard on Nov. 3, 2008. A transcript of the argument is available at
these decisions, and the Court seriously undermines its own credibility when it gives the appearance of engaging in a charade—dictating tort reform with a wink and a nod. It is all the more unfortunate since the outcome of many of these cases is completely defensible under another body of principles.

It is true, of course, that the shared sovereign immunity approach suggested here carries a few problems of its own. At the very least, it involves the expansion of federal common law, an idea that has been disfavored at least since Erie Railroad Co. v. Tompkins.\footnote{304 U.S. 64 (1938).} Nevertheless, in Boyle the Court plausibly identified military contracts as an area of special federal concern and thus appropriate for federal common-law development.\footnote{The Court noted that areas of “uniquely federal interests” had previously been limited to the obligations of the United States under contract and the civil liability of federal officers. While the liability of government contractors did not exactly fall into either category, it was sufficiently related to both to permit the extension. Boyle v. United Techs. Corp., 487 U.S. 500, 504-05 (1988).} Perhaps the Court’s description of that field as “unique” overstated the case. Certainly some lower federal courts have shown a willingness to apply basic tort precepts to carve out immunities in § 1983 and \textit{Bivens} cases and have done so in a carefully limited and principled way.\footnote{See supra text accompanying notes 65-76.} The same is true in many of the pre-Boyle government contract immunity cases.\footnote{See supra text accompanying notes 89-92, 106-08.} Maybe federal product liability regulation has now emerged as an area ripe for some federal common-law development as well.

If so, widely accepted understandings as to the circumstances under which responsibility should be attributed and tort liability imposed dictate the outlines of immunity from liability. If a defendant is confronted with liability resulting from conduct which was compelled by congressional mandate or regulatory command, fairness considerations demand that the sovereign immunity available to the governmental entity also be made available to the private actor. In the absence of compulsion, however, there is no reason that state tort law should not be permitted to demand that individuals and entities accept responsibility for having caused harm.

\footnote{304 U.S. 64 (1938).}

\footnote{The Court noted that areas of “uniquely federal interests” had previously been limited to the obligations of the United States under contract and the civil liability of federal officers. While the liability of government contractors did not exactly fall into either category, it was sufficiently related to both to permit the extension. Boyle v. United Techs. Corp., 487 U.S. 500, 504-05 (1988).}

\footnote{See supra text accompanying notes 65-76.}

\footnote{See supra text accompanying notes 89-92, 106-08.}