REMARKS OF HON. GUIDO CALABRESI†

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It is great to be here, both because it is always nice to come to NYU, and also because it is nice to see so many friends, old and new, among the people who are visiting NYU. Today, we are talking about preemption. This issue deals not just with the question of torts and pharmaceuticals: It deals with some of the deepest questions we have before us in terms of regulation and incentives in a time of crisis.

It seems to me, speaking as an academic and not as a judge, that there has been a tendency for courts to view the topic of preemption very narrowly and to lose many of the nuances that are really involved. Judges view preemption questions in terms of the case coming before them, and they give binary, yes or no, answers. But most of the issues are more complicated. I am going to try to sort out some of these issues, which are often conflated in the cases.

The first question that has to be asked is: Does national centralized decision-making, as between safety and accidents—and as to who bears the cost of safety or the cost of accidents—work better than local, diverse, and diffuse decision-making? Does one want localities deciding these questions in a variety of different ways, both in terms of who bears the cost and what the cost-benefit is, or is the decision best made nationally and uniformly? This question has several different aspects to it. For example, what are the added costs of having a variety of different cost-benefit decisions made? What are the costs that come from having one place do one thing and another place do another?

The second question is: What are the benefits of allowing different local decisions? We all know, and repeat, the Brandeisian

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notion that allowing different decisions fosters experimentation.[1] But we must also understand that in our system, local decision-making is very important so that we can have different values introduced into the system. We are profoundly red and blue. Abraham Lincoln was wrong when he said the nation could not live half-slave and half-free.[2] We did for a very long time live half-slave and half-free until *Dred Scott* said the country had to live all-slave.[3] Then the Abolitionists, who were right but repulsive as far as most Northerners were concerned, became acceptable: If it was going to be all one way, then it was going to be our way.

How often in America do we have, and want to have, different values, different notions of what life is worth, of what things are worth? In this sense it is interesting and perhaps not surprising that we have not had a national tort law in the United States. I believe that the United States is much more divided in terms of values than is Europe—I am talking about the core, old Europe, because those countries share similar values. And that may be why Europe can stand not having a strong central government. Consider the death penalty. Countries that have the death penalty may not join the European Union. In the United States, opinions are widely divergent on that topic. And so it is with other things. Europe had better watch out when it decides to expand beyond the core that has certain values, because it will then need a strong central government. We survived, with different values, only because we had a very strong central government at the time of the Civil War. So that is what the second question asks: What are the benefits of introducing different values into a decision-making system?

The third question is: What does the difference between localized and centralized decision-making tell us about who bears the burden of these decisions? In torts cases, the choice is not only as to how many accident costs we want, how many safety costs we want, and which ones. That is certainly an important issue. But there is also the question of who bears the costs. If we do not allow new drugs, some people are going to suffer. If we do allow new drugs, other people will suffer. Will the person who uses a drug that has come in more recently, more quickly, bear the cost, or will it be the person who doesn't get the drug because there has been a greater

1. *See* New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) ("It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.").

2. Abraham Lincoln, House Divided Speech (June 16, 1858).

3. Scott v. Sandford, 60 U.S. 393, 405–06 (1856).

delay? They are different people, and that is separate from the question of which alternative is more efficient.

The fact that underneath all of these choices there are distributional issues was brought home to me dramatically many years ago when I went to the hospital to see my friend Alex Bickel, who seemed very well except that he had just been diagnosed with terminal brain cancer. I knew that his illness was a result of his smoking. I was, and am, against prohibition because it generally is inefficient, and prohibiting smoking would have all sorts of terrible consequences. But I also knew that if smoking had been prohibited, Alexander Bickel would have lived because he would not have broken the law. So maybe the option of prohibition is not efficient, but the distributional consequences of one rule as against another were brought home to me. Therefore, in this question of where we decide, centrally or locally, there is not just the efficiency question. Because wherever there is a cost-benefit there are some people who bear the costs and some people who receive the benefits, and we must ask ourselves: Who will those people be?

All of this is completely separate from the question of whether the cost-benefit and distributional decisions are best made through regulations or through incentives. The cases, because of the way they come up, make it appear as if central decision-making means regulation, and local decision-making means incentives. Yet, that is not necessarily so. One could perfectly well have a national tort system with national standards, which would apply to drugs all over the country. And one could have local regulation and then consider whether such local regulations are preempted by federal rules (either regulatory or torts-like). We simply assume in these cases that because, by-and-large, local rules consist of tort incentives and, by-and-large, the national system is a system of administrative regulatory decision-making, that the tradeoff between torts and administrative regulation is what is involved in the question of preemption. But *that* tradeoff is a very different question from whether to have local decision-making as opposed to national decision-making. It is a question of what kind of system we want, regardless of the level of government at which it is implemented.

In addition to acting as if centralized decision-making is regulatory and localized decision-making is not, we often look at the two systems in an idealized or demonized way. Justice Scalia, for instance, talks about the tort system in the most disparaging terms.[4]

4. *See, e.g.*, Riegel v. Medtronic, Inc., 552 U.S. 312, 325 (2008) ("A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned

He may be right, but the existing tort system is not the only possible system of incentives (as against regulation) that we could have. That is, one could have, either at the national or at the local level, a totally different system of incentives, like the old New Zealand system, which would avoid the perceived flaws in current tort law. Conversely, Justice Breyer, known to some of his friends as "the Commissioner," sometimes describes agencies as if they were near-perfect.[5] Of course they are not. Others describe regulation as being inevitably corrupt, overtaken by, and in the hands of, the regulatees.[6] This too is an overstatement.

If we are serious, we should ask not just the questions of whether decisions should be made at the national or local level, and not just whether we should use regulation rather than incentives. Rather, we should also ask: Absent a perfect system, which system would work reasonably well? And, in doing so, we should consider variations from the existing regulation or tort models. Yet we talk about preemption in particular cases as if none of these alternatives are possible.

Now, of course, courts deal with specific cases that come before them. And, if the courts were only treating these issues in a traditional legal sense of saying, "this is what Congress said or this is what Congress intended," then speaking as if the universe of options were closed would be understandable. But, when courts address the broadest policy questions and decide one way or another—because, for instance, they like or do not like existing tort law—the issues become more complicated. Thus, one often finds people saying, "torts means no experts; regulation means experts." That is not necessarily so. It is possible to have a regulatory system comprised of rotating lay people, which would avoid the danger of having the decision-makers be co-opted by the regulatees, but which would also not have experts. Conversely, a system of incentives could be established through expert bodies. All of this gets

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with its benefits; the patients who reaped those benefits are not represented in court.").

5. *See* Medtronic v. Lohr, 518 U.S. 470, 506 (1996) (Breyer, J., concurring) (holding that courts should defer to the agency's preemption determination because of "special understanding of the likely impact of both state and federal requirements, as well as an understanding of whether (or the extent to which) state requirements may interfere with federal objectives").

6. *See, e.g.*, Richard A. Epstein, *Why the Modern Administrative State Is Inconsistent with the Rule of Law*, 3 N.Y.U. J. L. & LIBERTY 491, 492 (2008) (arguing that it is not possible to "shield administrative agencies in highly sensitive areas from various forms of factional and political influence that have little or nothing to do with technical expertise").

lost in the simplicity of the legal case before courts that know little about regulation and virtually nothing about torts.

The current discussion also fails to ask some subsidiary questions that arise in the light of these first questions that I have put to you. Who, where, and by whom are *minimum* standards of behavior best set, as against total standards of behavior? What institutions are best suited to decide the minimum levels we want individuals (and corporations) to live up to? And is this "minimum" decision best made locally or nationally? These may be very different questions from the "who, where, and what level" questions for setting standards *above* that minimum. The classic tort position was very simple on this issue: Administrative regulation and legislation are very good at setting minimum standards, but minimum standards—for example, laws whose violation establishes negligence per se—are never safe havens. That was a rather simplistic notion, and I am not sure that it is a notion that can survive today. But the question of whether minimum standards are best set locally or nationally, and whether they are best set by experts or by lay people, is rarely talked about in the cases involving preemption.

There are consequences to this failure. If the government at its highest levels sets total standards, it determines who is worth living and who is worth dying because it determines what is worth doing to save lives and what is not. Symbolically, that is a dangerous position in which to put the State. I am reminded of Justice Potter Stewart's question during the oral argument of the famous *Pentagon Papers* case.[7] There he asked [to paraphrase],

> Professor Bickel . . . . Let us assume that when the members of the Court go back and open up this sealed record we find something there that absolutely convinces us that its disclosure would result in the sentencing to death of a hundred young men whose only offense had been that they were nineteen years old and had low draft numbers. What should we do?"[8]

Professor Bickel started to answer as an academic, and then he remembered that he was a lawyer before the Court and so effectively said, "Justice Stewart, that isn't this case. Don't deal with it."[9] And of course Justice Stewart did not. Justice Black, who died shortly after writing an opinion in this case, told his clerks, who told to me: "Stewart asked the right question, but the answer was wrong." The problem is not that a hundred lives would be lost. In

7. N.Y. Times Co. v. United States, 403 U.S. 713 (1971).

8. *See* Transcript of Oral Argument at 45–46, *N.Y. Times Co.*, 403 U.S. 713 (No. 1873).

9. *See id.*

the parlance of the time, we waste a hundred lives all the time for things far less important than freedom of speech. The terrible aspect is that the Supreme Court of the United States would be saying that a hundred lives are not worth saving. That is why we try to save people crazy enough to row across the Atlantic, or spend millions to save hostages who are taken. Even when lives in some sense are not "worth it," symbolically they are much too important to ignore.

Justice Black's answer to this problem was rather dire [to paraphrase]: We should have an absolute rule against all prior restraints so that if people die as a result of publication, they do so before any court can be involved. That is, ensure that the hostages die before anybody can go rescue them.

Justice Black's approach was draconian. But, whether he was right or wrong, there is a danger in having the State make very clear what lives are worth saving and what lives are not. One advantage—and I am not saying that it wins out—of having the State, whether national or local, set minimum standards is that the State is then in the position of saying: People must do at least this much, but more should be done. The State thereby avoids being in the position of saying it is okay to kill someone.

Of course, the other side is that if we use an incentive system we come mighty close to pricing lives. We find ways to avoid having the State say that Dick Epstein is worth more than Peter Schuck. But we do it by creating a system that tells us that Epstein and Schuck are both worth exactly $87,327 (which sounds like rather much to me).

The other question that gets lost in this is whether these decisions are best made ex post or ex ante. Regulation tends to tell us what is acceptable ahead of time on the basis of what is known at that time. We all know that supposedly in torts, under the old Learned Hand test, liability for negligence is based on what a reasonable person should have known at the time the accident-causing event took place. But there is also strict liability, and, very often, torts decides on the basis of what we have learned because of the accident or after it and so creates incentives for people to think about what we do not yet know. Now again, is that good? Is it bad? Is it best done nationally? Is it best done locally? Is the decision best made by experts or not by experts if it is ex post or not? Is an ex post vantage point best for minimum standards or maximum standards? All these are the questions that are inherent in the problem of preemption.

Finally, there is the question of what kind of decision-makers we want to have make all these decisions. And this raises not only

the questions of: (a) what kind of decision-makers we want; if we want local or national, minimum or maximum, incentive or regulatory decisions; (b) when do we think lay people are good at making the decisions; and (c) when do we think experts are good at it. If the problem is as complex as I believe it to be, it also raises the question of who is best suited to make the decision *of what we do?*

If Congress speaks, we all know that we comply. But Congress rarely says anything, or if it says anything, it often does not know what it is saying. And that is so in both directions. Did Congress say something in *Medtronic*?[10] Did it say something in *Wyeth*?[11] I do not believe that Congress said anything in *Wyeth*, though some people have suggested that it did. But in *Medtronic*, yes, Congress did say something; but did Congress mean it? And if Congress now turns around and says it meant the opposite in *Medtronic*, does that really mean anything at all? In the temple of truth, should we not at least ask: How can we make sure that the decision, as to who makes these decisions, is better made? If Congress is not good at it, believe me, the courts are lousy. State courts, elected as they are in most places, federal courts, selected as we are—God help us!

A federal court like the Supreme Court—which understandably spends most of its time talking about civil rights, national security, and how many people should be hanged—does not know a darned thing about this issue. As far as I am concerned, there is only one Justice of the Supreme Court who really understands torts and that is Ruth Bader Ginsburg. The other Justice who comes close is Clarence Thomas. But who else can make these decisions if not courts?[12] A royal commission of the United States? I do not know, but I think we ought to think about all this because otherwise these decisions will be made in the most simplistic way, and, inevitably, the nature of the decisions will shape the commentary in these discussions.

Now, some will say, as good Burkean conservatives, that if there is no way of making a decision well, we should stick with traditions and old presumptions. And for a long time we did just that. The old presumptions held that one does not assume preemption; that courts should not presume that federal standards do more than es-

10. Riegel v. Medtronic, Inc., 552 U.S. 312 (2008).

11. Wyeth v. Levine, 129 S. Ct. 1187 (2009).

12. Some, usually administrative law professors, suggest administrative agencies should decide who decides. But when they do so, they almost always speak of idealized agencies and not the real life, flawed ones.

tablish the minimum.[13] That seems not to be working. But for a long time, the reason we stuck with presumptions like these was not because they were particularly good, but because we felt very uncomfortable with making any decisions in any other way.

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The underlying questions remain: how to decide between regulation and incentives, how to decide between regulation and incentives locally and nationally, how to decide between regulation and incentives when we are unwilling to bear the distributional costs of incentives or of regulations. If we do not think seriously about these questions then the whole nature of the society in which we have all grown up, that we have taken for granted—a system, that is, that makes predominant use of incentives that are well-controlled, fine-tuned, often bad, and with dramatic distributional consequences—will cease to be in ways that might surprise us. That will be true not just in torts, but in the economy as a whole.

Thank you.

13. *See, e.g.*, Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947) ("[W]e start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.").

REMARKS OF GILLIAN METZGER†

*GILLIAN METZGER**

I thought that I would begin by putting my priors on the table. On that front, I am actually surprised but pleased to find out that I might be agreeing more with Rick [Hills] than I was expecting to on this panel. On the institutional design question I share some concerns with Susan [Frederick] and Dan [Schweitzer]. However, in the preemption context my inclination is that federal agencies can, and have the capacity to, do a better balancing of the federalism and national interests than either Congress or the courts. And I also think that there are instances in which agencies can legitimately preempt on obstacle grounds, although I find the recent expansion in obstacle preemption very concerning.

The point I want to start with, however, relates back to Congress. I think it is hard to challenge the legitimacy gains of greater congressional involvement in this area. In particular, Congress needs to be involved in order to address the social insurance aspect of preemption cases. This is because agencies do not have the ability to say, without congressional approval, that even if we make the right systemic regulatory decision, somebody is going to get hurt and maybe compensation should be available. A decision to provide compensation has to be made at the congressional level. I agree, though, with Rick [Hills] that Congress has shown too much predilection for addressing preemption without the kind of clarity and specificity that is needed. In addition, if we are talking about issues that are going to end up having an administrative edge, the reality is that Congress generally delegates very broadly to agencies. I find it difficult to imagine Congress as willing or able to change that practice and delegate more clearly when it comes to administrative preemption. The typical reasons given for why Congress delegates broadly—the political difficulties of reaching agreement on regulatory specifics; the lack of time and expertise needed to ad-

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dress specific issues; the need to have regulatory schemes that are flexible and can respond to new challenges as they emerge—all apply in the context of administrative preemption.

What I am even more convinced of is that a greater role for agencies in the preemption context is simply inevitable. The reasons are not only the economic and national political reasons that Rick [Hills] mentioned, but additionally, I do not think that courts are going to enforce rules requiring Congress to play a central role. It is just too much at odds with the norms of the national administrative state that we have developed over the last century—and are only developing further—to think that is going to happen. So I truly believe that we need to face the fact that agencies will inevitably play a bigger role here. I happen to think that that is not a bad outcome. Although agencies have many of the pathologies that have been identified already today, they also have some important strengths in terms of their ability to apply area-specific expertise and weigh state and national interests in particular regulatory contexts. I believe that too often the national-state debate is presented as being necessarily the kind of stark conflict that it was under the Bush Administration, without much sympathy to state interests at the national level. I am not so sure that national and state regulatory interests are always as opposed to one another as is sometimes conveyed. Another point to note about agencies, which is important for what I want to get to, is that agencies are more amenable to being checked by a variety of different actors than either Congress or the courts. That matters because I think the issue on which we should be focusing—the real institutional design question—is: Accepting that agencies are inevitably going to be playing a role here, how do we structure their involvement to make sure that they make the best decisions about preemption? In particular for federalism interests, how do we structure their involvement to ensure that state and local interests are adequately heard, responded to, and taken seriously? That was what Rick [Hills] was getting at in terms of the Vice President,[1] and I have somewhat similar suggestions to make.

First, let me talk about a couple of other approaches. As Rick [Hills] mentioned, one of the things I, [Catherine Sharkey], and a number of others have advocated for is the traditional administrative law response of enhanced judicial review. And I do think that subjecting preemption determinations to a more searching scrutiny could have some traction. If you look at some of the preemption

1. *See* Roderick M. Hills, Remarks at the *New York University Annual Survey of American Law* Symposium: Tort Law in the Shadow of Agency Preemption (Feb. 27, 209) (transcript available at New York University Annual Survey of American Law).

regulations that came out under the Bush Administration, there are some fairly obvious APA [Administrative Procedure Act][2] issues that can be raised. For example, there are issues involving inadequate notice. Such APA procedural reversal might only serve to slow down adoption of the agency's preemptive position. But with an agency that is even nominally responsive, the possibility exists that such reversals might have some substantive effect down the road. You can again put this down to my priors; I tend to believe that agencies are not so committed to a pre-chosen path that they are not interested in hearing other voices or open to responding to states' concerns. Agencies are under-resourced to be sure, and can have programmatic tunnel vision. Sometimes agencies can be overly politicized. But I believe it is a mistake to assume that agencies will be unresponsive. The critical issue is designing agencies and their relationships with their political and judicial overseers so as to encourage agencies to take other interests and perspectives seriously. As a result, I see some potential for the option of enhanced judicial scrutiny to improve preemption determinations.

Another option at the national level is enhanced congressional oversight. [Catherine Sharkey] has spoken a little bit about that in terms of Executive Order 13132[3] and we heard some discussion today about FDA [Food and Drug Administration] oversight. There are some obvious avenues on this front that matter. The angle I would emphasize more, however—and Rick [Hills] made this point too[4]—involves intra-agency checks. I could not agree more with Rick [Hills] about trying to learn lessons from the example of cooperative federalism. If we accept the inevitability of federal agencies being involved in this area, a key question is how to structure the federal regulatory process to fully bring in state and local interests.

Another mechanism might be to try to require the establishment of advisory committees within each agency, embodying state and local interests, as a means to create ongoing contact between the different levels of regulators. Issues will of course exist about whom to put on such advisory committees to represent state and local interests. But what is needed is a formal intra-agency institutional structure to represent state and local interests [a] that has an existence beyond a particular issue, [b] that is not dependent on the agency triggering a request for comments in a particular case, and [c] that, over time and through ongoing interactions, can build confidence, relationships, and receptivity among federal, state, and

2. Administrative Procedure Act, 5 U.S.C. §§ 701–6 (2006).
3. Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 4, 1999).
4. *See* Hills, *supra* note 1.

local regulators. While I think the Vice President can also serve a role in terms of appeals from agencies, we really should consider building into the agencies greater sensitivity to state and local interests. This should include even those agencies that do not take a cooperative form, that implement more dual regulatory regimes, or that represent centralized federal regulatory power without a state analog. Some kind of advisory committee structure is one option for building such a formal institutional representation of federalism concerns.

There is also the option of trying to do more with the executive order and OMB [Office of Management and Budget]. That only works, of course, if you have an OMB that is sympathetic. But as Susan [Frederick] was saying, some potential exists here for a more centralized emphasis on taking state and local interests seriously. When that has happened—when agencies start taking the 13132 process of federalism generally more seriously—agency institutional culture can be significantly affected.

The last point I want to make gets outside of the executive branch and focuses instead on what states and local governments can do, and do collectively, independently of federal agencies. One of the things I find very interesting, when you look at preemption clauses, is the extent to which they reserve what I would call "complementary state measures." The language is often along the lines of, "state regulations that are identical and not in addition to federal regulation are preserved." This may create an opening for states to do more policing of the federal administrative process than has so far occurred. And it certainly is an opening I would like to see state and local governments explore. For example, regulated entities that are filing reports with the FDA of certain complications could also be required to file with states and, perhaps, local bodies. These governments would then be in a better position to police whether or not the FDA is adequately responsive to such filings and to petition the FDA or use their contacts at the federal government to increase national regulatory responsiveness. This approach is obviously much easier when there is a cooperative regulatory scheme. But one of the things that states may need to do is develop analogous regulatory competency in areas where they may have ceded too much to the federal regime, so they can play such a policing role. Developing such competency might also lead to more regulatory experimentation. For example, state-level agencies may be able to develop mechanisms that enhance regulators' access to information, so that tort suits need not be so important as information-gathering tools.

I am actually quite open to arguments that none of these ideas will work. The one point that I am certain of is that the issue that needs to be addressed is how agencies confront the federalism issue. I am skeptical that trying to bump up preemption determinations to Congress is going to work in the long run. And, as was said at the earlier panel, I am concerned that we are not going to end up with a very sensible regulatory regime if we try and leave preemption determinations in the first instance to the courts.