F. Suspension Clause

Extraterritorial Reach of Writ of Habeas Corpus. — Through drastic changes in everything from American politics and national security to privacy, the current “war on terror” has undoubtedly changed the landscape of American society. The extended war has also brought with it a flood of litigation that has tested whether longstanding American principles such as access to the courts remain vital outside the borders of the United States. Last Term, in Boumediene v. Bush, the Supreme Court held that foreign detainees at the Guantánamo Bay Naval Base in Cuba “have the constitutional privilege of habeas corpus” and that such a privilege cannot be withdrawn “except in conformance with the Suspension Clause.”

Finding that the review procedures outlined in the Detainee Treatment Act of 2005 (DTA) were not “an adequate and effective substitute for habeas corpus,” the Court held that the jurisdiction-stripping provision of the Military Commissions Act of 2006 (MCA) unconstitutionally suspended the writ. Boumediene was the latest blow in a line of decisions — including Rasul v. Bush and Hamdan v. Rumsfeld — that have subjected the Bush administration’s “war on terror” policies to the scrutiny of the judicial branch. It did not take long for critics of the Court’s decision to proclaim Boumediene an epic disaster that will undoubtedly threaten the lives of Americans, and for supporters to celebrate the decision as a victory for human rights. However, because the Court

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3 Id. at 2240.
5 Boumediene, 128 S. Ct. at 2240.
7 Boumediene, 128 S. Ct. at 2274.
10 See, e.g., Editorial, President Kennedy, WALL ST. J., June 13, 2006, at A14 (“We can say with confident horror that more Americans are likely to die as a result.”). Justice Scalia shared these sentiments, stating that Boumediene “will almost certainly cause more Americans to be killed.” Boumediene, 128 S. Ct. at 2294 (Scalia, J., dissenting). One critic, presidential candidate John McCain, went as far as labeling Boumediene “one of the worst decisions in the history of this country.” Posting of Elizabeth Holmes to WSJ.com Washington Wire, http://blogs.wsj.com/washwire/2008/06/13/mccain-condemns-supreme-court-guantanamo-ruling/?mod=homeblogmod_washingtonwire (June 13, 2008, 12:57) (internal quotation marks omitted).
11 See, e.g., News Release, Nat’l Ass’n of Criminal Def. Lawyers, Rule of Law Rules Again at Guantánamo (June 12, 2008), http://www.nacdl.org/public nada/newsreleases/2008m102opendocument (“Today’s decisions call the administration’s entire overseas detention program into ques-
adopted an uncertain and malleable test based on “absolute” and “indefinite” control of the detention site, Boumediene’s effect may not be as far-reaching as opponents feared or as supporters hoped. The territorial limits of the Court’s holding leave many questions unanswered and could allow an administration that is determined to keep detainees beyond the jurisdiction of U.S. courts to use other avenues of accomplishing its ultimate goal.

The petitioners were aliens being held at Guantánamo Bay Naval Base in Cuba after the U.S. government classified them as enemy combatants in the “war on terror.” Each petitioner denied being a member of al Qaeda or the Taliban and sought a writ of habeas corpus to contest his detention before a federal court. The district court initially dismissed all claims, finding that it had no jurisdiction to consider habeas petitions filed by aliens held outside the United States. The D.C. Circuit affirmed, but the Supreme Court reversed in Rasul, holding that the habeas statute extended to noncitizen detainees being held at Guantánamo and remanding the cases to the lower courts to decide the merits of the plaintiffs’ claims.

The petitioners’ cases were consolidated and heard in two separate district court proceedings, which reached opposing conclusions on the question of whether aliens at Guantánamo had any constitutional rights that could be vindicated through a habeas petition.

As the cases were pending in the D.C. Circuit, Congress passed the DTA, which stripped the federal courts of authority to hear habeas cases. In Hamdan, the Supreme Court ruled that the jurisdiction-stripping provision of the DTA did not apply retroactively to habeas cases that were pending. In response, Congress enacted the MCA, which eliminated federal courts’ jurisdiction to hear habeas applications from detainees designated as enemy combatants in all cases.

The D.C. Circuit vacated and dismissed the petitioners’ cases. The court held that the MCA’s provision was not an unconstitutional suspension of habeas corpus because aliens held by the United States...
in foreign territory do not have any constitutional right to habeas review. The court concluded that “habeas corpus would not have been available in 1789 to aliens without presence or property within the United States.”

It also relied on Johnson v. Eisentrager, in which the Supreme Court held that German war criminals confined in a U.S.-administered prison in Germany were not entitled to habeas.

After initially denying review, the Supreme Court granted certiorari. In an opinion by Justice Kennedy, the Court held that the petitioners had “the constitutional privilege of habeas corpus,” that the review procedures under the DTA did not provide a valid substitute for habeas corpus, and that therefore the jurisdiction-stripping provision of the MCA was “an unconstitutional suspension of the writ.”

After examining the origins of the writ, Justice Kennedy concluded that evidence of the writ’s geographic scope at common law was “informative, but . . . not dispositive.” Holding that the Suspension Clause lives even in Guantánamo, the Court refused to concede that “the Constitution necessarily stops where de jure sovereignty ends.”

Rather, the Court read its precedents as establishing that the Constitution’s extraterritorial application “turn[s] on objective factors and practical concerns, not formalism.” Based on the Court’s interpretation of Eisentrager and its other extraterritoriality opinions, the Court considered three factors relevant in determining the Suspension Clause’s reach: “(1) the citizenship and status of the detainee and the adequacy of the process through which that status determination was made; (2) the nature of the sites where apprehension and then detention took place; and (3) the practical obstacles inherent in resolving the pris-

23 Id. at 987–91.
24 Id. at 990.
26 Id. at 781. The detainees were German nationals who were in the custody of the United States Army after a military commission had convicted them of engaging in military activity against the United States in China. Id. at 765–66.
28 Justice Kennedy was joined by Justices Stevens, Souter, Ginsburg, and Breyer.
29 Boumediene, 118 S. Ct. at 2240.
30 Id. at 2244–47 (discussing the historical development of the writ in the English legal system and its importance to the Framers).
31 Id. at 2249. The Court reached this conclusion after noting that neither party had been able to find a case stemming from common law that fit the petitioners’ situation in Boumediene. Id. at 2248 (“Diligent search by all parties reveals no certain conclusions.”).
32 Id. at 2253.
33 Id. at 2258. The Court was also troubled by the separation of powers concerns raised by the Government’s formal sovereignty-based test, since the political branches would be allowed “to govern without legal constraint” in territories, such as Guantánamo, where the United States disclaimed legal sovereignty but still exercised plenary control. Id. at 2258–59.
oner’s entitlement to the writ.”\textsuperscript{34} The Court, applying this framework, distinguished the circumstances of the petitioners from those of the detainees in \textit{Eisentrager}. It noted that the petitioners denied they were enemy combatants and had not been afforded a “rigorous adversarial process”\textsuperscript{35} to determine their status.\textsuperscript{35} Furthermore, although the sites of the petitioners’ “apprehension and detentions [were] technically outside the sovereign territory of the United States,” the government’s control over Guantánamo was “absolute” and “indefinite,” unlike with the German prison in \textit{Eisentrager}.\textsuperscript{36} Finally, the majority could see “no credible arguments that the military mission at Guantánamo would be compromised” if the writ were extended there.\textsuperscript{37} The Court concluded that the Suspension Clause extended to Guantánamo and that, since Congress had not complied with the clause’s requirements, the prisoners were “entitled to the privilege of habeas corpus.”\textsuperscript{38}

The Court next analyzed whether the MCA’s jurisdiction-stripping measure violated the Suspension Clause by failing to provide an adequate alternative through the DTA’s review process.\textsuperscript{39} The Court determined that, among other things, the DTA review process suffered from the absence of provisions allowing petitioners to challenge the President’s authority to detain them indefinitely, to supplement the record on review with exculpatory evidence discovered after the combatant status review tribunal proceedings, or to request release.\textsuperscript{40} Therefore, the Court concluded that the DTA review process provided petitioners with an inadequate substitute for habeas.\textsuperscript{41} Finding no jurisdictional bars on the petitioners’ claims, the Court held that although prisoners are generally required to exhaust alternative remedies prior to seeking federal habeas relief, the petitioners were entitled to a prompt habeas hearing because they had been detained for several years “without the judicial oversight that habeas corpus or an adequate substitute demands.”\textsuperscript{42}

\begin{itemize}
\item \textsuperscript{34} \textit{Id.} at 2259.
\item \textsuperscript{35} \textit{Id.} at 2259–60.
\item \textsuperscript{36} \textit{Id.} at 2260.
\item \textsuperscript{37} \textit{Id.} at 2261.
\item \textsuperscript{38} \textit{Id.} at 2262.
\item \textsuperscript{39} \textit{Id.} The Court announced that it was taking the unusual step of deciding this issue, even though the D.C. Circuit had not reached it, because of “the gravity of the separation-of-powers issues raised . . . and the fact that these detainees have been denied meaningful access to a judicial forum for a period of years.” \textit{Id.} at 2263.
\item \textsuperscript{40} \textit{Id.} at 2271–74.
\item \textsuperscript{41} \textit{Id.} at 2274.
\item \textsuperscript{42} \textit{Id.} at 2274–76. However, the Court stressed that “[e]xcept in cases of undue delay, federal courts should refrain from entertaining an enemy combatant’s habeas corpus petition” before the combatant status review tribunal has reviewed his status. \textit{Id.} at 2276.
\end{itemize}
Justice Souter concurred.\textsuperscript{43} He asserted that the majority’s finding concerning constitutional habeas corpus followed logically from the \textit{Rasul} Court’s historical understanding of statutory habeas corpus.\textsuperscript{44} He also took issue with the dissenters’ claims that the Court “is somehow precipitating the judiciary into reviewing claims that the military . . . could handle within some reasonable period of time” and that the Court’s precedents on habeas jurisdiction represented “a judicial victory” over the elected branches.\textsuperscript{45} According to Justice Souter, “After six years of sustained executive detentions in Guantanamo, . . . today’s decision is no judicial victory, but an act of perseverance in trying to make habeas review, and the obligation of the courts to provide it, mean something of value both to prisoners and to the Nation.”\textsuperscript{46}

Chief Justice Roberts dissented.\textsuperscript{47} He argued that the DTA review process adequately protected any constitutional rights that aliens detained abroad as enemy combatants might enjoy, and criticized the majority for replacing the DTA review system “designed by the people’s representatives with a set of shapeless procedures to be defined by federal courts at some future date.”\textsuperscript{48} The Chief Justice argued that the Court should not have granted certiorari until the D.C. Circuit had assessed whether the remedies available under the DTA review process vindicated whatever rights the petitioners possessed.\textsuperscript{49}

Justice Scalia also dissented.\textsuperscript{50} Pointing to what he considered the “disastrous consequences” of the Court’s decision, Justice Scalia concluded that “[t]he Nation will live to regret what the Court has done today.”\textsuperscript{51} Justice Scalia asserted that the majority’s decision “will almost certainly cause more Americans to be killed”\textsuperscript{52} and will ultimately leave the question of “how to handle enemy prisoners . . . with the branch [the judiciary] that knows least about the national security concerns that the subject entails.”\textsuperscript{53}

\textsuperscript{43} Justice Souter was joined by Justices Ginsburg and Breyer.
\textsuperscript{44} \textit{Boumediene}, 128 S. Ct. at 2278 (Souter, J., concurring) (“[T]he jurisdictional question must be answered the same way in purely constitutional cases, given the Court’s reliance on the historical background of habeas generally in answering the statutory question [in \textit{Rasul}]. . . . [T]oday’s decision . . . is no bolt out of the blue.”).
\textsuperscript{45} Id. at 2278.
\textsuperscript{46} Id. at 2279.
\textsuperscript{47} The Chief Justice was joined by Justices Scalia, Thomas, and Alito.
\textsuperscript{48} \textit{Boumediene}, 128 S. Ct. at 2279 (Roberts, C.J., dissenting).
\textsuperscript{49} Id. at 2280–83.
\textsuperscript{50} Justice Scalia was joined by Chief Justice Roberts and Justices Thomas and Alito.
\textsuperscript{51} \textit{Boumediene}, 128 S. Ct. at 2307 (Scalia, J., dissenting).
\textsuperscript{52} Id. at 2294.
\textsuperscript{53} Id. at 2296.
He then turned to what he termed the “legal errors” of the majority opinion.54 Believing that the Court incorrectly derived a “functional” test from past precedents, Justice Scalia maintained that *Eisentrager* “held beyond any doubt . . . that the Constitution does not ensure habeas for aliens held by the United States in areas over which our Government is not sovereign.”55 Furthermore, he argued that the majority’s view of the territorial scope of the writ of habeas corpus before 1789 was mistaken: “[A]ll historical evidence points to the conclusion that the writ would not have been available at common law for aliens captured and held outside the sovereign territory of the Crown.”56

Although the Court asked broadly “whether foreign nationals, apprehended and detained in distant countries during a time of serious threats to our Nation’s security, may assert the privilege of the writ and seek its protection,”57 it answered its own question quite narrowly. Using a functional approach that took into account practical considerations, the Court limited its holding to Guantánamo Bay. In reaching this conclusion, though, the Court suggested — echoing Justice Kennedy’s concurrence in *Rasul*58 — that the Suspension Clause is more likely to apply in territories, like Guantánamo, over which the United States exercises “total military and civil control.”59 As detainees at other U.S. prisons across the globe begin to challenge their detentions, a key factor that will undoubtedly be debated is whether the United States has “absolute” and “indefinite” control over those prisons. With such bare-bones discussions in both *Rasul* and *Boumediene* of exactly how one is to determine whether the United States is exercising absolute and indefinite control over a detention facility, it is uncertain how lower courts are going to apply this test beyond Guantánamo Bay. Considering Justice Kennedy’s consistent focus on the lease agreement between the United States and Cuba, future determinations of the United States’s control may be highly influenced by the terms of any leasing agreement or other document detailing the rights of the United States.60 But what lower courts will consider beyond this factor remains to be seen.

54 Id. at 2294.
55 Id. at 2298–99 (emphasis omitted).
56 Id. at 2305.
57 Id. at 2248 (majority opinion).
59 See *Boumediene*, 128 S. Ct. at 2248.
60 According to Professor Barbara Olshansky, legal director of the International Justice Network, future legal challenges will turn on “whether the kinds of agreements or leases we have in a place like Bagram [Air Base in Afghanistan] meet the standard that’s set in *Rasul* for exclusive jurisdiction and control.” Daphne Eviatar, *Lawyers Consider Implications of Supreme Court Rul*
The Court did give some indication of how it would evaluate claims of detainees being held in other locales. A critical part of the Court’s framework in determining the reach of the Suspension Clause was “the nature of the sites where apprehension and then detention took place.”61 Attempting to distinguish Eisentrager, Justice Kennedy stated that “there are critical differences between Landsberg prison, circa 1950, and the United States Naval Station at Guantanamo Bay in 2008,” because “[u]nlike its present control over the naval station, the United States’ control over the prison in Germany was neither absolute nor indefinite.”62 This is not the first time that language like this has been introduced in a habeas case. Similar language appeared in Justice Kennedy’s concurrence in Rasul v. Bush, in which he distinguished Eisentrager by stating that “[w]hat matters is the unchallenged and indefinite control that the United States has long exercised over Guantánamo Bay.”63 When Kennedy again emphasized the U.S.’s “absolute” and “indefinite” control in Boumediene, he seemed to be articulating a test for determining whether the Suspension Clause extends to a particular territory outside of the United States.

However, neither Justice Kennedy’s brief opinion in Rasul nor his lengthy opinion in Boumediene offers lower courts much guidance in how to interpret, beyond the Guantánamo Bay context, the phrases “unchallenged and indefinite control” or “absolute and indefinite control.” In Rasul, the only evidence that Justice Kennedy used to illustrate the “unchallenged and indefinite control that the United States has long exercised over Guantánamo Bay” was the “indefinite lease” that existed between the two countries.64 Similarly, in Boumediene, Justice Kennedy again noted the unique terms of the lease and highlighted the fact that “[u]nder the terms of the 1934 Treaty . . . Cuba effectively has no rights as a sovereign until the parties agree to modification of the 1903 Lease Agreement or the United States abandons the base.”65 When discussing the “critical differences” between Landsberg Prison and Guantánamo Bay, Justice Kennedy gave a few examples of what would not constitute absolute and indefinite control.66 He cited

61 Boumediene, 128 S. Ct. at 2259.
62 Id. at 2260.
64 Id. at 487 (“From a practical perspective, the indefinite lease of Guantánamo Bay has produced a place that belongs to the United States, extending the ‘implied protection’ of the United States to it.” (quoting Johnson v. Eisentrager, 339 U.S. 763, 777–78 (1950))).
66 See id. at 2260.
the combined Allied forces’ jurisdiction over Landsberg Prison, which made the United States “answerable to its Allies for all activities occurring there”; the lack of long-term plans for occupying Germany; and the absence of intentions to displace German institutions. But Justice Kennedy set no additional criteria and discussed no other factors to help outline what constitutes absolute and indefinite control beyond Guantánamo Bay.

With limited guidance on what would be considered absolute and indefinite control and with the uncertainty surrounding future applications of such a test, lower courts may find it hard to determine how to handle prisoners in other international facilities. An administration determined to deny habeas to detainees may take advantage of such uncertainty in order to evade court supervision. If past history serves as any indication, such a scenario is in fact plausible. It is no secret that the Bush Administration chose to send detainees to Guantánamo in 2002 in an effort to place them beyond the jurisdiction of U.S. courts and to preclude them from challenging the fact and conditions of their detention. The Bush Administration believed that the judicial process was a significant threat to the United States; therefore, “one of the very first things the Administration lawyers all agreed on was that alien detainees should be housed at Guantánamo, precisely because they believed that the captives would thereby be beyond the reach of judicial process.” In fact, the U.S. government argued before the Ninth Circuit that U.S. courts would not have any jurisdiction over detainees even if they were being tortured or summarily executed.

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67 Id.
70 Gherebi v. Bush, 352 F.3d 1278 (9th Cir. 2003). According to the court in Gherebi, the United States asserted the power to do with [them] as it will, when it pleases, without any compliance with any rule of law of any kind, without permitting [them] to consult counsel, and without acknowledging any judicial forum in which its actions may be challenged. Indeed, at oral argument, the government advised us that its position would be the same even if the claims were that it was engaging in acts of torture or that it was summarily executing the detainees. To our knowledge, prior to the current detention of prisoners at Guantánamo, the U.S. government has never before asserted such a grave and startling proposi-
Despite several failed attempts to place detainees beyond the reach of judicial process, the Bush administration has continued to attempt to restrict detainees’ habeas rights. For example, after the Court ruled in *Rasul v. Bush* that the detainees held at Guantánamo Bay had at least some rights, the U.S. government relocated several suspected terrorists from Guantánamo Bay to other detention centers across the globe.¹¹ And some commentators have suggested that the Bush administration does not hold its “most sensitive and high-profile detainees” at Guantánamo for fear that they “will eventually be monitored by the U.S. courts.”²²

The Bush Administration’s response to *Rasul* certainly suggests the possibility of similar responses to *Boumediene’s* malleable holding from future administrations that may share the same political views regarding habeas. For example, an administration inclined to develop a new system of secret detention facilities, or to expand on a system that may already be in place, might be able to sidestep the protections created by the Court in *Boumediene* by creating a detention site with characteristics distinguishable from Guantánamo Bay.⁷³ Because the opinion could be read to cover detention facilities across the globe with leases similar to Guantánamo’s “all-but-*de-jure*-sovereignty lease,”²⁴ an administration looking to deny habeas rights to detainees would of course need to make sure that no such lease is *formally* entered into. Beyond this requirement, if an administration were to appear not to intend to govern *indefinitely*, it might be able to distinguish any detention center that meets these criteria from Guantánamo Bay. If there were distinctions between Guantánamo and other detention facilities across the globe, an administration could attempt to take advantage of

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¹¹ Eviatar, supra note 60.

²² HUMAN RIGHTS WATCH, THE ROAD TO ABU GHRAIB 12 (2004), available at http://www.hrw.org/reports/2004/usa0604/usa0604.pdf. According to Human Rights Watch, [t]he most sensitive and high-profile terrorism suspects have been detained by the United States in ‘undisclosed locations,’ presumably outside the United States, with no access to the [International Committee of the Red Cross], no notification to families, no oversight of any sort of their treatment, and in many cases no acknowledgement that they are even being held.


such distinctions by replacing Guantánamo as the detention site of choice with another facility that would put the detainees beyond the jurisdiction of U.S. courts. Newly captured “enemy aliens” and old detainees could just be shifted to a detention center where the government was not deemed to have “absolute” and “indefinite” control. Furthermore, if an administration wanted to be extra cautious in not activating Boumediene, it could call for other countries, even countries known for torturing their prisoners, to serve as “surrogate jailer[s]” for the United States. The implicit control that the United States could or would have over the captivity and interrogations of such suspects would be largely unknown and would, therefore, likely pass Boumediene’s “absolute” and “indefinite” control test.

Boumediene’s narrow holding recalls the concern that haunted Justice Black in his Eisentrager dissent: the Executive should not be able to “deprive all federal courts of their power to protect against a federal executive’s illegal incarcerations” by choosing “where its prisoners will be tried and imprisoned.” As Judge Rogers of the D.C. Circuit later pointed out, “confinement of the person, by secretly hurrying him to jail, where his sufferings are unknown or forgotten, is a less public, a less striking, and therefore a more dangerous engine of arbitrary government” than publicly confiscating a person’s estate or executing him without trial. These fears may still not be allayed by the Court’s holding in Boumediene because its limited nature leaves the door open for other U.S. detention facilities across the globe to become the new Guantánamo Bay.

The Boumediene majority rightly stated that “the costs of delay can no longer be borne by those who are in custody.” However, by limiting the scope of its judgment to Guantánamo detainees and by enacting an uncertain and malleable test based on “absolute” and “indefinite” control, the Court gave the administration an easy path around the ruling and left open the possibility that such delay is in the future for detainees being held outside Guantánamo. Accordingly, supporters should withhold their celebrations and critics should breathe a brief sigh of relief — at least until the next round of this seemingly never-ending saga. Yet one thing is clear: the Court’s “absolute” and “indefinite” test in Boumediene might ironically violate the Court’s own proclamation in the same case — “[t]he test for determining the scope of

75 See Don Van Natta, Jr., U.S. Recruits a Rough Ally To Be a Jailer, N.Y. TIMES, May 1, 2005, at A1 (detailing allegations that the United States sends terror suspects to countries, such as Uzbekistan, that are suspected of torturing their prisoners).
78 Boumediene, 128 S. Ct. at 2275.
[the Suspension Clause] must not be subject to manipulation by those whose power it is designed to restrain.79

II. FEDERAL JURISDICTION AND PROCEDURE

A. Federal Preemption of State Law

Preemption of State Common Law Claims. — Recent Supreme Court preemption decisions have been decried in the press as pro-business and detrimental to injured consumers' ability to receive compensation.1 In the context of medical devices, Congress has enacted prospective safety regulations, but it has been said to “all but ignore[] the remedial side” if such devices cause injury.2 Last Term, in *Riegel v. Medtronic, Inc.*,3 the Supreme Court held that the preemption provision in the Medical Device Amendments of 19764 (MDA) preempted state common law claims brought after a medical device subject to the most stringent level of federal regulation caused injury. Despite criticisms that it leaves tort victims uncompensated, preemption is necessary to ensure that federal regulatory agencies, like the Food and Drug Administration (FDA), are the only governmental actors able to impose requirements on manufacturers — thereby ensuring a nationally standardized system of safety regulations without myriad local variations. *Riegel* extends an evolving MDA jurisprudence that empowers this federal system, while preserving common law claims when the regulation systematically provides inadequate safety assurances, but it leaves open the question of how courts should treat claims alleging fraud in fulfilling FDA requirements. However, the rationale that underlies the Court’s MDA jurisprudence — that state law claims are only preempted when federal regulation has been complied with — indicates that courts should permit some fraud-based tort claims.

79 Id. at 2259.
1 See, e.g., Erwin Chemerinsky, *A Troubling Trend in Preemption Rulings*, TRIAL, May 2008, at 62; Jeffrey Rosen, *Supreme Court, Inc.*, N.Y. TIMES, Mar. 16, 2008, § 6 (Magazine), at 38, 66 (“[T]he business community . . . is trying to ensure that these consumers often have no legal remedy for their injuries. And the Supreme Court has been increasingly sympathetic to the business community’s arguments”); cf. James T. O’Reilly, *Drug Review “Behind the Curtain”: A Response to Professor Struve*, 93 CORNELL L. REV. 1075, 1077–78 (2008) (“[S]ome patients will inevitably become victims of unreasonably harmful or badly-prescribed drugs and medical devices . . . [b]ut precluding compensation to victims decreases drug sponsors’ insurance costs, and thus increases the potential profitability of engaging in the high-risk quest of making novel, effective drugs.” (footnote omitted)).